# Revision of European Ecolabel Criteria for Soaps, Shampoos and Hair Conditioners



## Background report including revised draft criteria proposal

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# Revision of European Ecolabel Criteria for Soaps, Shampoos and Hair Conditioners

## Background report including revised draft criteria proposal



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**ABBREVIATIONS**

| | |
|---|---|
| aNBDO | - Aerobic Non-Biodegradable Organics |
| anNBDO | - Anaerobic Non-Biodegradable Organics |
| ANEC | - European Association for the Coordination of Consumer Representation in Standardisation |
| AC | - Active Content |
| AI | - Active Ingredients |
| BCF | - Bioconcentration factor |
| BEUC | - Bureau Européen des Unions de Consommateurs |
| CDV | - Critical Dilution Volume |
| C&L | - Classification & Labelling |
| CLP | - Regulation on classification, labelling and packaging of substances and mixtures |
| CPNP | - Cosmetic Products Notification Portal |
| DALY | - Disability-adjusted life year |
| DID-list | - Detergent Ingredient Database |
| DSD | - Dangerous substance directive 67/548/EC |
| DPD | - Dangerous preparation directive 1999/45/EC |
| ECHA | - European Chemicals Agency |
| EPD | - Environmental Product Declaration |
| ESIS | - European chemical substances information system |
| GHS | - Globally Harmonised System |
| GNPD | - Global database of new products |
| GSP | - Good sustainability practice |
| IPCC | - Intergovernmental Panel on Climate Change |
| IUPAC | - International Union of Pure and Applied Chemistry |
| LCA | - Life Cycle Assessment |
| PAF | - Potentially Affected Fraction of species |
| PBT | - Persistent bioaccumulative toxic |
| PE | - Polyethylene |
| PET | - Polyethylene terephthalate |
| PNEC | - Predicted No Effect Concentration |
| PP | - Polypropylene |
| PVC | - Polyvinyl chloride |

| | |
|---|---|
| RSP | - Retail Selling Price |
| RSPO | - Roundtable on Sustainable Palm Oil |
| SCCP | - Scientific Committee on Cosmetic Products and Non Food Products intended for Consumers |
| SCENIHR | - Scientific Committee on Emerging and Newly Identified Health Risks |
| SCHER | - Scientific Committee on Health and Environmental Risks |
| SDS | - Safety data sheet |
| SF | - Safety factor |
| SVHC | - Substances of very high concern |
| TF | - Toxicity factor |
| vPvB | - Very persistent and very bioaccumulative |

**SUMMARY**

A proposal of revised EU Ecolabel criteria for the product group of "soaps, shampoos and hair conditioners"[1] is presented in this document. The initial recommendations for revision of the current criteria has been done based on input received from stakeholders who were involved in this revision process (among others the representatives of the cosmetic industry, of relevant associations, NGOs, Members of the EU Ecolabel Board and other)[2].

Further, the proposals for criteria revision are motivated and/or justified by the results obtained in the technical analysis: the Life Cycle Assessment (LCA) conducted (which assesses the environmental impacts of products covered by the scope of the product group along their life cycle) and the analysis of substances contained in these products[3].

Life cycle assessment of liquid soaps, solid soaps, shampoos and hair conditioners show that hot spots among all life stages of these products are related to use stage (20.5% of the total products impact), disposal to water (between 20 and 14% depending on the kind of product), packaging (between 17 and 24%) and chemicals used (44% of the total environmental impact for solid soaps, 23% for hair conditioners, 9% for shampoo and 10% for liquid soaps). Other stages (manufacturing of products (11.5% on average of the total products impact), distribution (7% of the total products impact) and waste packaging treatment (2% for bottles and 0.1% for solid soap packaging)) have lower load in the overall environmental impact of these products.

Ecolabelled soaps, shampoos and hair conditioners should not contain harmful ingredients and impurities. They should not pose any potential threat to human health and environment along the product life cycle. Analysis of the most commonly used substances that perform the same function in each category has been conducted and the identification of substances of concern (e.g. classified with H- and R- phrases and CLP regulation) has been made, based on ingredients inherent properties. The consideration of more stringent requirements (in comparison with the currently existing criteria) is proposed for some criteria in order to ensure better environmental performance of this product group. Special attention should also be given to the inclusion of health criteria, as indicated in the Commission Statement of 14 December 2006, accompanying the EU Ecolabel criteria development for this product group.

The following issues were initially proposed to the stakeholders involved in the revision process for consideration:

- Threshold values to be applied to the critical dilution volume toxicity (CDV) for each kind of products: soaps, shampoos and hair conditioners,
- Methodology to calculate CDV from the latest version of DID list,
- Surfactants biodegradability (i.e. must all surfactants be readily aerobically and anaerobically biodegradable?),

[1] Commission Decision of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:186:0036:0045:EN:PDF.

[2] See results of questionnaires on the current EU Ecolabel criteria for the product group under study and on the proposal for the new criteria in Appendix x of the "Technical Background Report" for the 1st AHWG meeting, available online at: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html .

[3] For more information see details in "Technical analysis" report, available online at the project's website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

- New criteria about chemicals and substances used in formulations intended for infants, babies and children,
- Revision of packaging requirements in function of the material used: plastic, metal, paper, etc.,
- Consideration of new requirements concerning energy consumption in industries,
- Proposal of a more stringent consumer testing. Discussion if consumer test should be different for professional use and household products,
- Requirements regarding sensitising substances,
- Application of nanomaterials in this product group.

The proposal with recommendations on the revision of the scope and of the criteria was divided into the following sections:

- Chapter 5: Revision of product group definition and scope,
- Chapter 6: Existing criteria and revision proposals,
- Chapter 7: Revised criteria proposal.

The rationale for the proposed amendments and new developments are given in Chapter 5 and 6.

# 1. MARKET ANALYSIS

In the first step, market analysis has been conducted in order to characterize the relevant European cosmetic market of the product group under study and its important tendencies at a quantitative and qualitative level. The following sections provide a summary of quantitative data for soaps, shampoos and hair conditioners: values of production, imports and exports. Further they present main characteristics of the cosmetic industry in Europe and the key players in this sector. The complete results of market analysis can be found in a separate report published at the project's website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

## 1.1 MARKET DATA

The European cosmetics industry represents one-third of the total cosmetics market and it has sale revenues close to these of the United States (US) and Japanese markets together[4].

Cosmetic market for the EU 27 is worth nearly €67.000 million/year (Retail Selling Price, RSP). Among the EU countries, Germany has the largest cosmetics market, valued annually around €12.000 million, followed by France (€11.000 million), the UK (€10.000 million), Italy (€9.500 million), and Spain (€8.000 million). The US market, the second important, reaches about €40.000 million/year. The third position is occupied by the Japanese market, with nearly €30.000 million/year. Arab markets as well as markets like India, China, Brazil or Russia are in continuous expansion, motivated by the gradual access of their population to fragrances and personal care products[4].

In 2010 there were 4000 companies operating in the EU cosmetics industry, two thirds being SMEs, and with direct and indirect employment estimated to be 1.7 million people[4].

European cosmetic products are demanded all over the world and export represents a key activity for the European companies of all sizes, especially SMEs. In 2010, trade with countries outside the EU 27 showed growth of over 16%, and it reached €12.5 billion (from €10.4 billion in 2009)[5].

## 1.2 STRUCTURE OF INDUSTRY AND PRODUCTION

The entire market for soaps is dominated by a small number of multinational companies which account for half of the market. These companies compete among each other with strong brand identity and big advertising budgets. There is fierce competition among these corporations, but soap products represent only a small part of their products range (in most cases, soap and detergents account for 20% of the group turnover).

The top stakeholders include L'Oréal, Unilever, Procter and Gamble, Colgate Palmolive and Johnson & Johnson. Despite this, there are also several hundreds of small and medium sized companies (SMEs) active at the market in most EU27 countries. In Table 1 the top global companies can be seen.



[4] COLIPA Activity Report 2010 – the work of Colipa in 2010, available online at: www.colipa.eu/downloads/3313.html
[5] Source: Eurostat

**Table 1. Top 10 global companies, based on new product introductions in years 2007-2010**

| Top 10 companies (excluding private label) | |
|---|---|
| 1 | L'Oréal |
| 2 | Estée Lauder |
| 3 | Procter & Gamble |
| 4 | Unilever |
| 5 | Beiersdorf |
| 6 | Coty |
| 7 | Kao |
| 8 | Revlon |
| 9 | Henkel |
| 10 | Johnson & Johnson |

*Source: Mintel Global New Product Database*

The studied product category comprises soaps, shampoos and hair conditioners. The highest growth during the last years was achieved for the category of soaps. The market is characterized by growing maturity and vast competition among major brands. Market expansion has been attributed mainly to new products development, such as liquid soaps for hand-washing and showers, supported by heavy media advertising and promotional activity carried out by the major brand manufacturers.

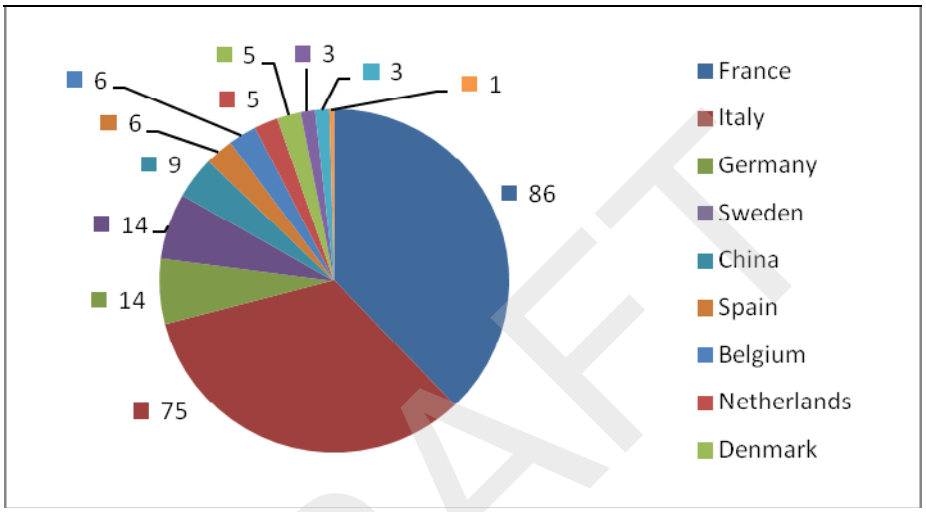
**Environmental issues as competitive strategy**

Several competitive strategies used in this sector have been characterized below. Among them there are some strategies that can be connected with the potential demand of the market for ecolabelled products:

- **Environmental approach.** The growing environmental concerns of the societies have led to the development of eco-friendly products, e.g. using natural, biodegradable ingredients, having biodegradable packaging and refill packages.
- **Ecolabel as a source of differentiation**. Companies tend to perceive the Ecolabel as a tool to improve their position against competitors:
    - Products may carry the ecolabelling trademark for marketing purposes. The Ecolabel is a well-known and well-reputed trademark in some regions.
    - Ecolabelling is a simple and cost-effective way to communicate environmental aspects and commitment to purchasers and consumers.
    - Ecolabel not only covers environmental issues but also quality requirements, since environmental and quality concerns often go together. It means that an Ecolabel licence is sometimes also seen as a mark of quality.

Currently there are around 230 products in the category of "soaps, shampoos and hair conditioners" which have the EU Ecolabel[6] (55 licences were given to manufacturers). If these data is analysed by countries, it can be seen in *Figure 18* that the country with a major number of ecolabelled products is France (86 products), followed by Italy (75), Germany (14), Sweden (14). Other countries are China, Spain, Belgium, Netherlands and Denmark, with less than 10 Ecolabelled products. If we look at the number of licences Germany leads with 12, followed by Italy with 11 and France with 7. Further, the Netherlands have 5 licences, UK – 4, Spain, Poland and Australia – 3, while Austria, Belgium, Denmark, China and Slovenia have 1 licence[7].

**Figure 1. Products with EU Ecolabelled products by country (2011)**




*Source: Elaboration from data given in Ecolabel website: www.eco-label.com*



Market segmentation and claims:

The cosmetic market is divided into several segments, which are as associated with distinct customer groups possessing a common set of special needs or characteristics. In soaps industry, for example, buyer groups can be segmented by factors such as income levels, frequency of purchase, understanding of the product, and other aspects. Soap, bath and shower market is segmented according to gender, but little has been done with regard to segmentation into age groups, apart from having products intended for babies, children and teenagers. Market trends have been gathered based on different market reports[8, 9, 10]. Elderly women and men have been largely not considered in this respect due to the assumption that they remain wedded to old-style bath additives and bar soaps. Given these trends in segmentation, the current main claims attributed to the products gives a guidance which concepts and attributes companies want to communicate and relate to their products to. Among the top 10 claims and 10 growing claims, there are some related to

[6] www.eco-label.com.
[7] In accordance with the information obtained per e-mail from DG Environment.
[8] Emerging worldwide markets. Personal care. ACNielsen. 2004.
[9] A Study of the European Cosmetics Industry. Global Insight. European Commission, Directorate General for Enterprise and Industry. November 2007.
[10] Trends on mass market beauty & personal care. Mintel (Mintel GNPD).

sustainability of products, such as "Ethical – Environmentally Friendly Package" or "Paraben free". The top 10 claims are given in Table 2.

**Table 2. Top claims and 10 growing claims (2009-2010)**

| Top 10 claims | 10 Selected claims showing a significant growth, 2009-2010 |
|---|---|
| Botanical / Herbal | Ethical – Environmentally Friendly Package |
| Moisturising / Hydrating | Ethical – Animal |
| Long - Lasting | Seasonal |
| Vitamin / Mineral Fortified | Mattifying |
| Dermatological tested | Time / Speed |
| Brightening / Illuminating | Paraben Free |
| Ethical – Animal | UV Protection |
| Time / Speed | Male |
| Seasonal | Long – Lasting |
| UV Protection | Limited Edition |

*Source: Mintel Global New Product Database*

**Product categories overview**

This final section presents the information about the market for each product category (differentiating between bar and liquid soap and shampoo and hair conditioner). All this information is based on monitoring the launch of new products in different markets in the above categories (See Table 3 and 4) based on the research of the information and data contained in the Mintel GNDP database (the Global New Products Database)[11].

**Table 3. Market characteristics for the category of bar and liquid soap[12]**

| | |
|---|---|
| Products launches | New product activity was split between Bar Soap with 53% of launches and Liquid Soap with 47%.<br>The UK led the way accounting for one fifth of European launches in this review period, followed by France with 12%, and Russia with 11%. |
| Natural ingredients | Naturalness is largely focused on the incorporation of plant ingredients and extracts in product formulations. |
| Protection & convenience | The possibility of using liquid soap as portable hand sanitisers which can be carried by consumers is an advantage of liquid soaps over bar soaps. |
| Sensitive skin | Launches suitable for sensitive skin accounted for a 6% of the market. |
| Ethical concerns | Refills offer consumers a greener and more economical option and maintained at consistent 4% share of the market. |
| Added benefits | Exfoliation can help make skin smoother and allows moisture to be better absorbed, therefore working in conjunction with other beneficial properties. |

[11] For details see the database website: http://www.gnpd.com/.
[12] Source: Mintel GNPD. Category Insight Bar & Liquid Soap (period under review: Q1 and Q2 2011)

| | |
|---|---|
| Targeted & seasonal launches | Penetration of bar soaps is slightly higher amongst men compared to women, who are more likely than men to use liquid soap hand wash products. |
| Fortified soaps | Some vitamins offer antioxidant benefits. They can be incorporated into products through the use of popular ingredients such as super-fruits. |
| Fragrances | Fragrances are extremely important in this market, since less than a third (29%) of launches during this period were un-fragranced. |
| Claims | Botanical/herbal and moisturising/hydrating were the top claims in nearly all regions; and ethical-animal products performed strongly in North America. Anti-bacterial was also a strong claim across the regions, highlighting on-going concerns relating to illness and hygiene. |
| Issues affecting the market | • **Saturation**. Products are failing to induce consumer engagement with brands. Most consumers do not care about what soap they buy.<br>• **Internal competition**. Bar soaps have an old fashioned image and their sales have fallen.<br>• **Economic Factors**. Over a half of consumers prefer to buy soap, bath and shower products that are on special offer. Almost four in ten consumers are willing to go to a further stock to buy products in promotion. |
| Trends forecast | • As consumers are increasingly concerned about the use of synthetic chemicals such as parabens, phthalates and colorants in cosmetics and toiletries, product innovation is likely to continue focusing on natural products formulated with botanical and herbal ingredients, such as argan oil.<br>• The aromatherapy proposition remains a strong feature of the category, but formulators could take products beyond the simplistic energising/relaxing axes.<br>• Products featuring skin care properties, mainly moisturisation, exfoliation and pH-balanced composition, remain another key area for new product development, appealing to consumers who are concerned about skin allergies or potential irritation.<br>• Although bar soaps appear to be in terminal decline, tapping into the nostalgia trend could be one way to rejuvenate the sector. With an elderly core consumer base that shows great loyalty to the traditional bar soap format, suppliers could take better advantage of nostalgia in product design and marketing, for example through packaging and fragrances that bring back memories and appeal to the consumer at an emotional level. |

**Table 4. Market characteristics for the category of shampoos and hair conditioners**[13]

| | |
|---|---|
| Products launches | Overall, new product launches decreased by 2% in the analysed period, i.e between 2010 and 2011. Shampoo dominated accounting for 64% of launches with the remaining 36% falling for Hair Conditioner. Europe retained the top spot as the most active region, accounting for 40% of total launches. The UK and Germany were the most active countries, accounting for 18% and 14% of launches, respectively, followed by Italy and Spain, with 9% and 8%, respectively. |
| A more natural image | In the six months under review, botanical/herbal remained the top claim, accounting for over half of total launches (55%). |
| Moisturising and nourishing | Moisturising/hydrating remained the second most active claim, featuring in 40% of total launches. |
| Fast acting and long-lasting | Busy consumers welcome products which are not only quick to use, but which also provide lasting results, to minimise the need for frequent hair washing and styling. |
| Caring for animals and environment | A steady 13% of launches featured the ethical-animal claim while products free from any animal ingredients accounted for a more limited 5% share.<br>The environmentally friendly package claim maintained at 10% share of total launches in this review period, with the focus on recyclability. |
| Fragrances and fortification | Just over a fifth (21%) of total launches featured the vitamin/mineral fortified claim.<br>According to the Mintel's consumer research, roughly a third of American men and half of American women are influenced by a pleasant fragrance when it comes to decide which brand of shampoo, conditioner, or styling product to purchase. |
| Claims | Shampoo was the dominant sub-category across regions and especially in the Middle East & Africa. Botanical/herbal and moisturising/ hydrating were top claims across all regions. Skin-friendly claims such as dermatological tested and pH neutral were especially important in Europe; vitamin/mineral fortified formulations showed heightened activity in Asia Pacific; and not testing products on animals was especially important in North America. |
| Issues affecting the market | • **Limited competition**. Shampoo and Conditioner products have such a specific purpose that they face limited competition. 2-in-1 shower gel/shampoo products pose some negligible competition for Shampoo.<br>• **More specialization**. Shampoos and Conditioners become increasingly specialised, catering for particular hair types (e.g. greasy, dry) or styles (curly, straight) or coloured hair etc, and compete better with premium and salon-only products. Moreover, as consumers have cut back on salon visits amid ongoing economic difficulties, they turn arguably to more premium and specialised products.<br>• **External influence**. An ageing population is likely to influence new products, since older people tend to have finer and more brittle hair and consequently they need products that focus on moisturisation and adding strength. The growth of popularity of styling appliances such as hair straightness will increase demand of products that offer moisturisation. |

[13] Source: Mintel GNPD (period under review: Q4 2010 & Q1 2011)

| | |
|---|---|
| Trends forecast | • The limited offers for men have held back usage of male-specific shampoos and conditioners. Manufacturers could examine segmentation along the lines of hair type, condition and ethnicity.<br>• For natural products –increase of the use of plant ingredients for more all natural/organic formulations and products which claim natural benefits is expected.<br>• Gentle formulations are expected to remain important given that consumer awareness of allergies/sensitive skin is rising. Milder products will especially appeal to people who need or want to wash their hair on a daily basis but are concerned about over-drying or damaging hair because of excess chemicals in product formulations.<br>• Brands could earn distinction by being transparent about not wasting resources or water. They could help consumers with portion control and weekly usage by introducing a subscription-based mailing service that offers concentrated sachets for refillable bottles, similar to intensive detergent sachets available in the laundry sector. This would not only pitch brands as green by saving water, but would also require less packaging and lower shipping costs for manufacturers - savings that could be passed on to the consumer.<br>• Manufacturers could better highlight ease of use and/or convenient packaging attributes such as if it is easy to open and to pour with one hand. |

### 1.3 CONCLUSIONS

- The European market of perfumery and cosmetics is the largest in the world. Germany has the largest market in the EU, followed by France, UK, Italy and Spain. These countries are leaders in number of new product launches and in volume of production, exports and imports.

- The biggest problem in the sector is saturation of the market with slow growth expected for the coming years to 2014 and where the sales values are unlikely to grow. In addition, the market is dominated by a small number of multinational companies which account for half of its value. In this context, the competitive strategies must offer higher added-value products. Among potential solutions there is offering of environmentally friendly products. As consumers require that these products are verified, this can be seen as great potential for the EU Ecolabel. It is nevertheless worth mentioning that packaging plays also a crucial role in consumers' choices, being one of the most important factors in decision of purchase.

- In a saturated market it is still possible to find a niche. Segmentation trends point to proliferation of products related to user's experiences (such as products designed to relax), while at the same time natural product concepts also become more and more important (in terms of composition and ingredients). New product launches try to capture the attention of consumers who look for simple, natural and environmentally friendly products. However, this simplicity does not mean that consumers do not demand products with specific properties (moisturizing, pH-balanced, etc.). Finally, it is believed that there are still niches available to be exploited, such as certain profiles of products e.g. for men, children and teenagers.

- In general there is interest in obtaining the EU Ecolabel for some products, especially products aimed at children and babies. However, few manufacturers take the initiative to get the

Ecolabel. They would apply for it if the market demanded it. Hence, it is very important to stimulate market demand, e.g. by informing customers on the importance to take the environmental issues into consideration when buying products. Moreover, it has to be noticed that there exists confusion in some standards and certifications, for example, on natural and organic certifications. Therefore, this provides a good opportunity for the Ecolabel, as it could properly inform the consumer and prevent this kind of confusion.

- In summary, it can be said that the current market context is favourable to host Ecolabel products. Companies gradually understand that consumers want to buy products that cause less harmful impacts to the environment. However, in order to achieve significant impact consumers must be well informed about what the Ecolabel stands for. Only then Ecolabel can be an added value for the product, differentiating it from other labels and schemes existing on the saturated market of cosmetics.

## 2. LEGISLATION

Cosmetic products and their ingredients are regulated by several directives and legal regulations in order to prevent the potential harmful impacts for human health and environment. These legislative acts are described briefly in this section.

### MAIN REGULATORY FRAMEWORK

- **Cosmetics Directive 76/768/EEC**[14] is the main regulatory framework for a finished cosmetic product and was adopted in 1976 in order to ensure the free circulation and safety of cosmetic products in the internal market. The Cosmetics Directive imposes requirements regarding substances that must not be present in cosmetic products and those that may be used in limited quantities. However, the Directive mainly regulates health impacts and it does not take into consideration environmental issues.
  The Cosmetics Directive was reviewed on 30 November 2009 and the new Cosmetic Products Regulation, **Regulation (1223/2009 on cosmetic products**, was adopted[15] replacing the Cosmetics Directive.

  "*The provisions of the Regulation aim at ensuring that consumers' health is protected and that they are well informed by monitoring the composition and labelling of products. The Regulation also provides for the assessment of product safety and the prohibition of animal testing. The Annexes of this Regulation give a list of prohibited substances (Annex II) or restricted substances (Annex III) with respect to use in cosmetic products. Certain colorants (other than those in Annex IV), preservatives (other than those in Annex V) and UV-filters (other than those in Annex VI) are also prohibited*. *The Regulation prohibits the use of substances recognised as carcinogenic, mutagenic or toxic for reproduction (classified as CMR), apart from in exceptional cases*"[16]. The new European Cosmetics Regulation takes also into account the latest technological developments, including the possible use of nanomaterials. Nanomaterials are defined and regulated by this new regulation, however, nano-sized UV-filters, pigments and preservatives are exempted.

  The new Regulation will apply from 2013; nevertheless, some of its provisions apply already from the end of 2010 (i.e. on concern substances which are carcinogenic, mutagenic or toxic for reproduction, i.e. classified as CMR.



[14] Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetics products (76/768/EEC) (OJL 262, 27.9.1976,P.169), available online at: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1976L0768:20100301:en:PDF.

[15] Regulation 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF.

[16] Information available at the website regarding European legislation: http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/co0013_en.htm.

**Other applicable EU legislation:**

- **REACH**[17]: **Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals**.

  The environmental concerns that cosmetic products may raise are considered through the application of REACH. REACH does not allow marketing of a chemical substance if it does not have appropriate registration, which has to be carried out by every legal entity that manufacture or import from outside of the European Union substances on their own, in preparations or in articles in quantities of 1 tonne or above per year. REACH places responsibility on industry to manage the risks that chemicals may pose to human health and environment, as well as to provide safety information that would be passed down the supply chain. The companies that do not undertake this procedure, will not be able to produce, sell or use their products and would consequently be forced to stop their activity.

  In addition to registration, REACH regulates other procedures such as the management of the risk and hazardous properties of the substance, authorisation of substances of very high concern (carcinogenic, mutagenic and/or toxic for reproduction, persistent, bioaccumulative and toxic or very persistent and very bioaccumulative) and the restriction on the manufacturing, placing on the market and use of certain dangerous substances, preparations and articles when an unacceptable risk to human health or the environment exists.

  Certain substances[18] that may cause serious and often irreversible effects on human health and the environment can be identified as Substances of Very High Concern (SHVC). REACH aims at ensuring that the risks resulting from the use of SVHCs are controlled and that the substances are replaced where possible. A Member State, or ECHA[19] on request of the European Commission, can propose a substance to be identified as an SVHC. Placing on the market and use of SVHC included in the Authorisation List: Annex XIV of REACH regulation, requires authorisation. A manufacturer, importer or downstream user can apply for the authorisation. Applications for authorisation are submitted to ECHA. At the end of the authorisation process, which includes a public consultation and the development of opinions by ECHA´s Committees on Risk Assessment and Socio-economic Analysis, the European Commission decides on the granting or refusing of authorisations.

  Substances of Very High Concern listed in Annex XIV of REACH Regulation (Authorisation list) are given in the table below:



[17] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Official Journal of the European Union L 396 of 30 December 2006; available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:en:PDF.

[18] http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation.

[19] European Chemicals Agency.

**Table 5. Substances of Very High Concern listed in Annex XIV (Authorisation List)**

| SUBSTANCE NAME | EC NUMBER | CAS NUMBER | SUNSET DATE | LATEST APPLICATION DATE |
|---|---|---|---|---|
| Tris(2-chloroethyl)phosphate (TCEP) | 204-118-5 | 115-96-8 | 21/08/2015 | 21/02/2014 |
| Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane | 221-695-9, 247-148-4 | 3194-55-6, 25637-99-4 begin_of_the_skype_highlighting end_of_the_skype_highlighting, 134237-50- end_of_the_skype_highlighting, 134237-51-7 begin_of_the_skype_highlighting end_of_the_skype_highlighting, 134237-52-8 begin_of_the_skype_highlighting | 21/08/2015 | 21/02/2014 |
| 2,4 – Dinitrotoluene (2,4-DNT) | 204-450-0 | 121-14-2 | 21/08/2015 | 21/02/2014 |
| Diarsenic pentaoxide | 215-116-9 | 1303-28-2 | 21/05/2015 | 21/11/2013 |
| Lead chromate | 231-846-0 | 7758-97-6 | 21/05/2015 | 21/11/2013 |
| Lead sulfochromate yellow (C.I. Pigment Yellow 34) | 215-693-7 | 1344-37-2 | 21/05/2015 | 21/11/2013 |
| Lead chromate molybdate sulphate red (C.I. Pigment Red 104) | 235-759-9 | 12656-85-8 begin_of_the_skype_highlighting | 21/05/2015 | 21/11/2013 |
| Diarsenic trioxide | 215-481-4 | 1327-53-3 | 21/05/2015 | 21/11/2013 |
| Dibutyl phthalate (DBP) | 201-557-4 | 84-74-2 | 21/02/2015 | 21/08/2013 |
| **Bis(2-ethylhexyl) phthalate (DEHP)** | 204-211-0 | 117-81-7 | 21/02/2015 | 21/08/2013 |
| **Benzyl butyl phthalate (BBP)** | 201-622-7 | 85-68-7 | 21/02/2015 | 21/08/2013 |
| **Diisobutyl phthalate (DIBP)** | 201-553-2 | 84-69-5 | 21/02/2015 | 21/08/2013 |
| **5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)** | 201-329-4 | 81-15-2 | 21/08/2014 | 21/02/2013 |
| 4,4'-Diaminodiphenylmethane (MDA) | 202-974-4 | 101-77-9 | 21/08/2014 | 21/02/2013 |

Source: European Chemicals Agency website

The identification of a substance as Substance of Very High Concern and its inclusion in the Candidate List is the first step of the authorisation procedure. Companies may have immediate legal obligations following such inclusion which are linked to the listed substances on its own, in preparations and articles. The Candidate list of substances of Very High Concern is given in Annex V. Chemicals that are restricted are referred to under Article 57 and listed in Annex XVII[20] of REACH, while Article 59 (1) sets out a procedure for the recommendation of chemicals considered posing risks to human health and/or the environment.

[20]European Chemicals Agency website: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/restrictions/list-of-restrictions

- **Directive 67/548/EEC**[21] refers to the **classification, packaging and labelling of dangerous substances**. This Directive sets out the criteria and the procedure to harmonise the classification and labelling of substances.

- **Directive 1999/45/EEC**[22] refers to the **classification, packaging and labelling of dangerous preparations**. This directive sets out rules on how to classify and label preparations for human health and environmental hazards. This Directive apply to the placing on the market of raw materials and starting materials but it shall not apply to cosmetic products in the finished state, intended for the final user which are already covered by Directive 76/768/EEC.

- **CLP: Regulation 1272/2008**[23] **on classification, labelling and packaging of substances and mixtures**. On 20 January 2009 this regulation entered into force. It aligns existing EU legislation to the United Nations Globally Harmonised System (GHS)[24]. The date from which substance classification and labelling must be consistent with the new rules was December 2010 and for mixtures will be June 2015. Then the CLP Regulation will replace fully the: Dangerous Substance Directive (67/548/EC) and the Dangerous Preparations Directive (1999/45/EC).

- **Directive 76/769/EEC**[25] of 27 July 1976 **on the approximation of the laws, regulation and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations**. This Directive compiles marketing and use restrictions for a wide variety of substances, preparations and products.

- **Directive 95/17/EC**[26] of 19 June 1995 **laying down detailed rules for the application of Council Directive 76/764/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products**.

- **Directive 80/232/EEC**[27] of 15 January 1980 **on the approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain pre-packaged products**.



[21] Commission Directive 2009/2/EC of 15 January 2009 amending, for the purpose of its adaptation to technical progress, for the 31st time, Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:011:0006:0082:EN:PDF.

[22] Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. OJ L 200, 30.7.1999, p. 1–68, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:200:0001:0068:EN:PDF.

[23] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, Official Journal of the European Union L353 of 31 December 2008, pp. 1–1355, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF.

[24] http://ec.europa.eu/enterprise/sectors/chemicals/documents/classification/.

[25] Council Directive of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (76/769/EEC) (OJ L 262, 27.9.1976, p. 201).

[26] Commission Directive 95/17/EC of 19 June 1995 laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products. OJL 140, 23/06/1995 P. 0026-0029: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0017:en:HTML.

27 Council Directive 80/232/EEC of 15 January 1980 on the approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain prepackaged products.OJL 51, 25.2.1980, p. 1-7. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31980L0232:en:HTML.

- **Directive 94/62/EC**[28] of 20 December 1994 **on packaging and packaging waste**. This Directive aims to prevent or reduce the impact of packaging and packaging waste on the environment. It contains provisions on the prevention of packaging waste, on the re-use of packaging and on the recovery and recycling of packaging waste.

- **Directive 98/8/EC**[29] of 16 February 1998 concerning the **placing of biocidal products on the market**. The basic principles of the Directive are[30]:

    - Active substances have to be assessed and the decision on their inclusion into Annex I of the Directive shall be taken at Community level.
    - Comparative assessment will be made at the Community level when an active substance, although in principle acceptable, still causes concern. Inclusion to Annex I may be denied if there are less harmful, suitable substitutes available for the same purpose.
    - Member States shall authorise the biocidal products in accordance with the rules and procedures set in Annex VI of the Directive. They can only authorise products which contain active substances included in Annex I.
    - The producers and formulators responsible for the placing of the market of the biocidal products and their active substances must apply for authorisation and submit all necessary studies and other information needed for the assessments and the decision making.
    - A biocidal product authorised in one Member State shall be authorised upon application also in other Member State unless there are specific grounds to derogate from this principle of mutual recognition.

  On 22 May 2012, the new Regulation on biocidal products (Regulation No 528/2012[31]) was adopted. It will replace Directive 98/8/EC from September 2013.



[28] European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste. OJL 365, 31.12.1994, p. 10-23. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0062:en:HTML.

[29] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, available online at: http://ec.europa.eu/environment/biocides/pdf/98_8_ec_web.pdf.

[30] European Commission website regarding biocides: http://ec.europa.eu/environment/biocides/index.htm.

[31] Regulation 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:FULL:EN:PDF.

## 3. COMPARISON OF ECOLOGICAL CRITERIA ESTABLISHED IN DIFFERENT LABELS

Several countries have their own environmental labels on personal care products[32]. However, there are differences in the focus and the scope of the different labels. In relation to the focus, there are three main areas these ecolabels address:

- **Sustainability/safety of a product**: It involves a comprehensive set of criteria for sustainably designing and manufacturing products that incorporate environmental and human health effects in their evaluation.
- **Organic content** (Standards for evaluating the organic content of the products are developed).
- **Natural** (i.e. refer to products from renewable or plentiful resources).

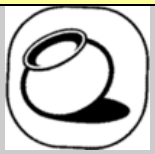
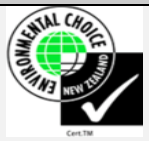
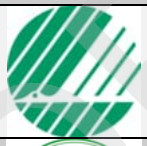
In this section we only examine the most known ecolabels from around the world for this product category (see Table 6)[33]:

**Table 6. Summary of other ecolabels applicable to soaps, shampoos and hair conditioners**

| ECOLABEL NAME | LOGO | REGION | PRODUCT CATEGORY | DATE OF ADOPTION |
|---|---|---|---|---|
| **ABNT Ecolabel** | | Brazil | Cosmetics / Personal Care | 1993 |
| **BDIH** | | Germany | Cosmetics / Personal Care | 1996 |
| **China Environmental Labelling** | | China | Cosmetics | 2003 |
| **Cradle to Cradle** | | U.S.A | Cosmetics / Personal care | 2005 |
| **Degree of Green** | | U.S.A | Cosmetics products | 2008 |
| **Earthsure** | | U.S.A | Cosmetics / Personal care | 2006 |
| **Ecologo** | | Canada | Cosmetics / Personal care | 1988 |

[32] An overview of Ecolabels and Sustainability Certifications in the Global Marketplace, Interim report document #2010-10-1, Nicholas Institute for Environmental Policy Solutions Duke University, Jay S. Golden, PhD, October 2010.

[33] Information on ecolabels on cosmetic/personal care available at the following website: http://www.ecolabelindex.com/ecolabels/?st=category,cosmetics_personal_care.

| ECOLABEL NAME | LOGO | REGION | PRODUCT CATEGORY | DATE OF ADOPTION |
|---|---|---|---|---|
| **Ecomark** |  | India | Cosmetics / Personal care | 1991 |
| **Environmental Choice New Zealand** |  | New Zealand | Cosmetics / Personal care | 1990 |
| **Environmental Product Declaration** |  | Sweden | Cosmetics / Personal care | 1999 |
| **Green Good Housekeeping Seal** |  | U.S.A | Cosmetics / Personal care | 2009 |
| **Green Seal** |  | U.S.A | Cosmetics / Personal care | 1989 |
| **Hungarian Ecolabel** |  | Hungary | Cosmetics / Personal care | 1993 |
| **Korean Ecolabel** |  | Korea | Cosmetics / Personal care | 1992 |
| **Nordic Ecolabel or Swan** |  | Denmark, Finland, Iceland, Norway, Sweden | Cosmetics / Personal care | 1989 |
| **Thai Green Label** |  | Thailand | Cosmetics / Personal care | 1994 |
| **Vitality Leaf** |  | Russia | Cosmetics / Personal care | 2001 |
| **Good Environmental Choice ( GEC)** |  | Sweden | Cosmetics / Personal care | 1998 |
| **GREEN MARK** |  | Taiwan | Personal care | 2007 |

A brief description of them is given below:

- **ABNT Ecolabel**[34]: Is a life cycle based ecolabel that is a voluntary scheme of environmental performance certification and labelling for Personal Care products in Brazil. The scope of the product category includes: shampoos, soaps (both solid and liquid), corporal cleansers, shampoos and both liquid and solid soaps for animals. It addresses the following issues: preservation of the environment, reduction of waste (recycling) and increased revenue (sale of scrap for recycling). The ABNT Ecolabel is a guarantee that the product/service of the company causes less environmental impact than other similar products available at the market.

- **BDIH**[35] **"Certified Natural Cosmetics**": is a recognized German eco-certification available in the personal care sector. Products marked with the BDIH seal use natural raw material such as plant oils, fats and waxes, herbals extracts and essential oils and aromatic materials from controlled biological cultivation or controlled biological wild collection. In addition to the careful selection of raw materials, the ecological impact of each product plays an important role.

- **China Environmental Labelling**[36]: Was initiated in 2003 by the Environmental Protection Administration Environmental Certification Centre (now called China Environmental United Certification Center – CEC). It provides environmental standards e.g. for cosmetics.

- **Cradle to Cradle**[37]**:** C2C concept bases on five criteria: Material Health, Material Reutilization, Renewable Energy Use, Water Stewardship, and Social Responsibility. This certification is a third-party sustainability label that requires achievement in multiple areas: use materials that are safe for human health and the environment across their life cycles, product and system design for material reutilization, such as recycling or composting, use of renewable energy, efficient use of water and maximum water quality associated with production and company strategies for social responsibility. This certification program applies to materials, sub-assemblies and finished products.

- **Degree of Green**[38]**:** *"is a new rating and educational program created to help retailers educate consumers and contractors about the real impact of "green" home improvement and home building products on the environment and on human health"***.** At the core of Degree of Green are data sheets that detail the environmental, health and sustainability attributes of cosmetic products. A top rating of 4 goes to product that have the least adverse effects on human health, the highest level of environmental sustainability and the least adverse effects on the environment.

[34] ABNT's Environmental Labeling, Criteria for Personal Care Products, available online at: http://www.abntonline.com.br/rotulo/en/Default.aspx

[35] German Association of Industries and Trading Firms for pharmaceuticals, health care products, food supplements and personal hygiene product, Certified Natural Cosmetics, website: http://www.kontrollierte-naturkosmetik.de/e/index_e.htm.

[36] More information available online at: http://www.greencouncil.org/eng/greenlabel/china.asp and http://www.sepacec.com/cecen/labelling/newpage/200406/t20040629_94151.htm.

[37] More information available online at: http://www.mbdc.com/detail.aspx?linkid=2&sublink=8.

[38] More information available at: Degree of Green: http://www.degreeofgreen.com/.

- **Earthsure**[39]**:** The objective of the Earth sure program is to provide comprehensive environmental data to purchasers so that the power of the market can move the economy towards overall environmental improvement. The Earth sure ecolabel discloses the environmental impact indicator results of the creation of each product.

- **Ecologo**[40]**:** is North America's largest environmental standard and certification mark. The products meet stringent standards of environmental leadership. The program compares product/services with others in the same category, develops rigorous and scientifically relevant criteria that reflect the entire lifecycle of the product and awards the Ecologo to those that are verified by an independent third party as complying with the criteria.
  The Ecologo Program is one of two such programs in North America that has been successfully audited by the Global Ecolabelling Network (GEN) as meeting ISO 14024[41] standards for eco-labelling.

- **Ecomark India**[42]: To increase consumer awareness, the Government of India launched this eco-labelling scheme in 1991 for easy identification of environmentally friendly products. The criteria follow a cradle-to-grave approach (from raw materials extraction, through manufacturing and use to disposal).

- **Environmental Choice New Zealand**[43]**:** A voluntary, multiple specifications based environmental labelling programme that operates to international standards and principles.

- **Environmental Product Declaration**[44]: The International EPD System has the objective to help and support organizations to communicate the environmental performance of their products (goods and services) in an understandable way.

- **Green Good Housekeeping Seal**[45]: The product is evaluated based on a wide range of environmental criteria, including ingredient and product safety, reduction of water use in manufacturing, energy efficiency in manufacturing and product use, packaging reduction, greenhouse gas emissions, and the brand's corporate social responsibility.

- **Green Seal**[46]**:** An independent non-profit scheme founded in 1989. Green Seal certifies thousands of products and services that meet science-base environmental standards. Green Seal utilizes a life-cycle approach to ensure tangible reductions in the whole environmental footprint.

- **Hungarian Ecolabel**[47]: was developed by the Hungarian Ministry of Environment in 1994. Goals and procedures meet the requirements of ISO 14024 standard. The objective of the

[39] More information available on line at: http://iere.org/earthsure.aspx.
[40] More information available on line at: http://www.ecologo.org/en/.
[41] ISO 14024:1999 Environmental labels and declarations - Type I environmental labelling - Principles and procedures.
[42] More information available on line at: http://ceeraindia.org/documents/ecomarkindia.htm.
[43] More information available on line at: http://www.enviro-choice.org.nz/.
[44] More information available on line at: http://www.environdec.com/.
[45] More information available on line at:http://www.goodhousekeeping.com/product-reviews/history/about-green-good-housekeeping-seal.
[46] More information available on line at: http://www.greenseal.org/.
[47] More information available on line at: http://www.kornyezetbarat-termek.hu/.

Hungarian Ecolabel is to promote environment-friendly products and to inform the consumers about the environmental characteristics of the products and services.

- **Korean Ecolabel**[48]**:** The Korea Ecolabel was launched into market by the government of the Republic of Korea in 1992. Improvement in ecoproducts and product environmental friendliness by setting up the eco-product standards. Award of the Korea Ecolabel to particularly eco-friendly products is primarily based on life-cycle analysis.

- **Nordic Ecolabel or "Nordic Swan"**[49]**:** is a voluntary ecolabelling scheme that evaluates a product´s impact on the environment throughout the whole life cycle. The label guarantees among other that climate requirements are taken into account and $CO_2$ emissions (and other harmful gasses) are limited – where it is most relevant. The Nordic Ecolabel is available for 65 product groups. The label ensures that products fulfill certain criteria using methods such as samples from independent laboratories, certificates and control visits. In 2011 a common criteria set for all cosmetic products (i.e. rinse-off and non rinse-off) was published.

- **Thai Green Label**[50]: was initiated by the Thailand Business Council for Sustainable Development (TBCSD) and formally launched in 1994 by the Thailand Environment Institute (TEI) in association with the Ministry of Industry. The Green Label is an environmental certification awarded to specific products that are shown to have minimum detrimental impact on the environment, in comparison with other products serving the same function. The Thai Green Label Scheme applies to products and services, not including foods, drinks and pharmaceuticals.

- **Vitality Leaf**[51]: was developed by NGO: St. Petersburg Ecological Union in 2001. Criteria for certification are developed using life cycle approach according to ISO 14024 standard. The main objectives of this ecolabel is to encourage the demand for and supply of environmentally preferable products and services, contribute to reduce environmental impacts of producers and improve the quality of the environment and to encourage the sustainable management of resources.

- **Good Environmental Choice (GEC)**[52]**:** Good Environmental Choice, or in Swedish Bra Miljöval[53], is the ecolabelling system established by the Swedish Society for Nature Conservation (SSNC), the largest environmental NGO in Sweden. The testing and award procedure is based on a life-cycle analysis. Today, the both labeling systems: the Swan of the Nordic Council and the Bra Miljöval are of equal standing on the Swedish market.**Green Mark**[54]: The Green Mark is a certification awarded to products that have gone through strict verification tests, belonging to the first 20-30% that has the lowest environmental impact. The mission of the Green Mark is to "promote the concept of recycling, pollution reduction,

[48] More information available on line at: http://el.keiti.re.kr/eng/index.do.
[49] More information available on line at: http://www.nordic-ecolabel.org/.
[50] More information available on line at: http://www.tei.or.th/greenlabel/.
[51] More information available on line at: http://www.ecounion.ru/en/site.php.
[52] More information available on line at: http://www.naturskyddsforeningen.se/in-english/.
[53] More information available on line at: http://www.naturskyddsforeningen.se/bra-miljoval/in-english/about-bra-miljoval/how-does-it-work/.
[54] More information available on line at: http://greenliving.epa.gov.tw/GreenLife/eng/english.aspx.

and resource conservation". The objectives of the Green Mark are to guide consumers in purchasing green products and to encourage manufacturers to design and produce them.

An overview of the requirements of the criteria documents for the most recognized European ecolabels are given in the table below:

**Table 7. Comparison of ecological criteria established in different labels**[55]

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| **Definition of the product group** | The association has organized over 440 producers and distributors of:<br>- Cosmetics and Natural Cosmetics<br>- Food Supplements<br>- Nutritional Foods<br>- Over the counter Medications<br>- Medical Devices<br>The makers of the products marked with the BDIH "Certified Natural Cosmetics" seal use natural raw material such as plant oils, fats and waxes, herbal extracts and essential oils and aromatic materials from controlled biological cultivation or controlled biological wild collection. In addition to the careful selection of raw materials, the ecological impact of each product plays an important role. | - All cosmetic products that are encompassed by Council Directive 76/768/EEC on cosmetics with subsequent amendments and adaptations and Cosmetics Regulation 1223/2009/EG for example skin care products, hair care products, decorative cosmetics, perfumes and sanitary products.<br>- Rinse-off products for animals, which are not covered by the cosmetics directive. | Liquid and solid soaps, hand cleaners, shower creams, hair shampoos, hair conditioners and sanitary napkins. |
| **Product** | No animal testing may be performed or commissioned when end products are manufactured, developed or tested.<br>It is prohibited to use raw materials obtained from dead vertebrates (e.g spermaceti, | The European Commission has prohibited animal testing for ingredients in cosmetic products as of March 2009. The prohibition extends only to fish, invertebrates are not covered by this ban on animal testing. | |

[55] Annex 2. Requirements of other ecolabels , Final report. EU Eco-label for shampoo and soaps". Ecolabelling Norway, Eskeland,, M.B, Svanes, E., 2006

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| | terrapin oil, mink oil, marmot fat, animal fats, animal collagen or living cells). | | |
| **All ingredients** | Raw materials obtained from plants should be used from:<br>- Controlled biological cultivation, taking quality and availability into account, or<br>- Controlled biological wild collections<br>Raw materials obtained from minerals and the use of inorganic salts is generally permitted, except for (deliberate rejection of):<br>- Organic-synthetic dyes<br>- Synthetic fragrances<br>- Ethoxylated raw materials<br>- Silicones<br>- Paraffin and other petroleum products<br>The criterion which determines which aromatic substances are permitted is mainly IOS 9235. | Musts not be classified as:<br>- Carcinogenic: Carc 1A/1B/2 with H350, H350i and/or H351 (Carc with R40, R45 and/or R49)<br>- Mutagenic: Mut 1B/2 with H340 and/or H341 (Mut with R46 and/or R68)<br>- Reproductive toxic: Repr 1A/1B/2 with H360f, H360D, H361f, H361d, H360fd, H361fd, H360Fd, H360Df, Lact. H362 (Repr with R60, R61, R62, R63 and/or R64)<br>- Sensitizing: Resp. sens. 1 with H334 or Skin sens. 1 with H317 (Xn with R42 or Xi with R43). | |
| **All ingredients** | For the production of natural cosmetics, it is permissible to use components which are extracted through hydrolysis, hydrogenation, esterification, transesterification or other crackings and condensations from the following natural materials: | - Substances that cause endocrine disruption (EU-list) are forbidden.<br>- Nanomaterials/particles (insoluble or biopersistent and intentionally manu-factured materials with one or more external structure in size 1-100 nm) are prohibited. Excepted from this | |

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| | - Fats, oils and waxes<br>- Lecithins<br>- Lanolin<br>- Monosaccharides, oligosaccharides and polysaccharides<br>- Proteins and lipoproteins<br>The actual raw material use is regulated by the positive list for development and production of certified natural cosmetics. | requirement is hydrated silica used as abrasives in toothpaste. If documentation is published by the SCCS demonstrating that the use of specific nanomaterials/particles in sunscreen products does not give rise to concerns in respect of health, then such specific nanomaterials/particles additionally may be approved for use as sun filter in sunscreen products.<br>- Substances that have been evaluated in the EU to be PBT or vPvB are prohibited.<br>- The following substances are prohibited from use in the product and ingredients:<br>- D4 (octamethylcyclotetrasiloxane, CAS 556-67-2) and D5 (decamethylcyclopentasiloxane, CAS 541-02-6)<br>- Borates and perborates<br>- Nitromusk and polycyclic musks<br>- EDTA (Ethylenediaminetetraacetic acid) and its salts (exemption for solid soap under R22).<br>- Triclosan<br>- Parabens (4-Hydroxybenzoic acid and its salts and esters) | |

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| **All ingredients** | | Total content of not readily biodegradable ingredients in:<br>a) Liquid soap, hand soap for industry, shampoo, shower gel, conditioner, bath foam, cleanser, exfoliant < 15 mg/g AI<br>b) Solid soaps < 5 mg/g AI | |
| **All ingredients** | | Total content of not anaerobically biodegradable ingredients in:<br>a) Liquid soap, hand soap for industry, shampoo, shower gel, conditioner, bath foam, cleanser, exfoliant < 15 mg/g AI<br>b) Solid soaps < 5 mg/g AI<br>or<br>c) Liquid soap < 2,5 mg/dose<br>d) Liquid hand soap for industry < 6 mg/dose | |
| **All organic ingredients** | | Total CDV must not exceed the following limits:<br>a) Liquid soap, hand soap for industry, shampoo, shower gel, conditioner, bath foam, cleanser, exfoliant < 13000 l/g AI<br>b) Solid soaps < 3000 l/g AI<br>Or | |

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| | | c) Liquid soap < 3000 l/dose<br>d) Liquid hand soap for industry < 8000 l/dose | |
| **All ingredients** | | LAS, APEO and APDs are excluded | |
| **Surfactants** | | All surfactants must be readily aerobically and anaerobically biodegradable | All surfactants must be readily biodegradable (aerobic) and anaerobically biodegradable.<br>Additionally surfactants must have a low residue of organic chlorinated compounds and LC50 must be lower than 1 mg/l. |
| **Preservatives** | To ensure that products are microbiologically safe, certain nature-identical preservatives are allowed in addition to natural preservatives. These are: benzoic acid (its salts and ethylester), salicylic acid and its salts, sorbic acid and its salts, benzyl alcohol.<br>When these preservatives are use, products must be labeled “preserved with…(name of preservative)”. | - Must be approved according to the Cosmetics Directive<br>- The use of preservatives for other purposes than preservation is not allowed<br>- Must not be potentially bioaccumulating (BCF<500/log Kow<4)<br>- Substances known to be degradation products of the constituent substances are also themselves considered to be constituent substances and consequently the same requirements apply. | - The use of preservatives for other purposes than preservation is not allowed.<br>- Must be potentially biodegradable according to OECD 302.<br>- Must have a BCF<100, or if BCF is not known the log Kow <3<br>- Toxicity results must be given for Daphnia and fish. Max Concentration = Lowest tox result * 200.<br>- The ingredient must not be potentially damaging for the health, considering allergenic, carcinogenic, genetic and teratogenic effects. Endocrine disruption effects are also considered. |

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| **Complexing agents** | | - NTA is not allowed<br>- EDTA and phosphonates are only allowed in solid soaps and only in total amount < 0,6 mg/g Al | - The complexing agent cannot have more than 100 points/gram according to the GEC points scheme.<br>- The ingredient must not be potentially damaging for the health, considering allergenic, carcinogenic, genetic and teratogenic effects. Endocrine disruption effects are also considered. |
| **Solvents** | | | - The solvent must be readily biodegradable<br>- The solvent must have a BCF < 100, or if BCF is not known the log Kow < 3<br>- LC50 > 100 mg/l<br>- The ingredient must not be potentially damaging for the health, considering allergenic, carcinogenic, genetic and teratogenic effects. Endocrine disruption effects are also considered. |
| **Thickeners and hydrotopes** | | | - The thickener/hydrotrope must be readily biodegradable. Thickeners that are not readily biodegradable are allowed < 0,5%<br>- The thickener/hydrotrope must have a BCF < 100, or if BCF is not known the log Kow < 3 |

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| | | | - LC50 > 10 mg/l<br>- The ingredients must not be potentially damaging for the health, considering allergenic, carcinogenic, genetic and teratogenic effects. Endocrine disruption effects are also considered. |
| **Humectant/emulsifier** | | | - The humectants/emulsifier must be readily biodegradable<br>- The humectants/emulsifier must be anaerobically biodegradable. Exception is made for ingredients not likely to end up in anaerobic compartments.<br>- The humectants/emulsifier must have a BCF< 100, or if BCF is not known the log Kow < 3.<br>- LC 50 > 1 mg/l<br>- The ingredients must not be potentially damaging for the health, considering allergenic, carcinogenic, genetic and teratogenic effects. Endocrine disruption effects are also considered. |
| **Conditioning agents** | | | - The conditioning agent must be readily biodegradable. Conditioning agent that are only potentially biodegradable are allowed in maximum amount of 2%.<br>- The conditioning agents must be |

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| | | | anaerobically biodegradable. Exception is made for ingredients not likely to end up in anaerobic compartments.<br>- The conditioning agent must have a BCF < 100, or if BCF is not known the log Kow < 3.<br>- LC 50 > 1 mg/l<br>- The ingredients must not be potentially damaging for the health, considering allergenic, carcinogenic, genetic and teratogenic effects. Endocrine disruption effects are also considered. |
| **Fragrances**[56] | | - Fragrances use must be in accordance with IFRA Guidelines<br>- Fragrances are not allowed in products aimed at infant, baby and/or child.<br>- Musk xylene and musk ketone are not allowed<br>- A fragrance/aromatic substance/fragrance substance in plant extract that is classified as sensitising with risk phrase R43 (H317) and/or R42 (H334), or is one of the 26 fragrances subject to declaration (see table 8 | - Fragrances are allowed in a maximum concentration of 0,5%.<br>- Fragrances use must be in accordance with IFRA Guidelines<br>- Nitro musks and polycylic musks are not allowed.<br>- Fragrance ingredients that are not active components (smelling) shall fulfil the requirements for other ingredients<br>- A total declaration of the contents mus t be given |

[56] See table 7, Restricted perfume ingredients (Nordic Swan).

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| | | below), must not be present in quantities greater than 0.001% (10 ppm) in leave-on products or 0.01% (100 ppm) in rinse-off products. | |
| **Colouring agents** | | Colouring agents must be approved according to Cosmetics Directive annex IV | Colouring agents must be readily biodegradable or be approved as colour in foodstuffs according to Swedish law. If a foodstuff colouring agent is used information about biodegradability must be given. |
| **Organic colouring agents** | | Organic colouring agents must not be potentially bioaccumulating (BCF<500/logKow<4) | |
| **Bases** | | | Only carbonates or hydroxides are approved as pH-increasing agents. |
| **Acids** | | | - Only organic acids are allowed as pH-decreasing agents.<br>- The conditioning agent must be readily biodegradable<br>- The conditioning agent must have a BCF < 100, or if BCF is not known the log Kow < 3.<br>- LC 50 > 1 mg/l |
| **pH-regulators** | | Boric acid, borates and perborates are not allowed. | |
| **Biological additives** | | | - Biological additives are allowed in a |

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| | | | maximum of 0,3% of the active content, i.e. product without water.<br>- Plant extracts must be extracted with water or solvents that fulfil the requirements in these criteria. |
| **Enzymes** | | - Enzyme preparations may be added even when containing substances classified as sensitising with R42 (H334) and/or R43 (H317).<br>- If added, enzymes must be as liquid or as a not dust producing granulate<br>- Use of enzymes in spray products is prohibited. | |
| **Other additives** | It is forbidden to disinfect organic raw materials and completed cosmetic products using radioactive radiation. | | - The additives must be readily biodegradable.<br>- The additives must be anaerobically biodegradable. Exceptions are made for ingredients not likely to end up in anaerobic compartments.<br>- LC 50 > 1 mg/l.<br>- The additives must have a BCF < 100, or if BCF is not known the log Kow< 3<br>- The additives must not be potentially damaging for the health, considering allergenic, carcinogenic, genetic and teratogenic effects. Endocrine disruption |

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| | | | effects are also considered. |
| **Packaging** | | - The packaging must fulfil the terms of the calculation<br>- Chlorinated plastics are not allowed in packaging including label<br>- It must be possible to separate all materials in the packaging (paper, card-board, plastic*, metal, glass) for sorting. Parts comprising mixed materials that cannot be separated are prohibited, with the exception of pump parts.<br>- Plastic packaging (including labels) containing PVC or plastic based on other types of halogenated materials must not be used.<br>- Primary packaging made from plastic should be marked according to the terms of the European Commission's decision of the 28th January 1997, 97/129/EC (EU, 1997), ISO 11469:2000, DIN 6120, part 2 or equivalent.<br>- Packaging must be designed so that appropriate dosing of product is made easier, i.e by making the hole not too big.<br>- Metal packaging may only be used for | - The only plastic materials allowed for packaging are polyethylene (PE), polypropylene (PP) and polyeteneterefталate (PET).<br>- The packaging must consist of single materials parts that are easy to separate from each other. Refill packaging weighing < 30% of the original primary packaging are exempt from this requirement.<br>- Carton packaging must consist of > 80% recycled fibre.<br>- If virgin fibre is used for the remaining part of the carton at least 30% of this part must come from FSC-certify forestry.<br>- Packaging must as much as possible be adjusted to the recommendations of "REPA".<br>- The packaging must not contain metal parts. Large packaging that is reused is exempt from this requirement. |

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| | | spray bottles/aerosols for hair styling products and shaving foams. The use of small parts made of metal, e.g. part of a hand pump or sealing foil, is permitted. Metal part may be used in packaging for decorative cosmetic products if the amount of metal does not exceed 15% of the total packaging weight. Mirror is not allowed as part of the packaging. | |
| **Product** | A neutral control body checks that the above criteria are complied with. The association's label is used to indicate that the criteria have been complied with. | The products efficiency must be satisfactory compared to existing products on the market | |
| **Information on the packaging** | | | The recommended dosage must be given on the packaging |
| **Ecological compatibility** | Only natural sources of raw materials, if possible certified by the EG-Bio-VO (EG regulation of ecological cultivation)<br>- environmentally-friendly manufacturing processes<br>- optimal degradability of raw materials and finished products<br>- economical, environmentally-friendly and recyclable packaging<br>- maintenance of natural life principles | | |

| CONCERNS | BDIH | NORDIC SWAN | GEC |
|---|---|---|---|
| **Social compatibility** | - raw materials from fair trading and Third World projects<br>- use and disposal<br>- cooperation | | |

Furthermore, according to the Nordic Swan, the following fragrance substances must not be present in the product in quantities exceeding 0.01%:

**Table 8. List of 26 fragrances allergens designated by the EU**

| Name | CAS number |
|---|---|
| Amyl cinnamal | 122-40-7 |
| Anisyl alcohol | 105-13-5 |
| Benzyl alcohol | 100-51-6 |
| Benzyl cinnamate | 103-41-3 |
| Cinnamyl alcohol | 104-54-1 |
| Farnesol | 4602-84-0 |
| Citral | 5392-40-5 |
| 2-(4-tert-Butylbenzyl) propionald-hyd | 80-54-6 |
| Eugenol | 97-53-0 |
| Linalool | 78-70-6 |
| Hydroxy-citronellal | 107-75-5 |
| Benzyl benzoate | 120-51-4 |
| Isoeugenol | 97-54-1 |
| Citronellol | 106-22-9 |
| Amylcin-namyl alcohol | 101-85-9 |
| Hexyl cinnam-aldehyd | 101-86-0 |
| Benzyl salicylate | 118-58-1 |
| d-Limonene | 5989-27-5 |
| Cinnamal | 104-55-2 |
| Methyl heptin carbonate | 111-12-6 |
| Coumarin | 91-64-5 |
| 3-Methyl-4-(2,6,6-tri-methyl-2-cyclohexen-1-yl)-3-buten-2-one | 127-51-5 |
| Geraniol | 106-24-1 |
| Oak moss and treemoss extract | 90028-68-55 begin_of_the_skype_highlighting |
| Hydroxy-methylpentylcyclohexenecarboxaldehyd | 31906-04-4 begin_of_the_skype_highlighting |
| Treemoss extract | 90028-67-4 |



The following table shows the ingredients specifically excluded in various ecolabelling criteria:

**Table 9. Overview of ingredients specifically excluded in Ecolabelling criteria**

| Ingredients | Ecolabel |
|---|---|
| Phosphonates | Thai Green Label, Green Mark |
| EDTA (Ethylenediaminetetraacetic acid) > 0,1 % | Thai Green Label, Green Mark |
| EDTA (Ethylenediaminetetraacetic acid) and its salts (exemption for solid soap under R22) + phosphonates excluded in other products than solid soap. Max 0,6 mg/g active content in solid soaps. | NORDIC SWAN |
| D4 (octamethylcyclotetrasiloxane, CAS 556-67-2) | NORDIC SWAN |
| D5 (decamethylcyclopentasiloxane, CAS 541-02-6) | NORDIC SWAN |
| Triclosan | NORDIC SWAN |
| Parabens (4-Hydroxybenzoic acid and its salts and esters) | NORDIC SWAN |
| Nitrilo TriAcetate (NTA) | Thai Green Label, Green Mark, NORDIC SWAN |
| Linear alkyl benzene sulphonates (LAS) | NORDIC SWAN |
| Alkyl phenol | Thai Green Label |
| Alkyl phenol ethoxylates (APEO) | Green Mark, NORDIC SWAN |
| Alkyl phenol derivatives (APD) | NORDIC SWAN |
| Perborates | Green Mark |
| Boric acid, borates and perborates | NORDIC SWAN |
| Musk xylene and musk ketone | NORDIC SWAN |
| Nitro musks and polycyclic musks | GEC, NORDIC SWAN |
| Fluorescent whitener | Green Mark |
| Dimethyl silicone copolymers | Thai Green Label |
| Branced carboxylic acids and alcohols | Thai Green Label |
| Quartenary protein hydrolysate | Thai Green Label |
| Polyethylene glycol (PEG) esters of branched carboxylic acids | Thai Green Label |
| Polyethylene glycol PEG > 30 EO | Thai Green Label |
| Polyvinylpyrrolidone (PVP) | Thai Green Label |
| 1,2-benzisothiazolin-3-one (BIT) | Thai Green Label |
| 2,4-dichlorobenzyl alcohol | Thai Green Label |
| Formaldehyde | Thai Green Label |
| Chloroacetamide | Thai Green Label |

| Ingredients | Ecolabel |
|---|---|
| 5-chloro-2-methyl-4-isothiazolin-3-one (CMI) | Thai Green Label |
| Ortophenylphenol | Thai Green Label |
| Ortononylphenol | Thai Green Label |
| Cyclohexanone | Thai Green Label |
| Hexane | Thai Green Label |
| Methanol | Thai Green Label |
| 1-butanol | Thai Green Label |
| n-butanol | Thai Green Label |
| t-butanol | Thai Green Label |
| Dearomatized white spirit D 100 and D 70 | Thai Green Label |
| Cyclohexanol | Thai Green Label |
| Decane | Thai Green Label |
| Heptane | Thai Green Label |
| i-parafins | Thai Green Label |
| Methyl isobutyl ketone | Thai Green Label |
| Higher aromates such as mesitylene | Thai Green Label |
| Chlorinated hydrocarbons | Thai Green Label |
| Toluene | Thai Green Label |
| Halogenated organic solvents | Thai Green Label |
| Butylated hydroxytoluene (BHT) > 0,01 % | Thai Green Label, Green Mark |
| Phosphates > 0,05 % | Green Mark |
| UV adsorption agents | Green Mark |
| PVC in packaging | Green Mark |

## 4. INTRODUCTION TO REVISION OF EU ECOLABEL CRITERIA

This following table summarises the preliminary proposals with recommendations on the revision of the scope and criteria for soaps, shampoos and hair conditioners. This proposal has been reviewed based on the results of the main environmental impacts in life cycle perspective and the identification and analysis of potential alternatives for substances of concern. The most important life cycle environmental impacts of this product group shall be addressed in the criteria document.

An overview on the current Ecolabel criteria versus the criteria proposed for consideration during the 1st AHWG meeting (and consulted already with some stakeholders through the questionnaire responses) is given below[57].

During the consultation phase it has been proposed to consider enlarging the scope of the product group to include other rinse-off products with similar purposes like shaving -foam, -gel, -cream and –soap. The consideration of shampoos for pets will also be a discussion point in the AHWG meeting.

The initial proposals for the revised criteria, discussed during the 1st AHWG meeting, are given in below Table. The revised criteria proposals are explained in detail in Chapter 6.

**Table 10. Overview of current Ecolabel criteria versus the revised criteria for soaps, shampoos and hair conditioners**

| CRITERIA | EXISTING EU ECOLABEL CRITERIA | Initial proposals of changes, modifications or amendments |
|---|---|---|
| **1. Toxicity to aquatic organisms** | **Critical Dilution Volume (CDV)**<br>CDV (ingredient i) = weight (i) × DF (i) × 1000/TF chronic (i)<br>CDV = Σ CDV (ingredient i)<br><br>**Critical Dilution Volume (CDV):**<br>-Liquid soaps, shampoos, shower products and other liquid cleaning products ≤ 20 000 L/g AC<br>- Solid soaps ≤ 3 500 L/g AC<br>- Hair conditioners ≤ 30 000 L/g AC | - Methodology to calculate CDV<br><br>- Decrease limits to apply to critical dilution volume toxicity (CDV) for each kind of products: soaps, shampoos and hair conditioners. |
| **2. Environmental harmful products** | N, R50/53: $W_{R50/53}$/25 % ≤ 1<br>N, R51/53: ($W_{R50/53}$/2,5 %) + ($W_{R51/53}$/25 %) ≤ 1<br>R52/53: ($W_{R50/53}$/0, 25 %) + ($W_{R51/53}$/2,5 %) + ($W_{R52/53}$/25 %)≤ 1<br>Rubbing/abrasive agents in hand cleaning agents are not included. | - Consider including this in criterion 8 – hazardous content and updating it to be based on CLP classification criteria. |

[57] The results of the questionnaire can be found in Annex I of the Technical Background Report for the 1st AHWG meeting, available online at: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

| | | |
|---|---|---|
| **3. Aerobic biodegradability** | **3a) Aerobic biodegradability of surfactants**: Each surfactant used in the product will be readily biodegradable.<br>**3b) Aerobic biodegradability of non-surfactants ($aNBDO_{non-surf}$):**<br>**aNBDO** = milligrams of not aerobically degradable non-surfactants per gram active content<br>- Liquid soaps, shampoos, shower products ≤ 30 mg/g AC<br>- Solid soaps ≤ 15 mg/g AC<br>- Hair conditioners ≤ 50 mg/g AC<br>Rubbing/abrasive agents in hand cleaning agents are not included. All ingredients (substances or preparations) exceeding 0,010% by weight of the final product will be considered. | - Surfactants biodegradability will be discussed (if all surfactants must be readily aerobically and anaerobically biodegradable).<br><br>- Decrease limits to apply to aNBDO. |
| **4.Anaerobic biodegradability ($annbo_{tox}$)** | **anNBDO** = milligrams of not anaerobically degradable toxic ingredients per gram active content. Toxic ingredient: Lowest acute toxicity is < 100 mg/l.<br>-Liquid soaps, shampoos, shower products ≤25 mg/g AC<br>- Solid soaps ≤ 15 mg/g AC<br>- Hair conditioners ≤ 50 mg/g AC<br>Rubbing/abrasive agents in hand cleaning agents are not included. | -Decrease limits to apply to anNBDO. |
| **5.Fragrances** | Fragrance must have been manufactured, handled and applied in accordance with the code of practice of International Fragrance Association. | -Discuss if sensitizing substances should be restricted to 0,010%.<br>-Discuss why a total exclusion is not possible.<br>-Consider possible extension of the scope to substances other than fragrances which are known to act as sensitizers for allergic skin reaction and contact dermatitis. |
| **6.Dyes or colouring agents** | Organic dyes or colouring agents must not be potentially bio-accumulating.<br>- BCF ≤ 100<br>- log Pow ≤ 3 | -According to CLP, a colouring agent or dye will be considered to be potentially bioaccumulating if the experimentally determined BCF is ≥ 500 or log Pow ≥4 – Discussion on threshold values.<br>Discussion point whether the scope of this criterion should be extended also to other substance groups founding the final product other than dyes or colouring agents |

| | | |
|---|---|---|
| **7.Biocides** | **a)** Biocides in order to preserve the product, and in the appropriate dosage for this purpose alone. This does not refer to surfactants which may also have biocidal properties.<br>**b)** Biocides with classification R50-53 are only permitted if they are not potentially bio-accumulating (BCF < 100 or log Pow < 3,0).<br>**c)** Preservatives must not release substances that are classified with the criterion 8a. | - According to CLP, biocides must not be potentially bioaccumulating (BCF is < 500 or log Pow <4) – Discussion on threshold values.<br>- Discuss which substances should be restricted: triclosan, parabens, formaldehyde and formaldehyde releasers.<br>- Take into account potential implications from the revised Biocides Directive. |
| **8.Environmental hazardous ingredients** | The requirements concern all ingredients (substances or preparations) exceeding 0,010 % by weight of the final product.<br>**a) Classified ingredients**<br>No constituent substance must be classified as CMR, toxic and hazardous to the environment in accordance with CLP or substances referred to in Article 57 of REACH. Maximum 0,1% (w/w) for substances that meet the criteria of Article 57 present in mixtures or in an article.<br>**b) Specified excluded ingredients**<br>- Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives<br>- NTA (nitrilo-tri-acetate)<br>- Boric acid, borates and perborates<br>- Nitromusks and polycyclic musks<br>**c) Specified limited ingredients**<br>**EDTA** and its salts and non-readily biodegradable phosphonates may only be added to solid soaps and only to a maximum content of 0,6 mg/g AC. | - Apply implications of Ecolabel Regulation 66/2010 Article 6(6) and expand R- and H- phrases list similarly to recently developed EU Ecolabel criteria for other product groups[58].<br>- Restriction on substances considered PBT, vPvB and/or those having endocrine disrupting properties.<br>- Include some specified excluded ingredients.<br>- Apply article 6.7 of Ecolabel Regulation 66/2010 in which no substance classified as substance of very high concern (SVHC) based on REACH shall be present in the Ecolabelled product. |
| **9. Packaging** | **a)** The weight/content relationship (WCR) is less that 0,30 g packaging per gram of product.<br>**WCR =Σ ((Wi + Ni) / (Di x r))**<br>If the packaging is reused r is set to 20 for plastics and 10 for corrugated board unless the applicant can document a higher number.<br>**b) Labelling of packaging**<br>Plastic parts of the primary packaging has been marked in accordance with DIN 6120, Part 2 or the equivalent (caps and pumps are exempted from this requirement).<br>**c) Dosage**<br>The packaging must be designed to make correct | - The WCR should be calculated taking into account refillable and refill packaging.<br>- More restringing weight limit (< 0,3 g packaging/g product).<br>- Packaging materials should not contain substances included in the candidate list of SVHC for authorization.<br>- Packaging requirements in function of the material used.<br>- It should be possible to separate |

[58] For details see Appendix II.

| | | |
|---|---|---|
| | dosage easy, e.g. by ensuring that the opening at the top is not too wide.<br>**d)** The packaging does not contain additives based on Cadmium, Mercury, Lead or compounds with these elements. The packaging does not contain additives that do not fulfil criterion 8. | all materials in the packaging (paper, cardboard, plastic, metal) for sorting. Parts comprising mixed materials that cannot be separated should be restricted, with the exception of pump parts. |
| **10. Fitness for use** | The product's fitness for use is demonstrated by:<br>- Laboratory test performed by test-institute or<br>- Consumer test according to Appendix I | Proposal to consider a more stringent consumer test. |
| **11.Information appearing on the eco-label** | Box 2 of the eco-label shall contain the following text:<br>• Minimal impact on aquatic ecosystems<br>• Fulfils strict biodegradability requirements<br>• Limits packaging waste | Add, depending on the final formulation of the criteria, e.g.:<br>• Limited use of substances of concern. |
| **12. Nano-materials** | | Discuss if nanomaterials/particles are used in this product group and what are the related concerns. |
| **13. Energy consumption** | | Discuss potential new requirements concerning energy consumption in industries. |
| **14. Substances used in products intended for infants, babies and children (**of less three years of age**)** | | New criteria about chemicals and substances used in formulations intended for infants, babies and children (of less three years of age).<br>- Discussion point: any substance raising concerns regarding allergic reactions such as asthma and contact dermatitis should be totally restricted if this is practical and technical feasible. |
| **15. Product Group Definition** | "any rinse-off substance and preparation intended to be placed in contact with the epidermis and the hair system with a view exclusively or mainly to cleaning them. That product group shall also comprise any rinse-off substance and preparation intended to be placed in contact with the hair system with a view to improve the condition of the hair (hair conditioners)". | The product group definition might include other rinse-off and non-leave on cosmetic products with similar purposes like shaving foam, shaving gel, shaving cream and shaving soap, shampoos for animals, especially pets, wet wipes for cosmetic purposes and cleansing and remover make-up products. |

## 5. REVISION OF PRODUCT GROUP DEFINITION AND SCOPE

In accordance with the Commission Decision establishing the ecological criteria for the product group of soaps, shampoos and hair conditioners[59] the current definition of this product group comprises "*any rinse-off substance and preparation intended to be placed in contact with the epidermis and the hair system with a view exclusively or mainly to cleaning them. That product group shall also comprise any rinse-off substance and preparation intended to be placed in contact with the hair system with a view to improve the condition of the hair (hair conditioners)*"[60].

The criteria for Ecolabel aim to promote the products which:

- Reduce water pollution,
- Minimise waste production,
- Reduce or prevent the potential risks for the environment related to the use of hazardous substances.

This product group covers products for both private and professional use and it does not cover products that are specifically marketed for disinfecting or anti-bacterial use.

At present, in order to be awarded the Community eco-label for soaps, shampoos and hair-conditioners, a product must fall within the product group "soaps, shampoos and hair-conditioners" and must comply with the ecological criteria set in the respective Commissions Decision.

**Consideration on the extension of scope and revision of definition**

***Scope of the product group***

In this revision process extension of the existing scope of soaps, shampoos and hair conditioners product group described above has been considered, taking into account that other cleaning products with a certain degree of similarity, for example a common function or a way of application or with similar chemical composition can exist and, although they have not been so far covered by the EU Ecolabel, they could be included in the scope in the revised criteria document. This was discussed in the 1st AHWG meeting and several stakeholders in general welcomed a possible extension of the current scope.

With this aim, typical ingredients of each new considered product were analyzed and compared with a typical composition of soaps, shampoos and hair conditioners[61]. First, a list of products which fulfils the same or a similar function of cleaning was prepared. The composition of the following products:

- shaving products: shaving-foam, -cream, -gel and -soap,
- toothpaste,
- shampoo for animals, especially pets,
- wet wipes,
- cleansing and remover make-up products,

[59] Commission Decision of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:186:0036:0045:EN:PDF.

[60] Note: disinfecting products (cleaning products with anti-microbial function) are excluded from the product group (from ordinary cleaning products).

[61] For details please see Appendix I: Scope of the product group.

was analysed in order to see if the ingredients and functions are similar to the products already covered by the existing criteria. Further, also the environmental fate of the considered products was analysed.

Based on the outcomes of this preliminary analysis[62] some products with rinse-off application were found to have a similar composition and are considered to be suitable to be included in the product group, as it is the case of **shaving foam, gel, cream and soap**. It is expected that products having similar ingredients have, from an LCA point of view, to a great extent a similar environmental profile. This would allow including these types of products even in this criteria revision.

Other products with cleaning function and rinse-off application proposed to be included are **pets' shampoos**. Products for animals are rinsed-off to water in the same way as shampoos and soaps for people and the composition is similar. There has been some interest in the ecolabelling of shampoos for pets (e.g. in Nordic Ecolabel), even though there are no labelled products on the market at the moment[63]. Some feedback regarding this extension has been received and this issue will be discussed during the 2nd AHWG meeting.

Further, some products with a similar way of application are not proposed to be included in the revised scope based on the results obtained because their composition differed too much from soaps and shampoos, as it was e.g. in the case of **toothpaste**.

Some other products with cleaning function, for example **wet wipes**, were found to have to a limited extent similar composition (except of the material used as support in wipes). Nevertheless, their way of application and the final disposal differ from those of the rinse-off products (wet wipes will be disposed with other household waste) and therefore it is not proposed to include them in the extended product group.

Concerning **cleansing and remover make-up products**, the composition differs from soaps and shampoos and the way of application is different from rinsed-off products, which causes that the final fate is different. In consequence they were excluded from the potential scope extension.

***Rationale***

When assessing the potential environmental impacts that a cosmetic product can cause, all life cycle stages have to be taken into account: ingredients manufacturing, product manufacturing, packaging and distribution, use and disposal after use with municipal waste or through wastewater (considering the possible final release of substances into the environment and the harmful effects that they could cause).

The release of the products into the environmental compartments (water, soil, air) will be determined partly by the way of application[64]. **Rinse-off products** will be disposed and diluted to water after use via the wastewater route, while **non rinse-off products** (e.g. wet wipes, cleansing and remover make-up) are initially applied to remain on body surfaces (skin), although a fraction of these chemicals can also reach the municipal sewage plants if they are eliminated e.g. by washing, or can accidentally reach the aquatic environment. Finally, those cosmetic products containing a solid

[62] For details please see Appendix I: Scope of the product group.
[63] Nordic Ecolabelling Cosmetic products 090 Background document – 16 February 2011. In the current version of the Nordic Swan criteria for Cosmetic Products the animal shampoos are included in the scope of the product group.
[64] Nordic Ecolabelling Cosmetic products 090 Background document – 16 February 2011.

single-use support (e.g. wipes) or those which are removed with solid cottons or single-use towels (e.g. cleansing and remover make-up) will be disposed as solid waste after being used.

After use the **rinse-off products** will be released to domestic wastewater, which is expected to be treated in a sewage plant before being released to aquatic environments. In the LCA conducted for this revision process, it was found that release to water was one of the life stages with major environmental impacts. After being treated, depending on the level of sewage treatment and on the properties of the ingredients, some substances will be degraded but a certain fraction of the ingredients from cosmetic products may end up in the aquatic environment or be adsorbed into the sludge. Therefore, for these products properties such as high biodegradability, low bioaccumulation and low toxicity to the aquatic environment are important[65] to guarantee that the products' ingredients will have low impact on the environment. For that reason the current EU Ecolabel criteria for this product group are aimed to high extent at reducing the impact of rinse-off products' ingredients released into the aquatic environment.

The environmental safety is determined basically by the environmental fate and the potential impact of a chemical in the specific environmental compartment[66]. Both aspects depend on the properties of the substances. The environmental fate is determined by the physicochemical properties such as water solubility, adsorption behaviour, volatility and biodegradability, which determine the distribution of a chemical in the environmental compartments (water, soil, air). The potential impact of a chemical in the specific environmental compartment is determined by the ecotoxicological properties.

The ingredients present in rinse-off products are to a certain extent different from those in non rinse-off products mainly because they differ in their purpose: use and function are different.

For example in most cases, more than 80% of the mass of organic product ingredients in rinse-off products are readily biodegradable, while in leave-on products are only more than 60%. This is mainly due to a significant percentage of polymeric and/or poorly soluble ingredients present in leave-on cosmetic products that biodegrade slowly or not at all. As a result, the biodegradability criterion could differ for both kinds of products and setting specific thresholds would be needed.

Another issue that is expected to differ for rinse-off and non rinse-off products is the toxicity. Rinse-off products will be disposed of after use via the waste water route. Consequently, a certain percentage of the ingredients from rinse-off cosmetic products may end up in the aquatic environment. Surfactants are the key components in rinse-off products and can interact with biological surfaces; therefore they are relatively toxic to aquatic organisms. Toxicity to the aquatic environment is thus of high importance for rinse-off products.

Aspects such as use of fragrances and nanomaterials could be also different for both types of products because leave-on products are initially applied to remain on body surfaces, and stricter requirements need to be taken into consideration.

Finally, some specific substances should be proposed to be restricted based on the composition on leave-on and rinse-off cosmetic products.

[65] Nordic Ecolabelling Cosmetic products 090 Background document – 16 February 2011. In the current version of the Nordic Swan criteria for Cosmetic Products the animal shampoos are included in the scope of the product group.

[66] Pharmaceuticals and Personal Care Products in the Environment Letter to the Editor ENVIRONMENTAL SAFETY ASPECTS OF PERSONAL CARE PRODUCTS— A EUROPEAN PERSPECTIVE. Environmental Toxicology and Chemistry, Vol. 28, No. 12, pp. 2485–2489, 2009 SETAC (USA).

Consequently, it can be expected that the environmental behaviour and impacts are different for these two product groups. For these reasons a new category for “leave-on cosmetic products” (non rinse-off products) could be created in the future, but taking into account different thresholds parameters for e.g. regarding biodegradability, toxicity, specific restricted substances. For products with this way of application (intended to be applied and absorbed by the skin or hair and not rinsed-off) other aspects have to be considered and additional criteria, which differ from those existing ones, would need to be developed. Differences in ingredients used and different impacts in the end of life phase would need to be analyzed further in a comprehensive study in order to develop the criteria for other cosmetic products than those already covered by the current product scope or products very similar to them in composition and environmental profile.

Furthermore, some stakeholders from MS expressed interest to cover within the scope of EU Ecolabel all cosmetic products. This proposal would, nevertheless, require extensive environmental evaluation of different product groups and appropriate determination of key environmental areas for which the criteria should be set. Such a development could be conducted in the future if it is proved that significant environmental improvement can be achieved.

Written stakeholders feedback received with regard to the first proposal for the revised Ecolabel criteria and the discussions around the 1st AHWG meeting supported including other rinse-off products with similar purposes like shaving foam, shaving gel, shaving cream and shaving soap. Less clear was the consideration on inclusion of shampoos for animals, especially pets and this will be discussed during the 2nd AHWG meeting again.

When including shaving foams and gels into the scope of the Ecolabel, it will be important to set additional criteria concerning the packaging, since today majority of these products is sold in aerosol containers, which have very different character to the packaging of the currently covered products.

The results and conclusions of the scope revision can be summarised as follows:

**Shaving products are proposed to be included in the product category under study due to a certain degree of similarity: similar chemical composition and environmental fate (they are rinsed-off to water).**

**Rinse-off products for animals are not covered by the cosmetics directive, but could be covered by the scope of the revised product group due to similar formulation and environmental fate.**

**The wet wipes for “cosmetic purposes” (such as facial wipes, cleansing wipes, hand and body wipes, or moist towelettes) are not proposed to be included in this product group because the way of application differs from the application of rinse-off products and the environmental profile is expected to be very different compared to the products analysed in the LCAs conducted in the project and presented in the technical background report.**

**An extension of the scope for toothpaste is not proposed because its composition differs significantly from the composition of the currently covered products. Further, an inclusion of toothpaste will need a comprehensive investigation for determining new or significantly modifying current criteria proposal as the user comes in contact with toothpaste through the mouth e.g. for substances criterion there is of relevance a different exposure path which would need to be investigated.**

**Cleansing and remover make-up products were not proposed to be included because the way of application is different from rinse-off products, which also causes that the final LCA environmental profile is different.**

***Definition of the product group***

Taking into account the definition of cosmetic products by the Regulation (EC) No 1223/2009:
*'**cosmetic product**' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;*
and the existing definition of the product group of soaps, shampoos and hair conditioners, the revised name and definition of this product group could be as follows:

"*any rinse-off substance and preparation intended to be placed in contact with the epidermis and the hair system with a view exclusively or mainly to cleaning them. That product group shall also comprise any rinse-off substance and preparation intended to be placed in contact with the hair system with a view to improve the condition of the hair (hair conditioners) and any rinse-off substance and preparation intended to be placed in contact with the epidermis with a view to protect it and to lubricate the hair before shaving (pre-shaving preparations)".*

Further, if animal products shall also be covered, the following sentence is proposed to be added: "***Shampoos for animals are eligible for EU Ecolabel***".

Moreover, as supported by many stakeholders and agreed in the 1st AHWG **a change of the product group name from "soaps, shampoos and hair conditioners" to "rinse-off cosmetic products"** is undertaken.
Comments have been received regarding the change the product group name to "Rinse off Cosmetic Products" based on the following arguments:

- "Rinse off" and "leave on" cannot exactly be attributed to the specific categories of cosmetic products therefore the name would be much vague. In case of hair-conditioners e.g. both kinds are offered, this is also the case for other products.

- The proposed scope will only include part of rinse-off products, e.g. external intimate hygiene products, mouth wash, toothpaste, exfoliation products, hair bleaching products etc. are or might be rinse-off products but will not be covered by the Ecolabel.

According to the stakeholder's input it is proposed to consider covering within the scope of the EU Ecolabel all cosmetic products in the future. Depending on the decision taken by the EU Ecolabelling Board, a new category for “leave-on cosmetic products” could be created or even criteria could be developed to cover all cosmetic products. Nevertheless, this proposal would require extensive environmental evaluation of different product groups and appropriate determination of key environmental areas for which the criteria should be set.

With the intention in the future to broaden the scope to other rinse-off cosmetic products, the decision of the product group name “Rinse-off cosmetic products” was presented. Although not all rinse off cosmetic products will be firstly included in the proposed scope, this issue is solved including the revised definition of the product group as follows:
"*any rinse-off substance and preparation intended to be placed in contact with the epidermis and the hair system with a view exclusively or mainly to cleaning them. That product group shall also comprise any rinse-off substance and preparation intended to be placed in contact with the hair system with a view to improve the condition of the hair (hair conditioners)* ***and any rinse-off substance and preparation intended to be placed in contact with the epidermis with a view to protect it and to lubricate the hair before shaving (pre-shaving preparations)****".*
Further, if animal products shall also be covered the following sentence is proposed to be added: "***Shampoos for animals (which are not covered by the cosmetics directive) are eligible for Ecolabel****".*

Based on this revised definition of the product group, products such as mouth wash, toothpaste and hair bleaching products are excluded because they are in contact with the *teeth and the mucous membranes of the oral cavity or changing the appearance of the hair*, which is not included in the definition. In case of hair conditioners that are not rinse-off, they will not be included by definition.

To avoid confusions, it can be added to the revised definition of the product group: The product group “Rinse-off Cosmetic Products” shall comprise soaps, shampoos, hair conditioners and pre-shaving preparations, i.e any rinse-off *substance and preparation intended to be placed (…).*

Furthermore, “rinse off” and “leave on” cannot exactly be attributed to the specific categories of cosmetic products because Cosmetics Directive 76/768/EEC (Regulation (EC) **No 1223/2009**, which will replace the Cosmetics Directive from 11 July 2013), mainly regulates health impacts and it does not take into consideration environmental issues as EU Ecolabel does.

If the product group name will be based on the categories of cosmetic products selected from the classification in the CPNP, the name will be also vague due to it will only include part of rinse-off products, e.g. make-up remover products, after-shaving products, scalp and hair roots care products are or might be: skin cleansing products, shaving and pre-/after-shaving products and hair and scalp products, but will not be covered by the Ecolabel.

**Feedback on the inclusion of pet shampoos**

To the question of the expansion to pet shampoos without insecticides and other biocides apart from conservation of the product, feedback has been received that these products did not really fit to the entire group, as they were not covered by the cosmetics directive and are used for animals and not for humans. Furthermore, they are not used regularly and by high share of the population of the EU.
In that sense, the stakeholder asked for information related to sales volume:
- compared to shampoos with insecticides and other biocides and
- compared to the other products groups soaps, shampoos, hair conditioners, shaving products.

According to the Mintel Database, from shampoo pets identified in the European market in 2012, **only the 28% of these products claim to have insecticide, anti-bacterial and anti-parasite properties**. The rest of pet grooming products, such as shampoo and cleansers products, have other claims such as pH neutral and skin-friendly, deodorizing, shine effects, conditionings, etc. Pet grooming products such as shampoo and cleansers are increasingly influenced by tendencies seen in personal care products for humans, in line with the humanisation of pets trend where pets are increasingly seen as part of the family. Accordingly, these products could be similar to human shampoos in terms of contents.

The number of pet shampoo products present in the European market identified in Mintel GNPD Database is of approximately 200 products, this is only **a 2% of shampoo products of the market** (the rest is intended for humans).

Regarding sales volume, no data is available in European Statistics (Eurostat), since there is no specific product group for pet shampoos (Prodcom categories and data). But according to the Mintel GNDP Database, data referred for the general category of pets supplies show that, while sales in many categories have declined in recent years as a result of the recession, the **pet supplies market has remained quite stable**. This is partly a function of the deep emotional bonds that many people have formed with their pets as well as strong demand for a broad range of goods that help owners care for their pets and keep them healthy.

There is demand on pet products environmentally friendly. There are several products in the market with claims related to natural composition, environmentally product, so there is **potential demand** of the EU Ecolabel for this kind of products.

This issue will be discussed still with the AHWG meeting's stakeholders.

## 6. EXISTING CRITERIA AND REVISION PROPOSALS

### 6.1 GENERAL REMARKS

The revision of the current Ecolabel criteria of the group product "soaps, shampoos and hair conditioners" is based on the outcomes of the technical analysis developed. The technical analysis[67] consists of two parts:

- A full Life Cycle Assessment for each product liquid soap, solid soap, shampoo and hair conditioner,
- Basic research on potential alternatives of hazardous substances.

The life cycle assessment has been conducted following the standards ISO 14040 and ISO 14044, and it allows identifying the potential environmental impacts of the products under study along the different life cycle stages. These environmental products profiles help to assess where requirements and criteria should focus (determination of key environmental areas for Ecolabel criteria development) and supports estimating the environmental savings that can be achieved via the Ecolabel criteria implementation. Complementary to this, outcomes of the specific analysis of substances raising concerns to human health and the environment (article 6.6 of the EU Ecolabel Regulation) were considered. The identification and analysis of potential alternatives of hazardous substances can serve as a supporting element to manufacturers in the research of indentifying environmentally better performing substances with a lower hazard level within a specific function group (e.g. surfactants, preservatives etc). This is possible as a preliminary identification of the most commonly used substances that perform the same function, was undertaken followed by an identification of the chemicals with inherent hazardous properties.

The identification of hazardous substances is based on their classification with Risk and Hazardous statements following the classification rules applied for chemicals via the CLP regulation[68]. Further, attention is given to substances of very high concern (Annex XIV of REACH Regulation[69]) and the ones which are in the candidate list for authorisation as referred to in REACH Regulation.



### 6.2 FUNCTIONAL UNIT AND REFERENCE FLOW

In accordance with the existing EU Ecolabel criteria document the functional unit is defined as follows:

> The Functional unit is 1 gram of 'Active Content (AC)'. AC is defined as the weight of organic ingredients in the product. It must be calculated on the basis of the complete formulation of the product. Rubbing/abrasive agents in hand cleaning agents are not included in the calculation of AC.

[67] For details please see the report "Preliminary results from the technical analysis, available at project website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

[68] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

[69] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Official Journal of the European Union L 396 of 30 December 2006; available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:en:PDF.

***Assessment and verification***:

The following information shall be provided:

- Technical description of the contents of the product (complete formulation), including known pollutants. The description must include a specification of quantities, CAS-No. and INCI designations;

- A specification of the function of each individual ingredient in the product, stating the purpose for which the component is added;

- Safety data sheet/Product data sheet with the names of the suppliers of all ingredients.

The active content of the product was found as the most suitable parameter to be used as it can be avoided that high diluted products gain advantages versus concentrated ones. Differently this problem would occur if standard dosages were used instead as the functional unit. Different products have different dosages depending on the efficiency of each product and its application. This issue was previously addressed in the last criteria development of 2006 (s. also final report of the EU Ecolabel criteria development for this product group[70]), as well as for other labels such as Nordic Swan[71] concluding for the option of "active content/ingredients".

Furthermore, based on the discussions conducted at the 1st AHWG meeting it was agreed to maintain the current term of Active Content in the current criteria revision process.

It is important to highlight here that the term "functional unit" used in the current criteria document is different with the term functional unit used in the context of the life cycle assessment. In the LCA conducted the functional unit refers to "washing action(s)" (this includes and makes clear that water use is also covered) and is measured with determining the so-called in LCA "reference flow". In the LCA conducted in the Technical Analysis part of the study the “functional unit" and "reference flow" have been defined as follows:

Functional unit: Washing action of a part of the body with the main objective of provides hygienic results and/or aesthetic improvements.

References flow: The amount of product contained in that bottle/package, as given in Table 11 below

**Table 11.** Reference flow for four kinds of products studied

| **Product** | **Reference flow** |
|---|---|
| Liquid soap (shower) | A bottle of 250 ml of liquid soap (containing 255 g of product), with the main function of personal washing and personal care for 20 washing actions |
| Shampoo | A bottle of 250 ml of shampoo (containing 255 g of product), with the main function of personal washing and personal care for 24 washing actions |

[70] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., 2006.
[71] Nordic Ecolabelling of cosmetic products, Nordic Ecolabelling of cosmetic products, Background document regarding ecolabelling, February 2011.

| Product | Reference flow |
|---|---|
| Hair conditioner | A bottle of 250 ml of hair conditioner (containing 255 g of product), with the main function of personal washing and personal care for 18 washing actions |
| Solid soap (hands) | A solid bar soap of 100 g with the function of hands washing and personal care for 50 washing actions |

Please see also more details in "Technical Background Report"[72]. In order to be consistent with the terminology used in the LCA and the current criteria it is necessary to introduce the term of "reference flow" in the latter document. The reference flow in the LCA (per definition) is quantifying the functional unit therefore is determined as given in the above Table 11. However, this is not practical for the criteria document in which the reference flow refers to the active content. Note here that in LCA the basis of the investigation is the washing action which can be quantified by using average values for the reference flow of e.g. 2g of solid soap. However, in the 2g of solid soap the active content could vary when different soaps are used. Similarly when different soaps are compared in fact their performance, as well their dosage corresponding to one washing action, can also vary. Although the active content is related to the rinsing performance the exact relation is currently not feasible to be determined with a standardised method. If this would have been the case then the reference flows could be identical.

To conclude, the functional unit is defined as used in LCA. The reference flow is defined differently in LCA and in the criteria document. In LCA is based to the quantification of the washing action whereas in the criteria it refers to the Active Content.
The following definition is therefore proposed for use in the criteria document:

Reference flow = the weight of product having 1 gram of 'Active Content (AC)'

On the whole the following formulation is proposed:

**Functional unit and reference flow**
The functional unit refers to washing actions using the product. The reference flow is defined as the weight of the quantity of product having containing 1 gram of 'Active Content (AC)'. AC is defined as the weight sum of organic ingoing substances in the product (expressed in grams). It must be calculated on the basis of the complete formulation of the product.
Water and rubbing/abrasive agents in hand cleaning agents are not included in the calculation of AC.

### 6.3 ISSUES REGARDING REVISION OF EXISTING CRITERIA

Issues which were taken into consideration in the current revision of the existing criteria are described in more detail below in the relevant sections, primarily for each of the currently valid criteria and afterwards for the new criteria areas. First, the current criteria formulation and assessment and verification procedure is given and the preliminary proposals for revision prepared

[72] Available online at the project's website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

for the first AHWG meeting are briefly described. Subsequently, the discussion on the changes resulting from the stakeholders' consultation and the revision process is presented. And finally the proposal of revised criteria is given in a separate section.

### 6.3.1 CRITERION 1: Toxicity to aquatic organisms

The current formulation of the criterion 1 is as follows:

The critical dilution volume toxicity (CDV) is calculated for each ingredient (i) and for the whole product using the following equation:

CDV(ingredient i)= weight (i) × DF(i) × 1 000/TF chronic (i)

CDV = Σ CDV(ingredient i)

where weight (i) is the weight of the ingredient (in grams) per functional unit. DF (i) is the degradation factor and TF chronic (i) is the toxicity factor of the ingredient (in milligrams/litre).

The values of DF and TF chronic shall be as given in the Detergent Ingredient Database list-part A (DID list-part A). If the ingredient in question is not included in the DID list-part A, the applicant shall estimate the values following the approach described in the DID list-part B. The CDV(tox) is summed for each ingredient, making the CDV for the product.

The total CDV of the product must not exceed the following values:

Shampoo, shower products and liquid soaps: 20 000 l/g AC

Solid soaps: 3 500 l/g AC

Conditioner: 30 000 l/g AC

***Assessment and verification***:

The exact formulation of the product must be given. Furthermore the exact chemical description of ingredients (e.g. identification according to IUPAC, CAS-no, INCI-name, purity, type and percentage of impurities, additives; for mixtures e.g. surfactants: DID-number, composition and spectrum of homologue distribution, isomers and trade names).

Copies of the Safety Data Sheet of all ingredients must be given.

The calculation of CDV and the related score shall be provided in detail. For all ingredients included in the DID-list the appropriate ingredient number must be given. For ingredients not included in the DID-list, test results and test methods for eco-toxicity (long-term effects (NOEC data) on fish, Daphnia magna, and algae), biodegradation and bioaccumulation shall be submitted. The reference for the relevant tests shall be the appropriate Annexes of Council Directive 67/548/EEC[73].



[73] OJ 196, 16.8.1967, p. 1.

During the 1st AHWG meeting the following issues were considered with regard to the above criterion:

- First, it has been proposed to consider modifying the method for Critical Dilution Volume (CDV) calculation,

- Secondly, the issue of extension and update of the DID list was mentioned,

- Finally, the stakeholders discussed the proposal of decreasing the threshold values of critical dilution volume (CDV) for each kind of product: soaps, shampoos and hair conditioners.

**Critical dilution volume**

Critical dilution volume (CDV) is used in the EU Ecolabel to assess toxicity of products to the aquatic environment. This criterion is very important for soaps, shampoos and hair conditioners, as they are rinse-off products which are released entirely to water during use phase or after use.

The CDV represents a risk-based parameter by combining the amount used, the (aerobic) biodegradability and the aquatic toxicity of the substances. It is considered a very important single parameter to ensure that an ecolabelled product complies with high environmental standards.

The CDV expresses the amount of water needed for the hypothetical dilution of a product. The unit is expressed in litters per functional unit.

The CDV is calculated based on the chronic toxicity and chronic safety factors. If no chronic test results are available, the acute toxicity and safety factor must be used.

The actual CDV calculation method, as given in the currently valid criteria document, refers to 1g of "active content" (AC), which is defined as the weight of organic ingredients in the product. The AC is calculated on the basis of the complete formulation of a product. Rubbing/abrasive agents in hand cleaning agents are not included in the calculation of AC. So, the CDV of each substance is linked to the share (%) of other substances. As a consequence, the more substances are added, the less CDV of dangerous substances is important and the CDV can be decreased by adding substances.

Initially, it was proposed to consider during the 1st AHWG meeting calculating the CDV value per 1 g of product, instead of per 1 g of AC; i.e. each ingredient's CDV would be calculated per total weight of the ingredients contained in the product[74].

Nevertheless, after discussion conducted during the stakeholders meeting it was agreed to keep the current calculation method. It has been indicated that the current CDV formula promotes concentrated products, while in the case of the proposed new one a risk exists that it could favour diluted products (i.e. with higher water content but lower efficiency). It was emphasized that from an environmental point of view, concentrated products should be supported as they require less transport and packaging material. Further, it was added that concentrated products are often less expensive, they require less water in the product chain and consequently fewer preservatives.

In some other product categories different approaches for calculating the CDV of the product are used in this respect. For example in the EU Ecolabel criteria for Laundry Detergents[75] the CDV is

[74] For details please see Technical background report for the 1st AHWG meeting, available online at: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

calculated according to the weight of each ingredient per recommended dose. Using this approach is relevant and could be appropriate in case of liquid soaps for which doses can be more easily determined e.g. in reference to hand washing. However, determining standard doses for shampoos and hair conditioners would not be straightforward e.g. the dosage is dependent to the length of the hair washed.

In the 1st AHWG it was highlighted that it would be good if the CDV could be linked to the performance (efficiency) of the product. Then the risk that products could be diluted to reach the CDV threshold values (which in consequence would result in lower product efficiency), could be avoided and a new formula could be used. Stakeholders input supporting this is welcome but incorporating this aspect in the CDV calculation is not easy and no alternative to the current calculation method, which could suit the product group under study, has been proposed so far.

An alternative method to calculate the CDV was proposed by a stakeholder during the AHWG based on the State of the Art Report on Mixture Toxicity: http://ec.europa.eu/environment/chemicals/pdf/report_Mixture%20toxicity.pdf. Nevertheless, the proposal is considered very comprehensive and complex. Due to the complexity of this new formula it is proposed to investigate it in more detail ahead the next criteria revision.

Based on the discussions held in the 1st AHWG meeting and the written feedback received from many stakeholders it was agreed to keep the current calculation formula, as given below:

CDVtox = $\Sigma$ CDV (ingoing organic substance i)

CDV (ingoing organic substance i) = weight (i) x DF(i) x 1000/TF chronic (i)

**Information for the DID list**

The Harmonised DID-list is the Detergent Ingredients Database List. Its development started in late 1992 and in 1995 the first list was established. The list was last revised in 2007 and has proved to be a suitable tool for the Ecolabel schemes and the applicants. It contains today 204 ingredients.

The main purpose of the list is to ensure that all licence applications are treated similarly (i.e. that the same values are used for similar ingredients). It also facilitates the process of licence application and handling making the background data for the several criteria generally available. Finally, the list serve as an aid to manufacturers, especially SMEs, who seek to substitute less environmentally preferable ingredients with better ingredients that fulfil the criteria without spending much money on testing.

In the DID-list version from 2007 CDV data for 19 anionic surfactants, 23 non-ionic surfactants, 3 amphoteric surfactants, 2 cationic surfactants, 19 preservatives and 103 of other substances is available.

[75] Commission Decision of 28 April 2011on establishing the ecological criteria for the award of the EU Ecolabel for laundry detergents; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:111:0034:0047:EN:PDF.

The DID-list is divided in two parts: the list itself and a written procedure for determining the parameter values for ingredients not on the list. The list contains a number of detergent ingredients and their environmental properties and some parameters based on environmental properties.

So far, ecological data were available only for very low share of chemicals due to REACH legislation this situation is expected to improve. REACH places responsibility on industry to manage the risks that chemicals may pose to human health and environment and does not allow marketing of a chemical substance if it does not have appropriate registration where a minimum data is needed for each chemical and a great number of ecotoxicological tests are expected to be performed in Europe. It should be emphasised that in this product group REACH will be fully implemented in 2018.

One important point emphasized during the stakeholders' consultation was the availability of information, and in particular availability of the CDV values of several ingredients used. It was mentioned that many substances which are widely used in this product group are not included in the current DID-list. If the ingredients are not included in the DID-list, it is difficult for manufacturers to validate data which they receive from their suppliers.

Ecolabelling Norway was assigned by the European Commission as leading Competent Body for the revision of the Detergent Ingredient Database (DID list). In January 2012 started a project to enlarge and update the DID-list and is planned to be finished by June 2013. Stakeholders' involvement was asked in supporting the project team with information and indications of substances which should be added to this list. In June 1st AHWG meeting was held to discuss the progress.

Another important point mentioned during the consultation process was the lack of data for the naturally derived ingredients with no toxicity and no issue of biodegradability. This type of substances is exempted from registration so any information was expected to be improved with REACH regulation. In this case, this type of substances can be penalized by the Ecolabel due to the fact that without data a CDV value cannot be calculated. To avoid penalizing substances which are present in nature and non-classified as hazardous, it has been proposed to take into account in the revision process of DID-list the approach of REACH. In this apporach data gaps are filled with QSARs - Quantitative Structure-Activity Relationships weigh of evidence or read-across.

It was also proposed by one of the stakeholders not to use safety factors (SF) to define the Toxicity Factor (TF) in the calculation of the CDV. With current approach a less toxic substance used at high volume may have a higher environmental impact than a more toxic one used at lower tonnage. On the other hand, if SFs are kept in the calculation of the CDV, information of tonnage should be integrated to avoid this problem. The issues regarding TF calculation are also proposed to be considered in the revision process of the DID-list, as this exceeds the scope of criteria revision for this product group.

**Proposed threshold values**

The following stricter limits for CDV were preliminarily proposed for discussing during the 1st AHWG meeting:

- Shampoos and liquid soaps: 18 000 l/g AC
- Solid soaps: 3000 l/g AC
- For hair conditioners this issue was left open for a discussion due to limited information.

An analysis of CDV threshold values contained in the new version of the Nordic Swan Ecolabel for cosmetic products shows that they are stricter than the current EU Ecolabel thresholds: in Nordic Swan the CDV values for liquid soap (including shower gel and bath foam), as well as for shampoo, is 13000 l/g of active ingredients (AI), while the CDV value for solid soaps is 3000 l/g AI. A comparison of the current EU Ecolabel and the current Nordic Swan CDV values is given in Table 12 below:

**Table 12. CDV values for Nordic Ecolabel and the current EU Ecolabel**

| | Nordic Ecolabel | EU Ecolabel |
|---|---|---|
| | **(l/g active ingredient)** | **(l/g AC)** |
| **Liquid soap, shampoo,** | **13000** | **20 000** |
| **Hair conditioner** | | **30 000** |
| **Solid soap** | **3 000** | **3 500** |

In order to propose new values for the revised EU Ecolabel criteria stakeholders including Competent Bodies were contacted and asked for information regarding the CDV values which are obtained by the currently existing products. 57 Ecolabelled products were analyzed based on the feedback from stakeholders[76]. The data from the previous report on the development of EU Ecolabel criteria for soaps, shampoos and hair conditioners[77] in 2006 was also included. It was found that the current CDV limits are higher than the average values found from the sample investigated in the case of liquid soap and shampoos (see Table 13). This indicates that a proposal for stricter CDV limits can be substantiated. In the case of solid soaps and hair conditioners only values for one product from each of these categories have been received directly, 2281 l/g AC and 4904 l/g AC, respectively. Based on this fact no definite conclusion could be derived and stakeholders are asked for additional comments.

**Table 13. CDV average values and current limits**

| PRODUCT | CDV (average 2012) (l/g AC) | | CDV (average 2006)[77] (l/g AC) | | Current limit (l/g AC) |
|---|---|---|---|---|---|
| | **Average** | Range | **Average** | Range | |
| **LIQUID SOAP** | **14717** | 7342 - 19909 | **18622** | 3600 – 83000 | **20000** |
| **HAIR CONDITIONER** | | | **73735** | 2300 - 380000 | **30000** |
| **SOLID SOAP** | | | **3925** | 2000 – 9300 | **3500** |

Sources: own work based on information from reports indicated in footnote and stakeholders 'information sent to the EC

[76] For further details see appendix IV: Summary of data.
[77] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., May 2006.

Moreover, based on feedback received from Competent Bodies the following threshold values are proposed:

- For shampoos and liquid soaps it was proposed to set values at 13 000 l/AC (aligned with the Nordic Swan label requirements) or 18 000 l/g AC,

- For solid soaps the values of 3000 (aligned with the Nordic Swan label requirements) or 3500 l/g AC were indicated,

- For hair conditioners different values were proposed of 10 000, 13 000, 25 000 or 28 000 l/g AC.

Combining the two elements of information received from the existing products and the stakeholders' feedback, it is possible to propose the following CDV limits for the revised criteria in case of shampoos, liquid soaps and solid soaps. For hair conditioners this was not possible and if no additional feedback is given keeping the current limits or limits close to the current threshold (i.e. of 25000 or 28000) could be considered:

- Shampoo and liquid soaps: 18000 L/g AC
- Solid soaps: 3000 L/g AC
- Hair conditioners: Discussion point

The final criterion formulation proposal is given in Chapter 7.

When including into the scope of the Ecolabel other rinse-off cosmetic products like shaving foam, shaving gel, shaving cream and shaving soap or shampoos for animals, especially pets, it is important to set also CDVs limits for these products. It will be discussed during the second AHWG meeting if the CDV limit for liquid soaps can be applied to shaving foam, shaving gel, shaving cream and shampoos for animals; and limits for shaving soaps can be the same as solid soaps.



### 6.3.2 CRITERION 2: Environmental harmful products

The current formulation of the criterion is as follows:

The product must not fulfil the requirements for classification for any of the following risk phrases according to Directive 67/548/EEC:

N, R50/53: (WR50/53/25 %) ≥ 1

N, R51/53: ((WR50/53/2,5 %) + (WR51/53/25 %)) ≥ 1

R52/53: ((WR50/53/0,25 %) + (WR51/53/2.5 %) + (WR52/53/25 %)) ≥ 1

WR50/53 = weight percent of ingredients that may be classified as R50/53.

WR51/53 = weight percent of ingredients that may be classified as R51/53.

WR52/53 = weight percent of ingredients that may be classified as R52/53.

Rubbing/abrasive agents in hand cleaning agents are not included.

***Assessment and verification***:

Test results for aquatic toxicity and biodegradation of relevant ingredients must be given, according to part 2, testing methods, of Directive 67/548/EEC. Toxicity results from the DID-list cannot be used since these are median values and are not in compliance with Directive 67/548/EEC.

If the lowest toxicity is ≤10 mg/l, then test results for potential bioaccumulation (Bio-concentration factor (BCF) or log Kow) must also be given. If no results are available the ingredient will be regarded as R 50/53. The following exceptions apply:

Fragrances and dyes: R 51/53.

Biological additives, i.e. plant extracts and other ingredients isolated from plants or animals and with little or no chemical alteration: R 51/53.

Any ingredient (substance or preparation) whose concentration exceeds 0,010 % by weight of the final product shall be considered regardless of if it is used in the formulation as a single substance or as a constituent of preparation. This also applies to each ingredient of any preparation used in the formulation that exceeds 0,010 % by weight of the final product.



During the stakeholder's consultation process it was highlighted that this criterion should also be updated to be based on CLP classification criteria. The classification criteria regarding CLP have changed in comparison with DSD (Dangerous Substance Directive 67/548/EC), so this will be taken into account. For example, when substances are classified under CLP as Aquatic Acute Category 1 (H400) or/and Chronic Category 1 (H410), it will be necessary to indicate an appropriate M-factor. This multiplying factor gives an increased weight to substances which are very toxic for the aquatic environment when mixtures containing them are classified. As a result it is possible that the number of classified mixtures may increase with CLP.

So far, 25% of substances classified as hazardous to the environment are allowed in products. One important point emphasized during the stakeholders´ consultation was to ensure that all Ecolabelled products of this product group do not contain substances classified as hazardous to the environment. This criterion covers areas which are also included in the new criterion regarding the excluded and restricted substances and mixtures as it is developed following the implications given in Article 6(6) and 6(7) of the new EU Ecolabel Regulation 66/2010. Therefore, it has been proposed to simplify the criteria set and have, if possible, only one criterion in which are all requirements regarding the use of substances covered. 65% of the stakeholders consulted already before the 1st AHWG meeting agreed with this proposal. In addition, in the 1st AHWG it was also concluded that the current criterion 2 should be taken out but its requirements should be integrated in the context of the new criterion on the use of substances and mixtures. Please, see on this also section 8 about environmental hazardous ingredients criterion.

Finally, it was asked by one of the stakeholders why rubbing/abrasive agents in hand cleaning agents are not covered by this criterion. The reason for not covering them in the current criteria was that rubbing/abrasive agents generally are of natural origin; usually inorganic and inert like for example bentonite clay.

The revised criterion formulation is given in Chapter 7.

### 6.3.3 CRITERION 3: Aerobic biodegradability and CRITERION 4: Anaerobic biodegradability

The current formulation of criterion 3 (Aerobic biodegradability) is as follows:

(a) Aerobic biodegradability of surfactants

Each surfactant used in the product shall be readily biodegradable.

***Assessment and verification***:

The exact formulation of the product as well as a description of the function of each ingredient shall be provided to the competent body.

The DID list-part A indicates whether a specific surfactant is aerobically biodegradable or not (the surfactants with an entry of 'R' in the column on aerobic biodegradability are readily biodegradable). For surfactants which are not included in the DID list-part A, the relevant information from literature or other sources, or appropriate test results, showing that they are aerobically biodegradable shall be provided. The tests for ready biodegradability shall be as referred to in Regulation (EC) No 648/2004 of the European Parliament and of the Council[78].

Surfactants shall be considered as readily biodegradable if the level of biodegradability (mineralisation) measured according to one of the five following tests is at least 60 % within 28 days: CO2 headspace test (OECD 310), Carbon dioxide (CO2) Evolution Modified Sturm test (OECD 301B; Council Directive 67/548/EEC Annex V.C.4-C), Closed Bottle test (OECD 301D; Council Directive 67/548/EEC Annex V.C.4-E), Manometric Respirometry (OECD 301F; Council Directive 67/548/EEC Annex V.C.4-D), or MITI (I) test (OECD 301C; Council Directive 67/548/EEC Annex V.C.4-D), or their equivalent ISO tests. Depending on the physical characteristics of the surfactant, one of the following tests might be used to confirm ready biodegradability, if the level of biodegradability is at least 70 % within 28 days: Dissolved Organic Carbon DOC Die-Away (OECD 301A; Council Directive 67/548/EEC Annex V.C.4-A) or Modified OECD Screening DOC Die-Away (OECD 301E, Council Directive 67/548/EEC Annex V.C.4-B), or their equivalent ISO tests. The applicability of test methods based on measurement of dissolved organic carbon needs to be appropriately justified as set out in Regulation (EC) No 648/2004.

All ingredients (substances or preparations) that exceed 0,010 % by weight of the final product shall be considered.

[78] (1) OJ L 104, 8.4.2004, p. 1.

This includes also each ingredient of any preparation used in the formulation that exceeds 0,010 % by weight of the final product.

(b) Aerobic biodegradability of non-surfactants (aNBDOnon-surf)

The content of ingredients that are not readily biodegradable (or have not been tested for aerobic biodegradability) must not exceed the following levels:

Shampoo, shower products and liquid soaps: 30 mg/g AC

Solid soaps: 15 mg/g AC

Conditioner: 50 mg/g AC

Rubbing/abrasive agents in hand cleaning agents are not included.

All ingredients (substances or preparations) exceeding 0,010 % by weight of the final product shall be considered. This includes also each ingredient of any preparation used in the formulation exceeding 0,010 % by weight of the final product.

***Assessment and verification***:

Identical to requirement 3(a).



While the current formulation of the criterion 4 (Anaerobic biodegradability) is as follows:

The content of ingredients that are not anaerobically degradable (or have not been tested for anaerobic biodegradability) and have a lowest acute toxicity LC50 or EC50 < 100 mg/l (similar to the classification limit for R52 in Directive 67/548/EEC) must not exceed the following levels:

Shampoo, shower products and liquid soaps: 25 mg/g AC

Solid soaps: 15 mg/g AC

Conditioner: 50 mg/g AC

Rubbing/abrasive agents in hand cleaning agents are not included.

***Assessment and verification***:

The DID list-part A indicates whether a specific ingredient is anaerobically biodegradable or not (the surfactants with an entry of 'Y' in the column on anaerobic biodegradability are biodegradable under anaerobic conditions). For ingredients which are not included in the DID list-part A or which are included with an entry '0' the relevant information from literature or other sources, or appropriate test results, showing that they are anaerobically biodegradable shall be provided.

The reference test for anaerobic biodegradability shall be OECD 311, ISO 11734, ECETOC No 28 (June 1988) or an equivalent test method, with the requirement of a minimum of 60 % ultimate biodegradability under anaerobic conditions. Test methods simulating the conditions in a relevant

anaerobic environment may also be used to document that 60 % ultimate biodegradability has been attained under anaerobic conditions (see Appendix II).

If several toxicity results are available the lowest validated value shall be used. The toxicity values on the DID-list are median values that cannot be used for this purpose.

All ingredients (substances or preparations) exceeding 0,010 % by weight of the final product shall be considered. This includes also each ingredient of any preparation used in the formulation exceeding 0,010 % by weight of the final product.

During the 1st AHWG meeting in Seville the following issues were addressed with regard to both above presented criteria:

- First, the issue whether all surfactants must be readily aerobically and anaerobically biodegradable was discussed.
- Further, the proposal of decreasing the threshold values for aNBDO (Aerobic Non-Biodegradable Organics) and for anNBDO (Anaerobic Non-Biodegradable Organics) was considered.

Basic elements used for classification of aquatic environmental impacts are: Acute aquatic toxicity; Potential for or actual bioaccumulation; Degradation (biotic or abiotic) for organic chemicals; and Chronic aquatic toxicity. Substances that rapidly degrade can be quickly removed from the environment. In the absence of rapid degradation in the environment a substance in the water has the potential to exert toxicity over a wide temporal and spatial scale[79]. Surfactants in this respect are considered relevant due to the fact that they are used in high amounts in liquid soaps, shampoos and conditioners[80]. Maximum and estimated amounts of surfactants used in products under study are presented in Table 14 below:

**Table 14. Surfactants used in studied products**

| | Liquid soaps | | Solid soaps | | Shampoos | | Hair conditioners | |
|---|---|---|---|---|---|---|---|---|
| | Maximum amount (Frame formulations COLIPA[81]) | Estimated amount (Technical report) | Maximum amount (Frame formulations COLIPA) | Estimated amount (Technical report) | Maximum amount (Frame formulations COLIPA) | Estimated amount (Technical report) | Maximum amount (Frame formulations COLIPA) | Estimated amount (Technical report) |
| Percentage of surfactants in product (% w/w) | 93% | 12.2% | 5% | - | 70% | 10% | 15% | 1.8% |

[79] Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF.

[80] Nordic Ecolabelling of cosmetic products Version 2.1 Background document regarding ecolabelling 16 February 2011.

[81] COLIPA GUIDELINES. Cosmetic Frame Formulations. Guidelines realized in collaboration with the European Association of Poison Centres and Clinical Toxicologists (EAPCCT). January 2000.

Notes:

- Concentration includes anionic and non-ionic surfactants, amphoretic surfactants and cationic surfactants.
- Amounts estimated in the technical report are lower than maximum concentrations of frame formulations of COLIPA. Estimated amounts are based in real formulations while in frame formulations of COLIPA maxim values are expressed, which are significantly higher than average content in products.

Most surfactants affects in a greater or lower extend the product toxicity to aquatic organisms due to their surface activity which allows reaction with the biological membranes of the organisms. The biological degradability varies according to the nature of the carbohydrate chain. Generally, the linear chains are more readily degradable than branched chains. Also the toxic effects vary with the chain structure. Generally an increase of the chain length in the range of 10 to 16, leads to an increase in toxicity to aquatic organisms[82].

During the AHWG meeting discussions arose whether it is important from the environmental point of view that all surfactants should be readily aerobically and anaerobically biodegradable. Some participants strongly supported the requirement that all surfactants shall be readily aerobically and anaerobically biodegradable, while other disagreed with the importance of the anaerobic biodegradability and questioned its environmental relevance[83] as well as the feasibility of fulfilling the respective criterion. For example the new Nordic Swan[84], the Good Environmental Choice as well in Swedish Bra Miljöval[85] ecolabel for cosmetics is required that all surfactants have to be readily aerobically and anaerobically biodegradable, regardless of their function. The ecological criteria for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners, as well as hand dishwashing detergents state that each surfactant used in the product shall be readily biodegradable. Surfactants that are not biodegradable under anaerobic conditions may be used in the product within specified limitations provided that the surfactants are not classified with H400/R50 (Very toxic to aquatic life) within the specified limit.

Ready biodegradability of surfactants is already required for products sold on the European market according to the Detergents Regulation (Regulation 648/2004/EC). However, this regulation does not define requirements to anaerobic biodegradability of ingredients according to the opinion of the Scientific Committee on Health and Environmental Risks (SCHER) that concluded that a requirement of anaerobic degradation of surfactants is not itself regarded as an effective measure of environmental protection. For this reason, with a general requirement to the biodegradability of the surfactants, the aNBDO/anNBDO criterion combined with the CDV criterion ensures that the overall content of not readily biodegradable and/or toxic substances is limited, giving to the manufacturers at the same time flexibility in the product composition.

Some of the CBs stakeholders substantiated their requirement regarding the anaerobic availability of surfactants with the following arguments:

[82] Procter & Gamble (http://www.scienceinthebox.com/en_UK/programs/natural_synthetic_en.html)
[83] http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_109.pdf
[84] Nordic Ecolabelling of Cosmetic products. Version 2.1., 2011.
[85] http://www.naturskyddsforeningen.se/bra-miljoval/in-english/about-bra-miljoval/how-does-it-work/.

"*There are many situations where the aerobic biodegradation of surfactants does not guarantee that they do not reach the environment, either there is no sewage treatment plant, or the passage in the sewage treatment plant is too fast, or flooding reduces the purification rate*.

*It is known that some surfactants adsorb to solid matter in the sewage sludge. This might reduce the actual degradation rates compared to laboratory values, resulting e.g. in a discharge via sewage sludge on agricultural land. Furthermore (and this is very important) this can result in a discharge to the sediment where anaerobic conditions prevail. This is a very strong argument to consider anaerobic degradability for surfactants.*

*Furthermore, some surfactants disturb the fermentation processes of the sewage sludge in the digestion towers. As the situation in anaerobic sediment is comparable to the digestion of sewage sludge, it is very likely that the biocoenosis in sediments is affected, but this has not been analyzed in scientific experiments yet. Anyway, there is no study to show that there is no negative effect on the microorganism populations.*

*Shampoos with the eco label should not contain substances that might have such negative effects. Unless these presumptions were not disproved the precautionary principle should suffice to include the anaerobic biodegradability in the Eco-Label criteria*".

Opposite opinions were, nevertheless, also expressed by other stakeholders. Some of the written feedback stated that "*if surfactants are readily biodegradable, there is no need to be also anaerobically biodegradable, because the tiny amount that ends up in sludge and eventually on agricultural soil will degrade aerobically further once the sludge has been amended on soil. Sludges are usually stored in anoxic condition at Sewage Treatment Plants but spreading on soil put back the sludge into aerobic condition. Furthermore, current legislation requires a period of 180 days before any crop are planted, to allow remaining organic chemicals to degrade further. In case there is no wastewater treatment and domestic sewer are directly discharged into river, a portion of the river may become anoxic and no aquatic organisms are present anymore. The only biological organisms still present in the rivers that should be protected are microorganisms that will start digesting organic matters. Once oxygen is back, readily biodegradable surfactants will be degraded before aquatic life is back".*

In general, industry disagreed with the proposal that all surfactants must be anaerobically biodegradable due to the proposed criterion does not demonstrate based on scientific publications the added value of this restrcition. LAS is a widely and most effective used surfactant and, at present, industry is not able to reformulate certain products without some currently used surfactants being non-anaerobically biodegradable such as LAS (linear alkyl benzene sulphonate).

The "Opinion on Anaerobic Degradation of Surfactants and Biodegradation of Non Surfactant Organic Ingredients" of the Scientific Committee on Health and Environmental Risks (SCHER)[86] was also mentioned. In accordance with this document the SCHER's opinion from 2005 was reconfirmed, stating that, based on the available scientific evidence:

- poor biodegradability under anaerobic conditions is not expected to produce substantial modifications in the risk for freshwater ecosystems as the surfactant removal in the WWTP seems to be regulated by its aerobic biodegradability,

[86] Scientific Committee on Health and Environmental Risks (SCHER), "Opinion on Anaerobic Degradation of Surfactants and Biodegradation of Non Surfactant Organic Ingredients", November 2008, available online at: http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_109.pdf.

- the requirement for ready and ultimate biodegradability under anaerobic conditions is not by itself regarded as an effective measure for environmental protection.

This opinion was supported by the Commission who conducted a study in 2009 to establish a knowledge base sufficient to review the anaerobic biodegradation of surfactants[87]. It was concluded that, in contrast to the adverse effects observed in the absence of aerobic degradation, the lack of anaerobic degradation does not seem to be correlated with any apparent risk for these environmental compartments, as a result anaerobic biodegradability should not be used as an additional pass/fail criterion for the environmental acceptability of surfactants. On the other hand, the information requirements of the REACH registration dossiers submitted by industry to the ECHA, ensure data on the health and environmental effects of substances, including surfactants such as linear alkyl benzene sulphonate (LAS). The chemical safety report demonstrates the safe use of the substances during their entire life cycle and consequently, this information should therefore be sufficient to decide whether restrictions on certain surfactants are needed from an environmental point of view.

According to REACH, LAS[88] does not pose a significant risk for the environment and human health. A chemical safety assessment was carried out for the first deadline in 2010 with an extensive database which allowed calculating Predicted No Effect Concentration (PNEC) in several compartments, as well as to demonstrate that LAS is neither a persistent bioaccumulative toxic (PBT) nor a (very persistent and very bioaccumulative) vPvB substance[89]. As a conclusion, this assessment shows that the risk characterisation ratio (RCR=PEC/PNEC) is less than one for all exposure scenarios and environmental compartments, therefore the risks to the environment are unlikely. Recent risk assessment carried out also confirms this conclusion[90].

For the discussion during the 2nd AHWG an approach proposed in the recently developed Ecolabel criteria for Industrial and Institutional Automatic Dishwasher Detergents is proposed for consideration regarding the issue of non-anaerobically biodegradable surfactants:

**"All non-ionic and cationic surfactants must also be biodegradable under anaerobic conditions".**

**Stakeholders are asked for their comments, also prior to the meeting.**

**Threshold values for the revised criteria for aerobic and anaerobic biodegradability of organic substances**

Furthermore, discussions regarding the threshold values for biodegradability were considered in the revision process. The threshold values for aerobic and non-aerobic biodegradability included in the existing EU Ecolabel criteria for soaps, shampoos and hair conditioners have been compared with the values included in the new Nordic Swan criteria document for cosmetic products. With regard to

[87] Report from the Commission to the European Parliamnet and the Council. Pursuant to Article 16 of Regulation (EC) N° 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, concerning anaerobic biodegradation. Brussels, 2009. Report available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0230:FIN:EN:PDF.

[88] Information on chemical properties of LAS registered substance is directly accessible via ECHA web: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fe772aa-2c02-269e-e044-00144f67d031/AGGR-ac3161f3-4caa-44c8-a5a6-c25c0371b7b9_DISS-9fe772aa-2c02-269e-e044-00144f67d031.html#L-56795e2a-31d0-4ea8-8d56-0f225a9bbbac.

[89] For more details see: http://www.heraproject.com/files/48-F-HERA_LAS_Report_(Version_4_-_June_09).pdf.

[90] REACH Chemical Safety Report, HERA LAS report 2012, D. Rasmussen et al.

**aerobic biodegradability of non-surfactants** stricter limit values are given in the Nordic Swan for ingredients that are not readily biodegradable than in the exisiting EU Ecolabel criteria (see Table 15):

**Table 15. aNBDO $_{non\text{-}surf}$ values for Nordic Ecolabel and EU Ecolabel**

| | Nordic Ecolabel | EU Ecolabel |
|---|---|---|
| | aNBDO$_{non\text{-}surf}$ (mg/g AI) | aNBDO $_{non\text{-}surf}$ (mg/g AC) |
| Liquid soap, shampoo, | 15 | 30 |
| Hair conditioner | 15 | 50 |
| Solid soap | 5 | 15 |

In the framework of the stakeholders' consultation and during the AHWG meeting stakeholders submitted their feedback regarding setting stricter threshold values for the aerobic biodegradation of non-surfactants in the EU Ecolabel. In general, most stakeholders agree to set more stringent values. Based on the analysis of more than 220 products submitted by CBs (79% thereof shampoos, shower gels and liquid soaps, 16% solid soaps and 5% hair conditioners) it was proposed by to set the threshold values as follows:

- for shampoos, shower gels and liquid soaps - 19 mg/g AC,
- for solid soaps - 13 mg/g AC,
- for hair conditioners - 40 mg/g AC

Further, 57 ecolabelled products were analyzed based on the feedback received from the stakeholders (other Competent Bodies and licence holders)[91]. The data from the report of the development of EU Ecolabel criteria for soaps, shampoos and hair conditioners[92] was also included. It was found that current limit of aNBDO is higher that the values available for average product in the case of liquid soaps and shampoos (see the table below). For solid soaps and hair conditioners, only data regarding one product from each of the categories have been obtained directly (the aNDBO values for these products were 48 mg/g AC and 8 mg/g AC, respectively), thus no conclusion could be made on this basis.

**Table 16. aNBDO $_{non\text{-}surf}$ average values and current limits**

| PRODUCT | aNBDO (average 2012) (mg/g AC) | | aNBDO (average 2006)[93] (mg/g AC) | | Current limit (mg/g AC) |
|---|---|---|---|---|---|
| | **Average** | Range | **Average** | Range | |
| **LIQUID SOAP** | **15** | 0-25 | 45 | 0-460 | **30** |
| **HAIR CONDITIONER** | | | 123 | 0-310 | **50** |
| **SOLID SOAP** | | | 13 | 0-47 | **15** |

Sources: own work based on information from reports indicated in footnote and stakeholders 'information sent to the EC

[91] For further details see appendix 16: Summary of data
[92] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., May 2006.
[93] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., May 2006.

Based on these outcomes of the consultation and the feedback received the following aNBDO $_{non\text{-}surf}$ (mg/g AC) limits threshold values are proposed for the revised versions of the criteria for **aerobic biodegradability**:

- Shampoo and liquid soaps: 20 mg/g AC
- Solid soaps: 10 mg/g AC
- Hair conditioners: 45 mg/g AC.

With regard to the **anaerobic biodegradability** criterion, Nordic Swan criteria sets also tighter limits than current EU Ecolabel criteria (please see below table):

**Table 17. anNBO values for Nordic Ecolabel and EU Ecolabel**

| | Nordic Ecolabel | EU Ecolabel |
|---|---|---|
| | $AnNBDO_{tox}$ (mg/g AI) | $anNBDO_{tox}$ (mg/g AC) |
| Liquid soap, shampoo, | 15 | 25 |
| Hair conditioner | 15 | 50 |
| Solid soap | 5 | 15 |

In the framework of the stakeholders' consultations and during the AHWG meeting stakeholders submitted their feedback, in general, most stakeholders agreed to set more stringent values for the anaerobic biodegradation in the EU Ecolabel. Based on the analysis of previously mentioned 220 ecolabelled products, submitted to the project team, the following threshold values were proposed:

- for shampoos, shower gels and liquid soaps - 21 mg/g AC,
- for hair conditioners - 40 mg/g AC
- for solid soaps - 13 mg/g AC,

Furthermore, 57 ecolabelled products were analyzed based on the feedback received from the stakeholders[94]. The data from the report of the development of EU Ecolabel criteria for soaps, shampoos and hair conditioners[95] was also included. It was found that current limit anNBDO is higher that the values for average product in the case of liquid soap and shampoos (see the following table), which indicates that it may be appropriate to propose stricter anNBDO limits. For solid soaps only data regarding one product were received, which did not allow to make any conclusion from this feedback. The reported value of anNBDO amounted 7 mg/g AC.

[94] For further details see appendix IV: Summary of data
[95] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., May 2006.

**Table 18. anNBDO average values and current limits**

| PRODUCT | anNBDO (average 2012) (mg/g AC) | | anNBDO (average 2006)[95](mg/g AC) | | Current limit (mg/g AC) |
|---|---|---|---|---|---|
| | **Average** | Range | **Average** | Range | |
| **LIQUID SOAP** | **15** | 3,6-29 | 62 | 0-410 | **25** |
| **HAIR CONDITIONER** | | | 141 | 0-530 | **50** |
| **SOLID SOAP** | | | 11 | 0-39 | **15** |

Sources: own work based on information from reports indicated in footnote and stakeholders 'information sent to the EC

Based on the data and information collected the proposed anNBDO (mg/g AC) limits are as follows:

- Shampoo and liquid soaps: 20 mg/g AC
- Hair conditioners: 45 mg/g AC.
- Solid soaps: 10 mg/g AC

It has been emphasized that for some substances **anaerobic biodegradability (anNBDO) values** can be difficult to obtain and thus the compliance with the requirements is difficult to prove. It has been suggested to apply in this situation a solution worked out in the criteria development for industrial and institutional laundry detergents and industrial and institutional automatic dishwasher detergents product groups[96]:

"*In the absence of documentation in accordance with the above requirements, a substance other than a surfactant may be exempted from the requirement for anaerobic degradability if one of the following three alternatives is fulfilled:*

*1. Readily degradable and has low adsorption (A < 25%) or*

*2. Readily degradable and has high desorption (D > 75%) or*

*3. Readily degradable and non-bioaccumulating.*

*Testing for adsorption/desorption may be conducted in accordance with OECD guidelines 106*".

This formulation is proposed to be included in the criterion regarding biodegradability.

The revised criterion formulation is given in Chapter 7.

### 6.3.4 CRITERION 5: Fragrances

The current formulation of this criterion is as follows:

Any ingredient added to the product as a fragrance must have been manufactured, handled and applied in accordance with the code of practice of the International Fragrance Association.

***Assessment and verification***:

[96] For detail see the document available online at: http://ec.europa.eu/environment/ecolabel/documents/Last-draft-Criteria-automatic-dishwasher-detergents-PRO.pdf.

A declaration of compliance with this criterion shall be provided to the competent body by the fragrance manufacturer.

During the 1st AHWG meeting the following issues were considered for the revision of the current criterion:

- Restriction of sensitizing substances classified as:
  - **H334 (R42):** may cause allergy or asthma symptoms of breathing difficulties if inhaled and/or
  - **H317 (R43):** may cause an allergic skin reaction.
- Extension of the scope of this criterion to substances other than fragrances known to act as sensitizers for allergic skin reaction and contact dermatitis.
- Proposal that all ecolabelled products intended for babies and for children under the age of three year should be fragrance-free.

There are more than 5 000 different fragrance substances, which are used frequently as mixtures in various consumer products; mainly in cosmetics but also in household products (e.g. room fresheners), textiles, shoes and even toys. Approximately 80% of the total fragrances volume is used in cosmetic products and 20% in household products[97]. Population come into daily contact with cosmetic products, at least 95% of the female and 75% of the male population[98].

Some fragrances are sensitizers and known triggers of allergic reactions such as asthma and contact dermatitis[99]. Approximately 35% of all allergic reactions to cosmetics are due to perfume ingredients, therefore fragrances are one of the major causes of allergic contact dermatitis remaining a significant clinical problem[100]. Fragrances with a low molecular weight come in close contact with the skin and cause contact allergy. The clinical manifestation is eczema, inflammatory skin disease. The face, neck, axillae and hands are the most affected areas in case of contact allergy.

In addition to the skin exposure, fragrances are volatile and therefore a perfume exposes also the eyes and naso-respiratory tract. Respiratory allergy occurs less frequently than contact dermatitis. Approximately 2-4% of population is affected by respiratory symptoms. In an epidemiological

[97] Scientific Committee on Consumer Safety SCCS Opinion on Fragrance allergens in cosmetic products, December 2011, available online at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf.

[98] Final report of the project supported by the 5th Framework Programme of the European Commission, under the Quality of Life and Management of Living Resources thematic programme, key action Environment and Health: (contract QLK4-CT-1999-01558) "Fragrance chemical allergy: a major environmental and consumer health problem in Europe", March 2003, available on line at: http://ec.europa.eu/research/quality-of-life/ka4/pdf/report_fragrance-allergy_en.pdf.

[99] Wijnhoven S.W.P., Ezendam J., Schuur A.G. , van Loveren H., van Engelen J.G.M, Allergens in consumer products, RIVM Report 320025001/2008, available online at: http://www.rivm.nl/bibliotheek/rapporten/320025001.pdf.

[100] Final report of the project supported by the 5th Framework Programme of the European Commission, under the Quality of Life and Management of Living Resources thematic programme, key action Environment and Health: (contract QLK4-CT-1999-01558) "Fragrance chemical allergy: a major environmental and consumer health problem in Europe", March 2003, available on line at: http://ec.europa.eu/research/quality-of-life/ka4/pdf/report_fragrance-allergy_en.pdf

investigation, a significant association was found between contact allergy and respiratory complaints related to fragrances[101].

Studies based on the limited testing with eight common fragrance allergens[102] performed on different parts of population show that contact allergy to fragrances affects 1 to 3% of the general population in Europe[103]. However, if the testing was performed with the full spectrum of fragrance allergens, this percentage might be higher. Approximately 16% of eczema patients in the European population are sensitised to fragrance ingredients. Prevention of contact sensitisation to fragrances is an important objective and thus is proposed to address this issue under the EU Ecolabel criteria by reducing the amount of allergens in products and consequently preventing the exposure to known contact allergens.

In 1999, the Scientific Committee on Cosmetic Products and Non Food Products intended for Consumers (SCCP), based on dermatological data reflecting the clinical experience[104], identified and prepared a list of 24 fragrance substances potentially resulting in contact allergy. They were divided into two lists (see also below tables):

- list A – indicating the most frequently reported and well recognized contact allergens,

- list B – indicating fragrances less documented as consumer allergens.

**Table 19. Fragrance chemicals most frequently reported as contact allergens**

| SUBSTANCES | CAS No |
|---|---|
| Amyl cinnamal | 122-40-7 |
| Amylcinnamyl alcohol | 101-85-9 |
| Benzyl alcohol | 100-51-6 |
| Benzyl salicylate | 118-58-1 |
| Cinnamyl alcohol | 104-54-1 |
| Cinnamal | 104-55-2 |
| Citral | 5392-40-5 |
| Coumarin | 91-64-5 |
| Eugenol | 97-53-0 |
| Geraniol | 106-24-1 |
| Hydroxycitronellal | 107-75-5 |
| Hydroxymethylpentylcyclohexenecarboxaldehyde | 31906-04-4 |
| Isoeugenol | 97-54-1 |

Source: SCCPNFP, 1999

[101] Elberling J, Linneberg A, Mosbech H, Dirksen A, Frolund L, Madsen F, Nielsen N H, Johansen J D. A link between skin and airways regarding sensitivity to fragrance products? Br J Dermatol 2004: 151: 1197-203.

[102] Fragrance Mix included in the standard patch test tray containing the eight most common allergens in Europe: amyl cinnamal, cinnamyl alcohol, cinnamal, eugenol, geraniol, hydroxycitronellal, isoeugenol, oak moss and sorbitan sesquioleate (added as an emulsifier).

[103] Scientific Committee on Consumer Safety SCCS Opinion on Fragrance allergens in cosmetic products, December 2011, available online at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf.

[104] The Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers Opinion concerning Fragrance Allergy in Consumers – A review of the problem – Analysis of the need for appropriate consumer information and Identification of consumer allergens, December 1999, available online at: http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf.

**Table 20. Fragrance chemicals less frequently reported as consumer allergens**

| Common name | CAS no |
|---|---|
| Anisyl alcohol | 105-13-5 |
| Benzyl benzoate | 120-51-4 |
| Benzyl cinnamate | 103-41-3 |
| Citronellol | 106-22-9 |
| Farnesol | 4602-84-0 |
| Hexyl cinnamaldehyde | 101-86-0 |
| Lilial | 80-54-6 |
| d-Limonene | 5989-27-5 |
| Linalool | 78-70-6 |
| Methyl heptine carbonate | 111-12-6 |
| 3-Methyl-4-(2,6,6-trimethyl-2-cyclohexe-1-yl)-3-buten-2-one (= γ-methylionone) | 127-51-5 |

Source: SCCNFP, 1999

In December 2011 the Scientific Committee on Consumer Safety (SCCS) issued an opinion on "Fragrance allergens in cosmetic products"[105]. It confirmed that contact allergy to fragrances may develop due to skin contact with a sufficient amount of such substances, among other through the use of cosmetics. The revision of the SCCNFP Opinion on fragrance allergy in consumers from 1999 confirmed that the findings of this report are still valid. It has also been stated that based on the review of the recent clinical and experimental studies more fragrance substances have been identified to have sensitising properties for humans. The analysis showed that 82 substances could be classified as established contact allergens in humans. Among them there are 54 single chemicals and 28 natural extracts (12 chemicals and 8 natural extracts thereof were found to pose a high risk of sensitisation).

Furthermore, two fragrances (natural mixtures) were added to the previously described list:

- Oak moss (90028-68-5)
- Tree moss (90028-67-4)

If one or more of these 26 fragrance ingredients are present in concentration of above 0.01% it is required that they are indicated on the product pack label in order to facilitate the consumers who may have allergic reactions to specific substances to identify and choose products which are appropriate for them.

In the framework of the open consultation it has been proposed to ban the use of twelve fragrance substances identified as posing a high risk of sensitisation to consumers. They are listed in Table 13-5 of the SCCS opinion mentioned above and given in this report in table below. It has been emphasized that limiting the exposure to these chemicals would aid protecting sensitised consumers from developing allergic contact dermatitis. Additionally, it has been asked to restrict the use of two substances: **chloroantranol and atranol** (main allergenic constituents of Everna prunasteri and Everna furfuracea), which presence in cosmetic products has been considered not safe by the SCCS.

[105] Scientific Committee on Consumer Safety SCCS Opinion on fragrance allergens in cosmetic products http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf.

**Table 21. Established fragrance contact allergens of special concern (single chemicals only)**

| |
|---|
| Cinnamal, |
| Cinnamyl Alcohol |
| Citral |
| Coumarin |
| Eugenol |
| Farnesol |
| Geraniol |
| Hydroxycitronellal |
| Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) |
| Isoeugenol |
| Limonene (oxidised) |
| Linalool (oxidised) |

Source: SCCNFP, 2011

Furthermore, SCCS established other lists with contact allergens in humans:
- Table 13-1 listing established contact allergens in humans
- Table 13-2 – "where sufficient animal evidence was present, these substances were categorised as established contact allergens in animals"
- Table 13-3 – "for other fragrance substances, combinations of limited clinical data together with structure activity relationship (SAR) considerations have been applied to indicate likely fragrance allergens in man".
- and Table 13-4 – "substances with insufficient human data were also considered as possible fragrance allergens. For these further tests (experimental/clinical data) are required".

Some stakeholders asked to restrict the use of the substances listed in 13-1, 13-2 and 13-3 and asked for their labelling by the manufacturer. In the current proposal the restriction of substances given in Table 13-5 (see Table 21 above) and additionally of **chloroantranol and atranol** (main allergenic constituents of Everna prunasteri and Everna furfuracea) are proposed. Consideration of extended restriction covering all substances listed in Table 13-1 will be also put for discussion during the 2nd AHWG meeting.

The International Fragrance Association (IFRA) issues recommendations for the safe use of fragrance ingredients in the form of Code of Practice. This document "provides recommendations for good operating practice and guidelines on fragrance ingredient safety assessment, and includes fragrance safety standards which may limit or ban the usage of certain fragrance materials"[106]. The recommendations for the safe use of fragrances ingredients are based on experimental evidence of sensitisation in healthy human volunteers but secondary prevention of clinical disease in sensitised consumers is not considered in the code of practice[107].

The IFRA Code of Practice was published for the first time in 1973 and it is amended on annual basis (if needed) with revisions of the existing use restrictions or introducing of new restrictions. The Code

[106] The International Fragrance Association (IFRA): Code of Practice, December 2006, available online at: http://www.ifraorg.org/en-us/code_of_practice_1.
[107] The Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers Opinion concerning Fragrance Allergy in Consumers – A review of the problem – Analysis of the need for appropriate consumer information and Identification of consumer allergens, December 1999, available online at: http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf.

is binding for all IFRA members. Currently it is being revised and a new version will be available soon. Among IFRA committees there is Environmental Task Force (ETF), which aims at advising the fragrance industry on the issues of environmental safety of fragrances. Further, it assists in the identification and management of environmental aspects of their use. In accordance with the current criteria document "any ingredient added to the product as a fragrance must have been manufactured, handled and applied in accordance with the code of practice of the International Fragrance Association".

During the 1st AHWG meeting it was discussed that setting a restriction on the use of substances classified as sensitizing should be included in the revised criteria set. Sensitizing substances are classified as:
- H334 (R42): may cause allergy or asthma symptoms of breathing difficulties if inhaled

- and/or H317 (R43): may cause an allergic skin reaction.

Additionally, a harmonisation between the criteria for this product group and the criteria from all purpose cleaners and other similar products was supported in order to ensure a general more horizontal harmonisation between various EU Ecolabel decisions and the equal level of strictness of criteria set for various product groups. Further, it was considered whether the scope of this restriction should apply to substances other than fragrances which are known to act as sensitizers for allergic skin reaction and contact dermatitis.

Based on the discussions conducted and the consultation process it is therefore proposed to restrict to 0.010 % by weight of the final product the use of sensitizing substances classified with H334 (R42) and/or H317 (R43) in rinse-off cosmetic products. This restriction will be included in the criterion on "Excluded or limited substances and mixtures" presented later in the report.

Additionally, a proposal regarding introducing a new restriction on the use of fragrances in products which are intended for babies and children under the age of three year was presented and discussed. According to Commission recommendation 98/485/EC of 1 July 1998, member states shall adopt the measures required to ensure a high level of child health protection in regard to some hazardous substances in childcare articles and toys intended to be placed in the mouth for children of age lower than three years.

Children bodies and immune systems are still in development and consequently children react more than adults to allergens. Higher respiratory rate and their thinner skin are factors contributing that children are more susceptible to the effects of allergens.

Children are at risk of developing allergies because every day their skin is exposed at an early age to well-known allergens in fragrances. Thus, the highest possible safety standards should be applied to children to avoid the exposure to products containing allergenic substances such as perfumes.

An analysis of perfume-free products has been conducted in the framework of the study. Its main results are presented below. First, in Table 22 below, the shares of perfume-free products among all products under study are indicated for each product group.

**Table 22. Share of perfume-free products**

| Product group | Percentage of perfume-free products |
|---|---|
| Liquid soaps | 1,5% |
| Solid soaps | 1,7% |
| Shampoos | 1,3% |
| Hair conditioners | 0,8% |

*Source: Mintel Global New Product Database*

In Table 23, the shares of products intended for babies in the product group under study are given, together with the percentage of perfume-free products among all baby products. Around 10% of baby products available at the market currently are marketed as fragrance-free. Only for solid soaps this share is lower. This is nevertheless, significantly more if compared with the total amount of perfume-free products available on the market.

**Table 23. Share of baby products and perfume-free baby products**

| Product group | Percentage of baby products | Percentage of perfume-free baby products in the total amount of baby products |
|---|---|---|
| Liquid soaps | 3,8% | 10% |
| Solid soaps | 5,1% | 3% |
| Shampoos | 3,0% | 11% |
| Hair conditioners | 0,3% | 12% |

*Source: Mintel Global New Product Database*


| Product group | Percentage of baby products | Percentage of perfume-free baby products in the total amount of baby products |
|---|---|---|
| Liquid soaps | 3,8% | 10% |
| Solid soaps | 5,1% | 3% |
| Shampoos | 3,0% | 11% |
| Hair conditioners | 0,3% | 12% |

*Source: Mintel Global New Product Database*


The proposal to introduce restriction on fragrances use in products intended for babies and children gained stakeholders' support; therefore it is proposed that all ecolabelled products covered by the scope of the revised criteria which are intended for use for babies and children under the age of three year should be fragrance-free. Infant, baby and/or children products refers to products that are marketed as designed and intended for infants, babies and/or children or have any of these words on the label/packaging.

**DEROGATIONS**

During the consultation process the stakeholders were asked to submit derogation requests for substances, which would be excluded or restricted by the new criterion on "Excluded or limited substances and mixtures", following the Article 6(6) of the EU Ecolabel Regulation 66/2010. The derogation can be granted in specific circumstances indicated in Article 6(7) of the regulation (as described in chapter 7). Industrial stakeholders submitted the following derogation request regarding the restriction set in the criterion on fragrances:

**Table 24. Short rationale for derogation request regarding fragrances**

| Ingredient type | CLP classification | DSD classification | Short Rationale |
|---|---|---|---|
| Perfumes | H412 Harmful to aquatic life with long-lasting effects | R52-53 | As already agreed for home care products. Fragrances must have been manufactured and/or handled in accordance with the IFRA code of practice. Fragrances are a very important part of the consumer perception. |

Source: Stakeholders 'information sent to the EC

The derogation is based on the following rationale submitted by the stakeholders:

"Limiting the use of perfumes that are classified as H412 would dramatically restrict their use in ecolabelled products, and would therefore reduce their consumer acceptance. The above requested derogation is also acknowledged for consumer home care products (laundry, machine dish wash and hand dish wash detergents as well as all purpose and sanitary cleaners), whose recently published new criteria (2011) all contain the same derogation.

With respect to maximum concentrations, these are already strongly limited by the CDV requirement through the very restrictive values for fragrances in the DID list. Actually if only H412 or non classified fragrances can be used, the entry in the DID list would need to be changed according to the below table:

**Table 25. Proposal to amend the DID list**

| Nr | Name | LC50/ EC50 | SF acute | TF acute | NOEC (*) | SF chronic | TF chronic | DF | Aerobic | An-aerobic |
|---|---|---|---|---|---|---|---|---|---|---|
| **Perfumes** | | | | | | | | | | |
| 142 | Current: Perfume ** | 2 | 1000 | 0.002 | | | 0.002 | 0.5 | I | N |
| 142a | Proposed: Perfumes H412 classified or not environmentally classified** | 10 | 1000 | 0.01 | | | 0.01 | 0.5 | I | N |

Source: Stakeholders 'information sent to the EC

Here the toxicity value is based on the lowest toxicity value (worst case), that is linked to the hazard classification of H412 (category 3) under the 2nd ATP to CLP (entry iii in table 4.0)[108]. The current eco-

[108] Commission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, available on line at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:083:FULL:EN:PDF.

toxicity value for perfumes would not be allowed, as it would make the perfume classify as H411 (R51/53).

Fragrances that are not classified for the environment should still be assessed as being H412, unless toxicity data is available that can be used to derive a lower TF as is currently already specified in the DID list".

The proposed derogation will be discussed in the 2nd AHWG meeting.

The revised criterion proposal is given in Chapter 7

### 6.3.5 CRITERION 6: Dyes or colouring agents

The current formulation of this criterion is as follows:

Organic dyes or colouring agents must not be potentially bio-accumulating. In the case of colouring agents approved for use in foodstuffs it is not necessary to submit documentation of bioaccumulation potential. In this context, a colouring agent or dye is considered to be potentially bio-accumulating if the experimentally determined BCF is > 100. If no BCF (Bio-concentration Factor) test result is available, bioaccumulation may be demonstrated by the log Pow (log octanol/water partition coefficient). If log Pow is > 3,0 the colouring agent or dye is considered as potentially bio-accumulating.

***Assessment and verification***:

The manufacturer must submit a test report or a published test result together with a reference to the publication. If the dye or colouring agent has been approved for use in foodstuffs a declaration from the manufacturer stating this fact must be submitted.

During the 1st AHWG meeting the following issues were considered for the revision of the current criterion:

- The issue of aligning the definition regarding potential bio-accumulation of substances with the CLP Regulation,
- Maintaining the thresholds given for the bioconcentration factor and log octanol/water partition coefficient at the currently valid levels: BCF ≤ 100 or Log Pow < 3 (harmonisation of the criteria for similar product groups, e.g. with all-purpose cleaners),
- Potential exclusion of dyes or colouring agents from product formulation.

Colouring agents and dyes are added to the product in very small amounts in order to colour the cosmetic itself. This function has been considered important in order to facilitate the consumer applying appropriate dosage of the product. It also influences the appearance of the product. There exist products which are colorant agents-free (transparent), nevertheless they constitute very niche

segment of the market and are intended for particularly environmentally and natural products oriented consumers.
This criterion does not refer to hair dyes, i.e. products which are used to change the colour of hair. They are not covered by the scope of this product group.
In the new Regulation 1223/2009 on cosmetic products substances addressed in the current criterion dyes and colouring agents, are grouped in one functional group called 'colorants'. The Regulation defines them as follows:
'colorants' means *substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants*.
The Regulation limits the use of colorants in cosmetic products to substances other than those which are listed in Annex IV[109]. 153 substances are listed in this annex. Colorants used in the product under study are used mainly to colour the product itself to influence its appearance and make easier dosing the product.

Contact of the human body with certain colorants, their impurities, or their decomposition products (that may occur during processing or storage of the cosmetic product) can produce allergic reactions, sensitization or photosensitization in susceptible people[110].

The concentrations of the colorants in cosmetic products are usually low, below 0.1%, and they represent a large variety of chemical structures which exhibit different ecological properties. During the initial development of the criteria[111] it has been emphasized that the environmental properties of colorants are often very poorly documented. Many of them are toxic; nevertheless they are used in very small quantities. In order to reduce the environmental and health related impacts of these ingredients it was agreed to exclude colorants that may bioaccumulate.

To ensure the manufacturers a sufficient choice of colorants, the substances which have been approved for use in food are also accepted in Ecolabelled products under study, since they are supposed to be evaluated as safe. Their list can be found at the EC website[112].

During consultation conducted it was asked what the availability of products not containing colorants was. The industry responded that such type of products do exist on the market but they constitute only several percentage of the total sales in some countries, while in other Member States it is very hard to sell such products. The colouring function is considered attractive for consumers, so in order to promote (and not decrease) the use of Ecolabel and consequently the consumption of products awarded with it, a total restriction of these agents would not be recommended.

The CLP Regulation[113] introduces a definition of bioaccumulation of substances. According to it "*Bioaccumulation of substances within aquatic organisms can give rise to toxic effects over longer time scales even when actual water concentrations are low. For organic substances the potential for*

[109] "and colorants which are listed there but not used in accordance with the conditions laid down in that Annex, except for hair colouring products referred to in paragraph 2" – for details see the Regulation 1223/2009.
[110] Rosenthal et al., 1988; Wei et al., 1994, 1995; Mselle, 2004; Antonovich and Callen, 2005; Klontz et al., 2005
[111] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., 2006.
[112] Lists of authorized food additives: http://ec.europa.eu/food/food/fAEF/additives/lists_authorised_fA_en.htm.
[113] Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) 1907/2006. OJL 353, 31.12.2008, p. 1-1355: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF.

*bioaccumulation shall normally be determined by using the octanol/water partition coefficient, usually reported as a log Kow. The relationship between the log Kow of an organic substance and its bioconcentration as measured by the bioconcentration factor (BCF) in fish has considerable scientific literature support. Using a cut-off value of log Kow ≥ 4 is intended to identify only those substances with a real potential to bioconcentrate. While this represents a potential to bioaccumulate, an experimentally determined BCF provides a better measure and shall be used in preference if available. A BCF in fish of ≥ 500 is indicative of the potential to bioconcentrate for classification purposes. "*

The issue whether the bioconcentration factor and log octanol/water partition coefficient shall be adjusted to the levels set in the CLP was discussed with the stakeholders during the 1st AHWG meeting on the criteria revision. Based on the feedback received the thresholds given in the currently valid criteria document will be maintained, i.e. the values:

- BCF ≤ 100
- Log Pow < 3

will be kept.

Stakeholders supported keeping the criterion with stricter BCF and Log Pow values but not adding additional restrictions.

Thus, based on the precautionary principle, the thresholds given in the currently valid criteria will be maintained. The current criterion formulation will not change in the revised criteria draft proposal. The stricter (than given in the CLP) threshold values of BCF and Log Pow will be further valid in order to indicate if a substance is considered to be potentially bio-accumulating. Only the change of name from 'dyes and colouring agents' to 'colorants' is proposed to be done to align with the terms used in the new Cosmetic Regulation 1223/2009.

This revised criterion proposal can be found in Chapter 7.

### 6.3.6 CRITERION 7: Biocides

The current formulation of this criterion is as follows:

(a) The product may only include biocides in order to preserve the product, and in the appropriate dosage for this purpose alone. This does not refer to surfactants which may also have biocidal properties.

***Assessment and verification***:

Copies of the safety data sheets of any preservatives added shall be provided, together with information on their exact concentration in the product. The manufacturer or supplier of the preservatives shall provide information on the dosage necessary to preserve the product.

(b) Biocides, either as part of the formulation or as part of any preparation included in the formulation, that are used to preserve the product and that fulfil the criteria for classification with R50-53 or R51-53 risk phrases, in accordance with Directive 67/548/EEC or Directive 1999/45/EC of the European Parliament and of the Council (1), are only permitted if they are not potentially bio-accumulating. In this context, a biocide is considered to be potentially bioaccumulating if the bio-concentration factor (BCF) is > 100 or, if no BCF-results are available, the log Pow (log octanol/water partition coefficient) is > 3,0.

***Assessment and verification***:

Test results for aquatic toxicity must be supplied. If the lowest toxicity is ≤ 10 mg/l a test result for ready biodegradability must be given. If the biocide is not readily biodegradable test results for bioaccumulation potential must be given. Test procedures are as specified in Directive 67/548/EEC.

(c) Preservatives must not release substances that are classified in accordance with the criterion 8a.

***Assessment and verification***:

A completed and signed declaration from the biocide manufacturer.



During the 1st AHWG meeting the following issues were considered for the revision of the current criterion:

- Maintaining the thresholds given for the bioconcentration factor and log octanol/water partition coefficient: BCF ≤ 100 or Log Pow < 3 (harmonisation of the criteria for similar products, e.g. with all-purpose cleaners).

- Restriction of the following substances:
  - Triclosan
  - Parabens
  - Formaldehyde
  - Formaldehyde releasers: Bronopol (2-bromo-2-nitropropane-1,3-diol), 5-bromo-5-nitro-1,3-dioxane, sodium hydroxyl methyl glycinate, DMDM Hydantoin, Diazolidinyl urea and Imidazolidinyl Urea.

The new Cosmetic Regulation 1223/2009 defines the 'preservatives' as *substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product*.

Preservatives function is to ensure that products are safe to use by the consumers over long period and to maintain the appearance of the product.

The term preservatives will be used instead of biocides for this particular group in the criteria document.

Annex V of the new Cosmetic Regulation lists the preservatives (56 positions) which are allowed for use in cosmetic products.

Although preservatives are used in small amounts, due to their toxicity, requirements regarding this functional group are seen very important. The combination of high toxicity, poor degradability and bioaccumulation gives a high risk for environmental damage. In the current criteria document it is required that if a preservative fulfils the criteria for classification with H410/R50-53 or H411/R51-53 risk phrases it is only permitted to be used in the product if it is not potentially bio-accumulating. A substance is considered to be potentially bioaccumulating if the bio-concentration factor (BCF) is > 100 or, if no BCF-results are available, the log Pow (log octanol/water partition coefficient) is > 3.0.

During the stakeholders consultation process it has been discussed and agreed to keep the current formulation of the criterion with the strict values of the BCF and log Pow and not to align them with the less strict thresholds given in CLP the Regulation. Based on the precautionary principle, the thresholds given in the currently valid criteria will be maintained.

Further, the proposal of restricting the use of several substances found as problematic was also considered. They are listed below:

- **Triclosan** (5-chloro-2-(2,4-dichlorophenoxy)phenol)[114] is a preservative added to soaps, hair conditioners and shaving cream products. Triclosan is classified as an agent that may cause adverse environmental effects[115]. Based on its classification[116], triclosan should be restricted: H410: very toxic to aquatic life with long lasting effects, H315: causes skin irritation and H319: causes serious eye irritation. Some studies[115] have shown that the use of triclosan in cosmetic products is also a matter of concern from a toxicological point of view.
  Due to its classification, triclosan would be excluded from ecolabelled products through the criterion on excluded or restricted substances and mixture, which restricts substance sclassified with H410; nevertheless, as derogation for H410 is under consideration for the functional group of preservatives, it is proposed to exclude for time being triclosan explicitly in the revised criteria.
- **Ethyl-, methyl-, propyl- and butyl-Parabens** - In 1999, the European Union adopted a Strategy on Endocrine Disrupters and committed significant resources to develop and classify a priority list of suspected endocrine disrupting chemicals[117]. A candidate list with 553 substances with evidence of endocrine disruption was reviewed and classified in three categories: Category 1 – evidence of endocrine disrupting activity in at least one species using intact animals; Category 2 – at least some in vitro evidence of biological activity related to endocrine disruption; Category 3 – no evidence of endocrine disrupting activity or no data

[114] Scientific Committee on Consumer Products (SCCP) Opinion on Triclosan, January 2009, available online at: http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_166.pdf.
[115] Norwegian Scientific Committee for Food Safety, Risk assessment on the use of triclosan in cosmetics, 2005, available online at: http://vkm.no/dav/117573d6c4.pdf.
[116] For details see the information contained at ECHA website :http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031/AGGR-09e9b0f0-bf29-4975-8fbe-a3a2dd0ac2be_DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031.html#L-137752f6-fbea-4638-b8d8-acce5e212979.
[117] For more information, please see: http://ec.europa.eu/environment/endocrine/strategy/short_en.htm.

available. Ethyl-, methyl-, propyl- and butyl- parabens are all categorised as potential endocrine disrupters (Category 1) under the EU strategy for endocrine disrupters. Safer alternatives to parabens exist[118], and around 5,4% of products are now marketed as "paraben-free"; therefore it is proposed to exclude these parabens from use in this product group.

- **Formaldehyde** - Formaldehyde is a known sensitizer and a known carcinogen, however in the Cosmetics Directive is accepted as preservative. The new Regulation on cosmetic products requires that "All finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0,05 %". Based on its classification[119]: H351: suspected of causing cancer, H301: toxic if swallowed, H311: toxic in contact with skin, H331: toxic if inhaled; H314: causes severe skin burns and eye damage and H317: may cause an allergic skin reaction should be restricted the use of formaldehyde in ecolabelled products. In accordance with the current list of R/H phrases formaldehyde would automatically be excluded by the abovementioned criterion on excluded and restricted substances and mixtures, which will be included in the revised criteria document.

- **Formaldehyde releasers:** Formaldehyde releasers are used as preservatives that decompose to form formaldehyde upon degradation. The amount of formaldehyde released can be above the classification limits for formaldehyde[120]. There are some studies that demonstrate that people exposed to formaldehyde releasers may experience allergic reactions[121]. The following formaldehyde releasers are proposed to be restricted:

    - **Bronopol (2-bromo-2-nitropropane-1,3-diol)**: According to Annex VI of CLP, harmonised classification and labelling for certain hazardous substances, bronopol is classified as H312: harmful in contact with skin , H302: harmful if swallowed, H335: may cause respiratory irritation, H318: causes serious eye damage and H400: Very toxic to aquatic life. Bronopol has a moderate capacity for inducing skin allergies. It is a strong eye irritant and to be capable of causing difficulties in breathing and induce eczematous reactions in people who are already sensitized.

    - **5-bromo-5-nitro-1, 3-dioxane**: is reported to be moderately allergenic on skin because it releases formaldehyde under basic conditions.

    - **Sodium hydroxyl methyl glycinate (SHMG)**: Formaldehyde-releasing preservative that has been associated with allergic contact dermatitis, possibly due to the formaldehyde they release. Studies on SHMG in animals have demonstrated potential for sensitization and dermatitis, and the state

[118] For more information see details in "Preliminary results from the technical analysis" report, tables 26, 43 and 51 with different variants that fulfil equivalent function: preservatives., available online at the project's website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

[119] For details see the information contained at ECHA website: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d8ad2a1-0d51-13f7-e044-00144f67d249/AGGR-aa1957ab-42e8-43c6-856d-09b14245e171_DISS-9d8ad2a1-0d51-13f7-e044-00144f67d249.html#L-9cf4f64b-5725-4012-aad3-657063a4f5b6.

[120] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., 2006.

[121] http://share.eldoc.ub.rug.nl/FILES/root2/2010/Formretof/de_Groot_2010_Contact_Dermatitis.pdf.

of formaldehyde-allergic patients have been reported to improve when products containing SHMG are avoided[122].

- **DMDM Hydantoin**: Is an antimicrobial formaldehyde releaser preservative. People exposed to such formaldehyde-releasing ingredients may develop a formaldehyde allergy. It is also a strong skin, eye, and lung irritant.
- **Diazolidinyl Urea**: Is an antimicrobial preservative that acts as a formaldehyde releaser in cosmetics and personal care products. It is effective against a broad spectrum of bacteria, fungi and yeast. It may cause allergy on skin when it is exposed to this substance.
- **Imidazolidinyl Urea**: Is an antimicrobial preservative that acts as a formaldehyde releaser in cosmetics and personal care products.

Preservatives must not release substances that are classified in accordance with the requirements of the new criterion on excluded substances and mixtures. During the stakeholders consultation there was support to exclude the above described substances from the EU Ecolabelled products. And, although several of the mentioned in this section chemicals would be excluded from ecolabelled products through the criterion on excluded or restricted substances and mixtures, as derogation for some R/H phrases is under consideration for the functional group of preservatives, it is proposed to indicate them explicitly at this stage of criteria revision process. When the criteria document is finalised a cross-check on substances, which are automatically excluded by the general criterion on substances, should be conducted.

Additionally, several new substances have been proposed for consideration to be restricted in Ecolabelled products:

- Chloromethylisothiazolinone (CMIT) / methylisothiazolinone (MIT),
- Cetrimonium chloride,
- Silver, silver salts and silver derivates.

In the technical analysis report it was found that preservatives widely used in all liquid products with the highest value for ecotoxicity were: Methylisothiazolinone (9,75E+03 PAF m3.kg-1 emitted), triclosan (2,74E+03 PAF m3.kg-1 emitted) and finally Methylchloroisothiazolinone (1,39E+03 PAF m3.kg-1 emitted). Triclosan, mentioned before, was proposed to be restricted based on its classification as very toxic to aquatic life with long lasting effects.

Chloromethylisothiazolinone (CMIT) and methylisothiazolinone (MIT) have been associated with allergic reactions, however, they are not proposed to be restricted in this criteria revision because they are commonly used and there are no alternatives available so far, which are as effective and active within such wide pH range as the isothiazolinones. In the table below, the indicated dosage is related to the specific MIC (Minimum Inhibitory Concentration) of each biocide:

[122] Sodium hydroxymethylglycinate, Rusell k, Jacob SE. Dermatitis. 2010 Apr 21 (2):109-10.

**Table 26. Biocide activity scheme**

| BIOCIDE | ACTIVITY | DOSAGE | pH EFFICIENCY RANGE |
|---|---|---|---|
| | | | 2 3 4 5 6 7 8 9 10 |
| 2-Bromo-2-Nitropropane-1,3-diol (BRONOPOL) | Batteri | 0,01-0,1% | |
| Diazolinidyl urea | Batteri Gram-e muffe | 0,03-0,3% | |
| DMDM hydantoin | Funghi | 0,15-0,4% | |
| Glutaraldehyde | Batteri, funghi | 0,02-0,2% | |
| Imidazolinidyl urea | Batteri, funghi | 0,05-0,5% | |
| CMIT + MIT | Batteri, funghi | 0,006-0,0015 | |
| Parabens | Batteri, funghi | 0,30% | |
| Zinc Pyrithione | Batteri, funghi | 0,025-0,10% | |

Source: Stakeholders 'information sent to the EC

As it can be seen the dosage of CMIT and MIT added to the product is very low.

Analysis of availability of alternatives to be used by the manufacturers as preservatives in cosmetic products show that if triclosan, parabens, formaldehyde and formaldehyde releasers (such as bronopol) are restricted, it will be very difficult to apply for Ecolabel as substitutes (e.g. the above mentioned isothiazolinones) are very scarce. The stakeholders' feedback received emphasized that many alternative preservatives require low pH, which is nevertheless not suitable e.g. for hand washing products. Very few alternatives stable in anionic systems at pH 6-7 exist. From the DID list, the only suitable alternative indicated in the feedback was sodium benzoate. Nevertheless, it requires pH below 5.5 so cannot be used for a hand-wash. It was furthermore emphasized that the costs can be by 30% higher and the amount used would have to be much bigger, than the amount of isothiazolinones, which are very effective, if the substitutes are to be used.

At the same time, the project team was informed that, among others, the Danish Environmental Protection Agency is about to investigate MIT and other isothiazolinones with regards to their sensitising potentials. Additionally, MIT is already classified with the following H-statements: Acute Tox. 3 H301, Acute Tox. 3 H311, Aquatic Acute 1 H400, which would exclude its use from the ecolabelled products above certain concentration. CMI and MI, are usually used and sold as a preparation: **reaction mass of CMI/MI (3:1)** because their wider effectiveness in combating bacteria, fungi and yeasts and also their cheaper price. The pH of the product to be preserved is one of the main factors that limit the use of preservatives. Depending on the stabilization and other compounds present in the formulation, the CMI/MI can be used with no pH values above 10 (**almost with no pH restrictions comparing with other preservatives**). If only CMI separately is used, the CMI component begins to degrade quickly. CMI degradation also occurs in systems containing small amounts of reducing agents such as sulphites, sulphides or sulphur containing amino acids. That´s one of the reason why CMI/MI is almost always used in preparation.

According to the ESIS classification[123], if the concentration of CMI/MI (3:1) is ≥ 0,0015% (15ppm), it must be classified as Skin Sens 1; H317. This explains why the preparations of CMI/MI are found in a

[123] For details, please see the website: http://esis.jrc.ec.europa.eu/ .

concentration below 15 ppm as then a classification is avoided. Therefore, the dosage used will depend on the concentration of CMI/MI but almost always below 15 ppm (to avoid classification).

Cetrimonium chloride is a quaternary ammonium salt. In cosmetics and personal care products, this ingredient is used in the formulation of hair conditioners, other hair care products and in some skin care products. Although quaternary ammonium derivative formulations have the potential to be sensitizing, especially when combinations of the concerned compounds are used, the Scientific Committee on Consumer Safety[124] stated that the use of cetrimonium chloride does not pose a risk under the following concentrations limit - up to 2.5% in rinse-off hair care products.
The EU Cosmetics Directive allows it to be used at a maximum concentrations of 0,1%.
Cetrimonium chloride is not classified as dangerous in accordance with the CLP classification. For these reasons, cetrimonium chloride was not proposed to be restricted, and its maximum content is already set by the Cosmetics Directive.

Finally, silver, silver salts and silver derivates were proposed by stakeholders for consideration to be restricted in Ecolabelled products. Research regarding the degree of risk associated with silver is not conclusive but regulatory action is expected with the EU Biocide Directive. Although use of silver appears to be growing in some markets, its presence in this product group, as it is shown in the technical analysis report, is very limited. Because of cost and the fact that a biocide function is not considered to be valuable in all products, they are expected to play only niche roles, such as in sportswear. For that reason, silver derivates were not proposed to be excluded in this revision process.

As it is proposed to group all substances relevant criteria under one common criterion XX "**Excluded or limited substances and mixtures**", based on the above written, the new criterion is proposed to include (with regard to preservatives):

- **in the sub-section 'Specified excluded substances'**: the following substances: triclosan, ethyl-,methyl-, propyl- and butyl-parabens, formaldehyde and formaldehyde releasers ( bronopol, 5-bromo-5-nitro-1,3-dioxane, sodium hydroxyl methyl glycinate (SHMG), DMDM hydantoin, diazolidinyl urea and imidazolidinyl urea.

- **in the sub-section regarding preservatives:**

(i) The product may only include preservatives in order to preserve the product, and in the appropriate dosage for this purpose alone. This does not refer to surfactants, which may also have biocidal properties.

(ii) Preservatives must not release substances that are classified in accordance with the requirements of Criterion 3b or/and are endocrine disrupters.

(iii) It is prohibited to claim or suggest on the packaging or by any other communication that the product has an antimicrobial or disinfecting effect.

[124] Opinion of the SCCS on Alkyl (C16, C18, C22) trimethylammonium chloride, other uses than as a preservative, 8 December 2009. For more details: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_012.pdf.

(iv) The product may contain preservatives provided that they are not bioaccumulating. A biocide is not considered bioaccumulating if BCF < 100 or logPow < 3,0. If both BCF and logPow values are available, the highest measured BCF value shall be used.

Although the Regulation 1223/200932 on cosmetic products does not currently restrict substances with endocrine disrupting effects, Article 15(4) "calls upon the Commission to review this Regulation with regard to substances with endocrine-disrupting properties, when EU, or internationally, agreed criteria for identifying substances with endocrine disrupting properties are available, or at the latest by 11 January 2015". In the framework of the work on the Biocidal Products Directive (BPD) 98/8/EC31, approximately 400 substances are under review for PBT (Persistent, Bioaccumulative or Toxic), or CMR (carcinogen, mutagen or toxic for reproduction) or potential endocrine disruptive properties. Identified substances will be included in the Annex I[125].

In the framework of the consultation process, industry submitted derogation request regarding the restriction on preservatives in the product under study. The proposed derogation request is given below:

**Table 27. Short rationale for derogation request regarding biocides**

| Ingredient type | CLP classification | DSD classification | Short Rationale |
|---|---|---|---|
| Biocides used for preservation | H411 Toxic to aquatic life with long-lasting effects<br>H412 Harmful to aquatic life with long-lasting effects | R51-53 and R52-53 | Biocides can only be added in order to preserve the product, plus they may not be bioaccumulative as specified in the CLP. |

Source: Stakeholders 'information sent to the EC

*"Preservatives are essential to deliver a safe product to consumers. Due to their nature (as they are intended to actively prevent microbial growth within cosmetic products, usually by attacking/fighting germs) the great majority of effective preservatives are classified for their environmental effects. In order to be able to produce microbiologically safe Ecolabelled products, derogation for these classified preservatives is needed. Preservatives still need to be proven to be not bioaccumulative. Note that the recently published consumer home care products (laundry, machine dish wash and hand dish wash detergents as well as all purpose and sanitary cleaners), all contain the same derogation to allow effective preservation of the products, under the restriction that the preservatives are not bioaccumulative.*

*No maximum levels will need to be set as these preservatives are typically used at very low concentrations (regulated under the Cosmetic Products Regulation) and their levels are very much restricted through the CDV requirement as well."*

[125] For more information, please see the website of the DG Environmental on the endocrine disrupting substances, available at: http://ec.europa.eu/environment/endocrine/strategy/euapproach_en.htm.

**Anti dandruff agents: Zinc pyrithione (ZPT)**

*ZPT is an antifungal and antimicrobial agent used since the 1960s to help treat a variety of scalp and skin conditions. Dandruff is affecting >40% of the population (Schwartz, J.R. et al., 2004). Antidandruff actives in hair care products, especially those with high proven efficacy and low environmental profile are regarded as highly valuable for a large number of consumers. The Nordic Ecolabel criteria foresee derogation for zinc compounds. ZPT fulfils a very important function for a large number of consumers and cannot be easily replaced by other ingredients with both similar efficacy and better environmental profile. In addition, it has clearly been demonstrated (REACH registration dossier) that ZPT, as degradable antidandruff agent, does not pose a risk to the environment.*

*No maximum levels for the derogation of ZPT need to be set in the Ecolabel criteria as maximum concentrations in ready for use preparations are already established under the Cosmetic Products Regulation (1223/2009).*

The proposed criterion formulation is given in Chapter 7.

### 6.3.7 CRITERION 8: Environmental hazardous ingredients

The current criterion formulation is as follows:

The requirements concern all ingredients (substances or preparations) exceeding 0,010 % by weight of the final product. This includes also each ingredient of any preparation used in the formulation exceeding 0,010 % by weight of the final product.

(a) Classified ingredients

No constituent substance must be classified as carcinogenic (Carc), mutagenic (Mut) or toxic to reproduction (Rep) including rules for self-classification class III.

***Assessment and verification***:

Copies of the safety data sheets shall be provided for all ingredients (whether substances or preparations). A signed declaration prepared by the manufacturer of ingredients and showing compliance with this criterion shall be provided by the applicant.

(b) Specified excluded ingredients

The following ingredients shall not be included in the product, either as part of the formulation or as part of any preparation included in the formulation:

— Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives

— NTA (nitrilo-tri-acetate)

— Boric acid, borates and perborates

— Nitromusks and polycyclic musks

***Assessment and verification***:

A completed and signed declaration from the manufacturer must be submitted.

(c) Specified limited ingredients

Ethylenediaminetetraacetate (EDTA) and its salts and non-readily biodegradable phosphonates may only be added to solid soaps and only to a maximum content of 0,6 mg/g AC.

***Assessment and verification***:

A completed and signed declaration from the manufacturer must be submitted.

During the 1st AHWG meeting the following issues were considered for the revision of the current criterion:

- Restrictions on substances or mixtures meeting the criteria for classification with certain hazard statements in accordance with CLP Regulation and restriction of candidate list of substances of very high concern (SVHC) (compliance with the new EU Ecolabel Regulation 66/2010). Expanding the list of H-statements similarly to recently developed EU Ecolabel criteria in other product groups.
- Restriction on substances considered PBT (Persistent, Bioaccumulable and toxic), vPvB (very persistent and very bioaccumulable) and/or those having endocrine disrupting properties.
- Exclusion of certain specific substances, e.g.:
    - Phthalates: Bis(2-methoxyethyl) phthalate, diisobutyl phthalate (DIBP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl)phthalate (DEHP).
    - D4 (octamethylcyclotetrasiloxane)
    - Butylated Hydroxi Toluene (BHT)
    - Some preservatives: triclosan, parabens (Ethyl-, methyl-, propyl- and butyl-Parabens), formaldehyde and formaldehyde releasers (bronopol, 5-bromo-5-nitro-1,3-dioxane, sodium hydroxyl methyl glycinate (SHMG), DMDM hydantoin, diazolidinyl urea and imidazolidinyl urea).

Limiting hazardous environmental impact from the product group of soaps, shampoos and hair conditioners is important, as most ingredients of rinsed-off products normally end up in the aquatic environment through sewage treatment systems after use and sometimes they can be released directly to aquatic environment. The Cosmetics Directive does not prohibit use of substances in cosmetic products on the basis of their environmental properties. On the contrary, the EU Ecolabel regulation requires that ecolabelled products have reduced impact on the environment.

LCA studies showed that chemicals used for manufacturing of this product group have relevant load in the overall environmental impact of these products, i.e. 44% of the total environmental impact for solid soaps, the 23% for hair conditioners, 9% for shampoos and 10% for liquid soaps.

The environmental impacts associated with substances used are mainly related to the use of land and the use of non-renewable energy to synthesize them. Potential environmental impacts that these substances can cause if they are released to different environment compartments are also taken into account. In the following figures the distribution of environmental impact for each product and the contribution of each life stage to different environmental impact categories are presented.

The life stage "release to water" includes the treatment of sewage water once the product has been used. The wastewater contains the water used during washing action and the rinsed-off product (soap, shampoo or hair conditioner). This stage has important values in all environmental impact categories.

**Figure 2. Distribution of environmental impact for midpoints impact categories (liquid soap)**

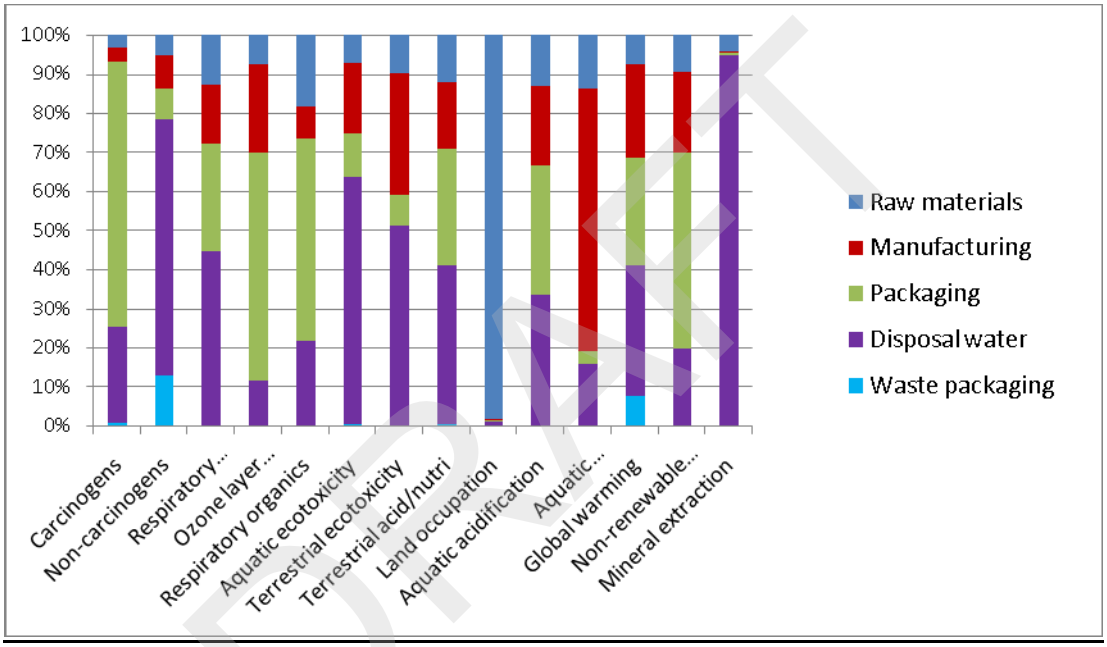


**Figure 3. Distribution of environmental impact for midpoints impact categories (solid soap)**

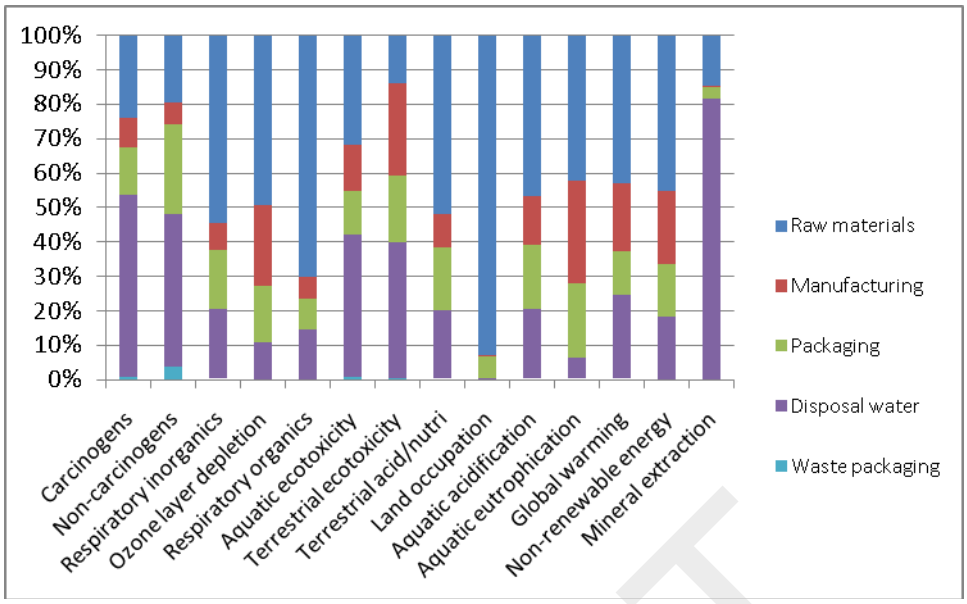



**Figure 4. Distribution of environmental impact for midpoints impact categories (hair conditioners)**

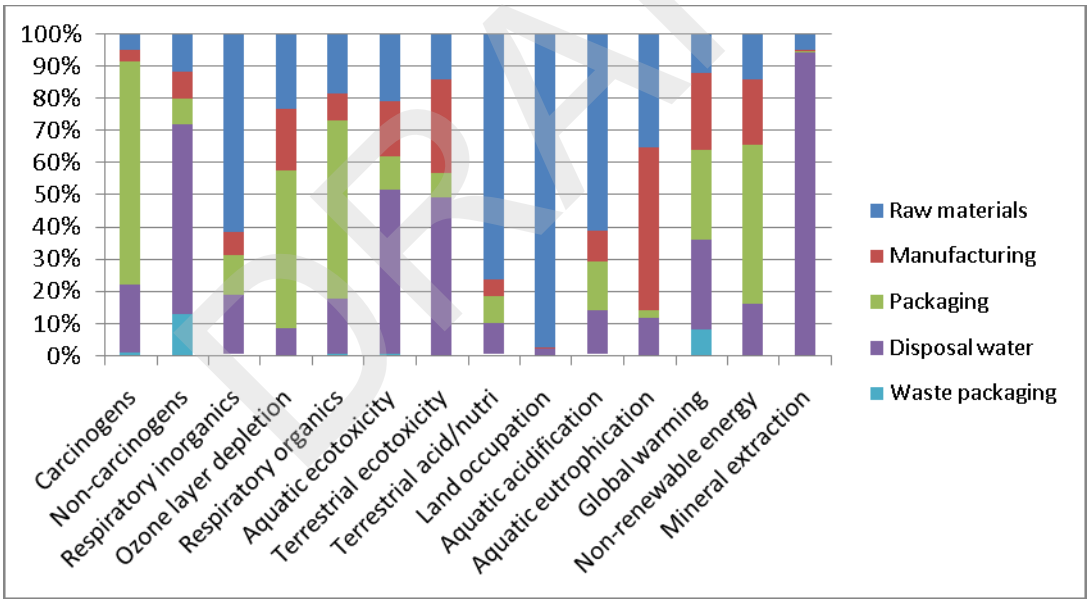
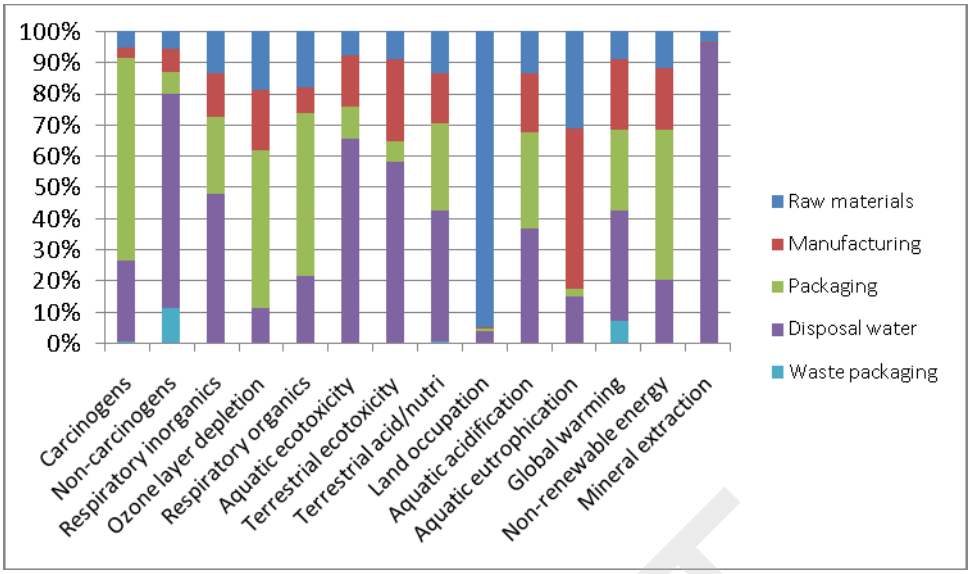


**Figure 5. Distribution of environmental impact for midpoints impact categories (shampoo)**




In accordance with the new EU Ecolabel Regulation 66/2010 the following general requirements about substances should be met in order to award the products with the EU Ecolabel:

*"The EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency".*

The Regulation allows for derogation of specific substances under strictly defined conditions:

*"For specific categories of goods containing substances referred to in paragraph 6, and only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared with other goods of the same category, the Commission may adopt measures to grant derogations from paragraph 6".*

Finally, there is a provision regarding exclusion from derogation for substances classified as the substances of very high concern:

*"No derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 and that are identified according to the procedure described in Article 59(1) of that Regulation, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations higher than 0,1 % (weight by weight)".*

These requirements are reflected in the proposed criterion on "Excluded and limited substances and mixtures", as it is also done in other recently developed or revised criteria documents for other product groups.

Further, being proactive (taking as basis the precautionary principle) some specific substances which raise environmental or health related concern have also been discussed and considered to be specifically excluded or restricted in the product group under study. They are briefly presented below:

**Phthalates** - Some phthalates can be found in rinse-off cosmetic formulations. It is assumed that they are added in the perfume mix. Phthalates such as **Bis(2-methoxyethyl) phthalate, diisobutyl phthalate (DIBP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl)phthalate (DEHP)**, should be restricted because they are classified as toxic for reproduction and present in the candidate list of Substances of Very High Concern or in the authorisation list according to REACH regulation.

On February 17, 2011 the European Commission named 6 chemicals as the first entrants on the Authorization list[126], known as Annex XIV, which means that the next substances: dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl)phthalate (DEHP) were moved from the candidate list to the authorisation list under the EU REACH regulation (see Table 28). On February 14, 2012, eight more substances of very high concern were added, e.g. diisobutylphtalate (DIBP) was also moved to the authorisation list.

On December 19, 2011 bis(2-methoxyethyl) phthalate was included in the candidate list of substances of very high concern for authorisation.

**Table 28. Substances of very high concern subjected or candidates to authorization**

| Substance name | EC Number | CAS Number | Inclusion List | Classification |
|---|---|---|---|---|
| Bis(2-methoxyethyl) phthalate[127] | 204-212-6 | 117-82-8 | Candidate list | Toxic for reproduction (article 57 c) |
| Diisobutyl phthalate (DIBP)[128] | 201-553-2 | 84-69-5 | Authorisation list | Toxic for reproduction (article 57c) |
| Dibutyl phthalate (DBP)[129] | 201-557-4 | 84-74-2 | Authorisation list | Toxic for reproduction (article 57c) |
| Benzyl butyl phthalate (BBP)[130] | 201-622-7 | 85-68-7 | Authorisation list | Toxic for reproduction (article 57c) |
| Bis (2-ethylhexyl)phthalate (DEHP)[131] | 204-211-0 | 117-81-7 | Authorisation list | Toxic for reproduction (article 57c) |

Source: European Chemicals Agency website

[126] COMMISSION REGULATION (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') http://eur lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2011R0143:20110221:EN:PDF.

[127] Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern: http://echa.europa.eu/documents/10162/d60da5c8-85de-4cb2-b95a-fada9451373b .

[128] Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern: http://echa.europa.eu/documents/10162/d418f8b0-ba93-402a-97fd-1e340d22c541.

[129] Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern: http://echa.europa.eu/documents/10162/5196d655-7b11-41b2-acba-c8709064fac8.

[130] Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern: http://echa.europa.eu/documents/10162/19fd114d-eb69-4012-a107-8ceb97787733.

[131] Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern: http://echa.europa.eu/documents/10162/b8395d41-b6d5-427c-8294-d46997e8835d.

As mentioned before, no derogations shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006.

**D4 (octamethylcyclotetrasiloxane)** CAS 556-67-2 is used as an emollient or solvent although is not in the list of most commonly used substances. The Cosmetic Toiletry and Perfumery Association (CTPA) indicate that the cyclic siloxanes used in cosmetics is, in general, in the following main areas:

- As hair-conditioning agents
- As skin-conditioning agents (emollient)
- As solvents

The types of products in which they are reported to be used include: aftershave lotions, perfumery products, shampoos, conditioners and shaving products[132].

Based on its classification[133] H413: may cause long lasting harmful effects to aquatic life, H361: suspected of damaging fertility or the unborn child and H226: flammable liquid and vapour, should be restricted. It is restricted in Nordic Ecolabelled products as it is considered to be persistent in the environment. In Canada, D4 has been added to "List of Toxic Substances in Schedule 1 of CEPA 1999", which means it is considered toxic and is subject to governmental regulation.

**Butylated Hydroxy Toluene (BHT, CAS 128-37-0)** – BHT is used as an antioxidant/preservative in cosmetic products, mainly in shampoos, deodorants, body lotions and make-up, usually at a concentration of 0,1% or less. It is classified as H410 (R50/53) - very toxic to aquatic life with long lasting effects[134]. Based on the classification, it should be restricted. BHT can also induce allergic reactions in the skin[135].

**Triclosan** (5-chloro-2-(2,4-dichlorophenoxy)phenol )[136] is a preservative added to soaps, hair conditioners and shaving cream products. Triclosan is classified as an agent that may cause adverse environmental effects[137]. Based on its classification[138], triclosan should be restricted: H410: very toxic to aquatic life with long lasting effects, H315: causes skin irritation and H319: causes serious eye irritation. Some studies[115] have shown that the use of triclosan in cosmetic products is also a matter of concern from a toxicological point of view.

**Ethyl-, methyl-, propyl- and butyl-Parabens** - In 1999, the European Union adopted a Strategy on Endocrine Disrupters and committed significant resources to develop and classify a priority list of suspected endocrine disrupting chemicals[139]. A candidate list with 553 substances with evidence of endocrine disruption was reviewed and classified in three categories: Category 1 – evidence of endocrine disrupting activity in at least one species using intact animals; Category 2 – at least some in vitro evidence of biological activity related to endocrine disruption; Category 3 – no evidence of

[132] Brooke D N, Crookes M J, Gray D and Robertson S. Science Report – Environmental Risk Assessment Report: Octamethylcyclotetrasiloxane. For more details: http://publications.environment-agency.gov.uk/PDF/SCHO0309BPQZ-E-E.pdf

[133] http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d9d2de7-dd46-653e-e044-00144f67d249/AGGR-d50b7533-2f91-4049-9110-98ba0524a880_DISS-9d9d2de7-dd46-653e-e044-00144f67d249.html#L-03cd909b-6f8e-4aee-9d90-52aa86e337e2.

[134] http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d82f461-e7b6-3a89-e044-00144f67d249/AGGR-51b3c77a-ec07-4b3e-a1e2-870ae9e21d5e_DISS-9d82f461-e7b6-3a89-e044-00144f67d249.html#L-abb9496c-aaa4-455b-8305-187c411b237d.

[135] U.S. National Library of Medicine, in Haz-Map: Occupational Exposure to Hazardous Agents, 2010, http://hazmap.nlm.nih.gov.

[136] Scientific Committee on Consumer Products (SCCP) Opinion on Triclosan, January 2009, available online at: http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_166.pdf.

[137] Norwegian Scientific Committee for Food Safety, Risk assessment on the use of triclosan in cosmetics, 2005, available online at: http://vkm.no/dav/117573d6c4.pdf.

[138] http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031/AGGR-09e9b0f0-bf29-4975-8fbe-a3a2dd0ac2be_DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031.html#L-137752f6-fbea-4638-b8d8-acce5e212979.

[139] For more information, please see: http://ec.europa.eu/environment/endocrine/strategy/short_en.htm.

endocrine disrupting activity or no data available. Ethyl-, methyl-, propyl- and butyl- parabens are all categorised as potential endocrine disrupters (Category 1) under the EU strategy for endocrine disrupters. Safer alternatives to parabens exist[140], and around 5,4% of products are now marketed as "paraben-free".

**Formaldehyde** - Formaldehyde is a known sensitizer and a known carcinogen, however in the Cosmetics Directive is accepted as preservative. Based on its classification[141]: H351: suspected of causing cancer, H301: toxic if swallowed, H311: toxic in contact with skin, H331: toxic if inhaled; H314: causes severe skin burns and eye damage and H317: may cause an allergic skin reaction should be restricted the use of formaldehyde in ecolabelled products.

**Formaldehyde releasers:** Formaldehyde releasers are used as preservatives that decompose to form formaldehyde upon degradation. The amount of formaldehyde released can be above the classification limits for formaldehyde[142]. There are some studies that demonstrate that people exposed to formaldehyde releasers may experience an allergic reaction[143]. The following formaldehyde releasers are proposed to be restricted:

- **Bronopol (2-bromo-2-nitropropane-1,3-diol)**: According to Annex VI of CLP, harmonised classification and labelling for certain hazardous substances, bronopol is classified as H312: harmful in contact with skin , H302: harmful if swallowed, H335: may cause respiratory irritation, H318: causes serious eye damage and H400: Very toxic to aquatic life. Bronopol has a moderate capacity for inducing skin allergies. It is a strong eye irritant and to be capable of causing difficulties in breathing and induce eczematous reactions in people who are already sensitized.
- **5-bromo-5-nitro-1, 3-dioxane**: is reported to be moderately allergenic on skin because it releases formaldehyde under basic conditions.
- **Sodium hydroxyl methyl glycinate (SHMG)**: Formaldehyde-releasing preservative that has been associated with allergic contact dermatitis, possibly due to the formaldehyde they release. Studies on SHMG in animals have demonstrated potential for sensitization and dermatitis, and formaldehyde –allergic patients have been reported to improve when products containing SHMG are avoided[144].
- **DMDM Hydantoin**: Is an antimicrobial formaldehyde releaser preservative. People exposed to such formaldehyde-releasing ingredients may develop a formaldehyde allergy. It is also a strong skin, eye, and lung irritant.
- **Diazolidinyl Urea**: Is an antimicrobial preservative that acts as a formaldehyde releaser in cosmetics and personal care products. It is effective against a broad spectrum of bacteria, fungi and yeast. It may cause allergy on skin when it is exposed to this substance.

[140] For more information see details in "Preliminary results from the technical analysis" report, tables 26, 43 and 51 with different variants that fulfil equivalent function: preservatives., available online at the project's website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

[141] For details see the information contained at ECHA website: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d8ad2a1-0d51-13f7-e044-00144f67d249/AGGR-aa1957ab-42e8-43c6-856d-09b14245e171_DISS-9d8ad2a1-0d51-13f7-e044-00144f67d249.html#L-9cf4f64b-5725-4012-aad3-657063a4f5b6.

[142] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., 2006.

[143] http://share.eldoc.ub.rug.nl/FILES/root2/2010/Formretof/de_Groot_2010_Contact_Dermatitis.pdf.

[144] Sodium hydroxymethylglycinate, Rusell k, Jacob SE. Dermatitis. 2010 Apr 21 (2):109-10.

- **Imidazolidinyl Urea**: Is an antimicrobial preservative that acts as a formaldehyde releaser in cosmetics and personal care products.

**The following fragrances substances identified as posing a high risk of sensitisation to consumers:**

**Table 29. Established fragrance contact allergens of special concern (single chemicals only)**

| |
|---|
| Cinnamal |
| Cinnamyl Alcohol |
| Citral |
| Coumarin |
| Eugenol |
| Farnesol |
| Geraniol |
| Hydroxycitronellal |
| Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) |
| Isoeugenol |
| Limonene (oxidised) |
| Linalool (oxidised) |

Source: SCCNFP, 2011

Moreover, the SCCNFP opinion identified also the substances: Chloroantranol and antranol (the main allergenic constituents of *Evernia prunastri and Evernia furfurace)* as allergens with should not be present in products for the consumer.

During the stakeholders consultation there was support to exclude the fourteen above mentioned substances from the EU ecolabelled products. Additionally, several new substances which may disrupt the hormonal system (so-called EDCs) have been proposed by stakeholders for consideration to be restricted in Ecolabelled products:

- 3- benzylidene camphor,
- 4-methylbenzylidene camphor,
- 4-nitrophenol,
-4,4' –dihydroxybenzophenone,
- Benzophenone-1,
- Benzophenone-2,
- Benzophenone-3,
- Butylparaben,
- Dicyclohexyl phthalate (DCHP),
- Diethyl phthalate (DEP),
- Dihexyl phthalate (DHP),
- Ethylhexyl methoxycinnamate,
- Metam natrium,
- Propylparaben,
- Quadrosilan,
- Resorcinol,
- Tert-butylhydroxiyanisole (BHA).

Butylparaben and propylparaben were already proposed to be restricted based on their classification as potential endocrine disrupters (Category 1) under the EU strategy for endocrine disrupters.

Regarding to dicyclohexyl phthalate (DCHP), diethyl phthalate (DEP) and dihexyl phthalate (DHP), they are not included in the candidate list of substances of very high concern for authorisation. Opinion on phthalates in cosmetic products provided by the Scientific Committee on Consumer Products (SCCP)[145], concluded that:

- Dicyclohexyl phthalate (DCHP): Despite the lack of adequate toxicological data, for low concentration of DCHP found in perfumes, it is suggested that unintentional exposure from perfume and other cosmetics would have no measurable risk for the consumer.

- Diethyl phthalate (DEP): Is found at higher concentrations in perfumes, however DEP has low toxicity. There is some epidemiological evidence for DEP of impairment of some reproductive function markers (sperm motility, concentration, morphology, DNA damage) in the human male, but the results are not consistent. The toxicity of this phthalate, where data is sparse, is low (lower than for other phthalates).

- Dihexyl phthalate (DHP): Is a plasticizer mainly used in the manufacture of polyvinyl chloride (PVC) and other plastics (including tool handles and PVC flooring) but not in cosmetic products[146]. No current harmonised classification in Annex VI of CLP is provided.

For these reasons and base on a prioritization system , they were not proposed to be restricted.

Regarding to 3- benzylidene camphor, 4-methylbenzylidene camphor, 4-nitrophenol, 4,4' –dihydroxybenzophenone, Benzophenone-1, Benzophenone-2, Benzophenone-3, Ethylhexyl methoxycinnamate, Metam natrium and Quadrosilan, they are not usually present in this product group, thus no restrictions have been proposed.

Finally, resorcinol and tert-butylhydroxyanisole (BHA) have numerous uses, including in cosmetics.Tert-butylhydroxyanisole (BHA) is an antioxidant and preservative in cosmetics but specifically is found in lipstick and eye shadow, while resorcinol is used[147] in oxidative hair colouring products which are not included in the scope in this product group.

**Restriction on sensitizing substances**

Based on the discussions conducted it was supported to extend the standard list of H/R phrases by two additional ones referring to sensitizing substances:

H334 (R42) May cause allergy or asthma symptoms or breathing difficulties if inhaled

[145] Opinion of the Scientific Committee on Consumer Products on phthalates in cosmetic products, 2007. For more details, see: http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_106.pdf.

[146] Background document to the Opinion proposing harmonized classification and labelling at Community level of Di-n-hexyl phthalate (DnHP), Committee for Risk Assessment (RAC), 13 September 2011. For more details see: http://echa.europa.eu/documents/10162/0fc1bf32-1cd4-4294-a7fc-7ba778f78f13.

[147] Opinion on resorcinol, Scientific Committee on Consumer Safety, 23 March 2010. For more details see: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_015.pdf.

H317 (R43) May cause allergic skin reaction

Based on the consultation process, it is proposed to restrict to 0.010 % by weight of the final product the use of fragrance substances classified with H334 (R42) and/or H317 (R43) in rinse-off cosmetic products.

The proposal to introduce **restriction on fragrances use in products intended for babies and children** gained stakeholders' support; therefore it is proposed that all ecolabelled products covered by the scope of the revised criteria which are intended for use for babies and children under the age of three year should be fragrance-free. Infant, baby and/or children products refers to products that are marketed as designed and intended for infants, babies and/or children or have any of these words on the label/packaging.

A possible harmonisation between the criteria for this product group and the criteria from all purpose cleaners and other similar products was also supported in order to ensure a general more horizontal harmonisation between various EU Ecolabel decisions and the equal level of strictness of criteria set for various (similar) product groups

**Criterion formulation**

In accordance with the new EU Ecolabel Regulation and the recent developments of criteria for other product groups, the below given criterion formulation is proposed to be included in the revised criteria document.

It has been discussed with the stakeholders that in the revised criteria proposal all substance related criteria should be included in the criterion on "Excluded and restricted substances and mixtures". Therefore, the requirements on colouring agents, fragrances and biocides are also incorporated in this criterion, as discussed in previous sections.

**Criterion: Excluded or limited substances and mixtures**

### *a) Specified limited and/or excluded ingoing substances*

The following ingoing substances must not be included in the product, neither as part of the formulation nor as part of any mixture included in the formulation:

- Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives
- NTA (nitrilo-tri-acetate)
- Boric acid, borates and perborates
- Nitromusks and polycyclic musks
- Phthalates: Bis(2-methoxyethyl) phthalate, diisobutyl phthalate (DIBP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl)phthalate (DEHP).
- D4 (octamethylcyclotetrasiloxane)
- Butylated Hydroxi Toluene (BHT)

- The following preservatives: triclosan, parabens, formaldehyde and formaldehyde releasers (bronopol, 5-bromo-5-nitro-1, 3-dioxane, Sodium hydroxyl methyl glycinate (SHMG), DMDM Hydantoin, Diazolidinyl Urea and Imidazolidinyl Urea).
- The following fragrances: Cinnamal, Cinnamyl Alcohol, Citral, Coumarin, Eugenol, Farnesol, Geraniol, Hydroxycitronellal, Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), Isoeugenol, Limonene (oxidised), Linalool (oxidised), Chloroantranol and Atranol.
- Ethylenediaminetetraacetate (EDTA) and its salts and non-readily biodegradable phosphonates may only be added to solid soaps and only to a maximum content of 0,6 mg/g AC

***Assessment and verification:*** *the applicant shall provide a completed and signed declaration of compliance.*

***b) Hazardous substances and mixtures***

According to the Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel, the product or any component of it shall not contain substances meeting criteria for classification with the hazard statements or risk phrases specified below in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EC nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006. The risk phrases below generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures apply.

List of hazard statements and risk phrases:

| **Hazard statement**[148] | **Risk Phrase**[149] |
|---|---|
| H300 Fatal if swallowed | R28 |
| H301 Toxic if swallowed | R25 |
| H304 May be fatal if swallowed and enters airways | R65 |
| H310 Fatal in contact with skin | R27 |
| H311 Toxic in contact with skin | R24 |
| H330 Fatal if inhaled | R23/26 |
| H331 Toxic if inhaled | R23 |
| H340 May cause genetic defects | R46 |
| H341 Suspected of causing genetic defects | R68 |
| H350 May cause cancer | R45 |
| H350i May cause cancer by inhalation | R49 |

[148] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

[149] Council Directive 67/548/EEC with adjustment to REACH according to Directive 2006/121/EC of the European Parliament and of the Council and Directive 1999/45/EC of the European Parliament and of the Council as amended.

| **Hazard statement**[148] | **Risk Phrase**[149] |
|---|---|
| H351 Suspected of causing cancer | R40 |
| H360F May damage fertility | R60 |
| H360D May damage the unborn child | R61 |
| H360FD May damage fertility. May damage the unborn child | R60/61/60-61 |
| H360Fd May damage fertility. Suspected of damaging the unborn child | R60/63 |
| H360Df May damage the unborn child. Suspected of damaging fertility | R61/62 |
| H361f Suspected of damaging fertility | R62 |
| H361d Suspected of damaging the unborn child | R63 |
| H361fd May damage fertility. May damage the unborn child | R62-63 |
| H362 May cause harm to breast fed children | R64 |
| H370 Causes damage to organs | R39/23/24/25/26/27/28 |
| H371 May cause damage to organs | R68/20/21/22 |
| H372 Causes damage to organs | R48/25/24/23 |
| H373 May cause damage to organs | R48/20/21/22 |
| H400 Very toxic to aquatic life | R50/50-53 |
| H410 Very toxic to aquatic life with long-lasting effects | R50-53 |
| H411 Toxic to aquatic life with long-lasting effects | R51-53 |
| H412 Harmful to aquatic life with long-lasting effects | R52-53 |
| H413 May cause long-lasting effects to aquatic life | R53 |
| EUH059 Hazardous to the ozone layer | R59 |
| EUH029 Contact with water liberates toxic gas | R29 |
| EUH031 Contact with acids liberates toxic gas | R31 |
| EUH032 Contact with acids liberates very toxic gas | R32 |
| EUH070 Toxic by eye contact | R39-41 |
| Sensitising substances | |
| H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled | R42 |
| H317 May cause allergic skin reaction | R43 |

[1] *Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006*

[2] *Directive 67/548/EEC with adjustment to REACH according to Directive 2006/121/EC and Directive 1999/45/EC as amended*

Note that this criterion also applies to known degradation products such as formaldehyde releasers.

Substances or mixtures which change their properties through processing (e.g., become no longer bioavailable, or undergo chemical modification in a way that removes the previously identified hazard) are exempted from the above requirement.

The final product must not be labelled according to the hazard statements above and moreover the final product formulation shall not contain any hazardous substances, or combinations thereof, that result in the formulation being greater than 0.85 of the limit required for classifying dangerous substances as defined within ANNEX II of Directive 1999/45/EC and as required by the Regulation (EC) No 1272/2008 (CLP Regulation).

**Derogations**

The following substances are specifically exempted from this requirement:

| Ingredient type | Hazard Statement | Risk phrase |
|---|---|---|
| **For discussion**<br>Surfactants < 25% in the product | H412 Harmful to aquatic life with long-lasting effects<br>When readily biodegradable | R52-53 |
| Fragrances | H412 Harmful to aquatic life with long-lasting effects<br>H413: May cause long-term adverse effects to aquatic life | R52-53<br>R53 |
| Antifungal, antimicrobial agent: Zinc pyrithione (ZPT) | H400 Very toxic to aquatic life | R50 |
| Preservatives* | H411 Toxic to aquatic life with long-lasting effects<br>H412 Harmful to aquatic life with long-lasting effects<br>H413: May cause long-term adverse effects to aquatic life | R51-53<br>R52-53<br>R53 |

** Derogation is only for criterion 3)b. Preservatives should comply with criterion 3)e.*

***Assessment and verification:*** *The applicant shall demonstrate compliance with this criterion by providing a declaration on the non-classification of each ingoing substance into any of the hazard classes associated to the hazard statements referred to in the above list in accordance with Regulation (EC) 1272/2008, as far as this can be determined, as a minimum, from the information meeting the requirements listed in Annex VII of Regulation (EC) 1907/2006. This declaration shall be supported by summarized information on the relevant characteristics associated to the hazard statements referred to in the above list, to the level of detail specified in section 10, 11 and 12 of Annex II of Regulation (EC) 1907/2006 (Requirements for the Compilation of Safety Data Sheets).*
*Information on intrinsic properties of substances may be generated by means other than tests, for instance through the use of alternative methods such as in vitro methods, by quantitative structure activity models or by the use of grouping or read-across in accordance with Annex XI of Regulation (EC) 1907/2006. The sharing of relevant data is strongly encouraged.*

*The information provided shall relate to the forms or physical states of the substance or mixtures as used in the final product.*
*For substances listed in Annexes IV and V of REACH, exempted from registration obligations under Article 2(7)(a) and (b) of Regulation 1907/2006 REACH, a declaration to this effect will suffice to comply with the requirements set out above.*
*The applicant shall also demonstrate compliance with this criterion by providing the calculations as required based on the R-phrases/H-statements that apply to the formulation and as indicated using the rules provided by the CLP Regulation.*

**c)** ***Substances listed in accordance with article 59(1) of Regulation (EC) No 1907/2006***

No derogation from the exclusion in Article 6(6) of the Regulation (EC) No66/2010 shall be given concerning substances identified as substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006, present in the product in concentrations higher than 0.010 % (weight by weight).

***Assessment and verification****:* The list of substances identified as substances of very high concern and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here: http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Reference to the list shall be made on the date of application. The applicant shall provide the exact formulation of the product to the competent body. The applicant shall also provide a declaration of compliance with this criterion, together with related documentation, such as declarations of compliance signed by the material suppliers and copies of relevant Safety Data Sheets for substances or mixtures.

***d)*** ***Fragrances***

i. Products intended for infants, babies and children under the age of three year should be fragrance-free. Infant, baby and/or children products refers to products that are marketed as designed and intended for infants, babies and/or children or have any of these words on the label/packaging.

ii. Any ingoing substance added to the product as a fragrance shall be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). The code can be found on IFRA website: http://www.ifraorg.org. The recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials shall be followed by the manufacturer.

***Assessment and verification:*** *the applicant shall provide a signed declaration of compliance.*

### *e) Preservatives*

i. The product may only include preservatives in order to preserve the product, and in the appropriate dosage for this purpose alone. This does not refer to surfactants, which may also have biocidal properties.

ii. Preservatives must not release substances that are classified in accordance with the requirements on hazardous substances.

iii. It is prohibited to claim or suggest on the packaging or by any other communication that the product has an antimicrobial or disinfecting effect.

iv. The product may contain preservatives provided that they are not bioaccumulating. A biocide is not considered bioaccumulating if BCF < 100 or logPow < 3,0. If both BCF and logPow values are available, the highest measured BCF value shall be used.

***Assessment and verification:*** *the applicant shall provide copies of the safety data sheets of any preservative added, together with information on their BCF and/or logPow values and information on their exact concentration in the product. The manufacturer or supplier of the preservatives shall provide information on the dosage necessary to preserve the product.*

### *f) Colorants*

Colorants allowed in the product must not be potentially bio-accumulating. A colorant is considered not bioaccumulating if BCF ≤100 or log Pow < 3.0. If both BCF and log Pow values are available, the highest measured BCF value shall be used. In the case of colorants approved for use in foodstuffs it is not necessary to submit documentation of bioaccumulation potential.

***Assessment and verification:*** *the applicant shall provide copies of the safety data sheets of any colorant added, or documentation to ensure that the colorant agent is approved for use in foodstuff.*



## 6.3.8 CRITERION 9: Packaging

The formulation of the current criterion is as follows:

(a) The Weight/Content Relationship (WCR) must be less than 0,30 g of packaging per gram of product, and is calculated as follows.

$WCR = \Sigma ((Wi + Ni)/( Di \times r))$

Where;

Wi = the weight (in grams) of packaging-component i (this applies to both primary or secondary packaging), including any labels.

Ni = the weight (in grams) of the packaging component that comes from virgin material rather than recycled sources (this applies to both primary or secondary packaging). If the packaging component does not contain recycled material then Ni = Wi.

Di = the weight in grams of product that the packaging-component contains.

r = the Return number, i.e. the number of times the packaging-component i is used for the same purpose through a system of return or refill (by default r = 1 if no reuse occurs).

If the packaging is reused r is set to 20 for plastics and 10 for corrugated board unless the applicant can document a higher number.

***Assessment and verification***:

Presentation of the calculation of WCR.

(b) Labelling of packaging

To allow for identification of different parts of the packaging for recycling, plastic parts in the primary packaging must be marked in accordance with DIN 6120, Part 2 or the equivalent. Caps and pumps are exempted from this requirement.

***Assessment and verification***:

Completed and signed declaration.

Sample of primary packaging.

(c) Dosage

The packaging must be designed to make correct dosage easy, e.g. by ensuring that the opening at the top is not too wide.

***Assessment and verification***:

Description of the dosage device.

(d) The packaging must contain neither additives based on Cadmium or Mercury or compounds with these elements, nor additives that do not fulfil criterion 8.

***Assessment and verification***:

Declaration from the packaging producer.



During the 1st AHWG meeting, the following issues were discussed:

- Options of modifying the formula to calculate Weight/Content Relationship (WCR). It was agreed that the formula should take into account availability of refillable and refill packaging. The issue of using bioplastics and/or biodegradable plastics for packaging purposes should also be analysed.

- Setting stricter limit for WRC, according to current data regarding ecolabelled products.
- Disposable toiletries (not refillable), such as shampoo and soap, shall not be used (to align the criteria with the criteria for the EU Ecolabel Tourist accommodation services).
- Sustainable sourcing of packaging materials (e.g. of paper and cardboard).
- Packaging shall not contain substances included in the candidate list of Substances of Very High Concern (SVHC) for authorization.
- Specific packaging requirements for different kinds of material used: plastic, metal, paper and cardboard.
- It should be possible to separate all materials in the packaging (paper, cardboard, plastic, metal) for further treatment. Parts comprising mixed materials that cannot be separated should be restricted, with the exception of pump parts.
- Additional requirements regarding aerosol packaging - due to the potential extension of the scope by shaving foams and gels.

Packaging has an important load in the overall life cycle impact of the products under study. According to life cycle assessment carried out in the framework of the current study on average 22% of products' impact can be assigned to packaging and packaging waste. Impacts of packaging come mainly from the material used (derived from resources and energy consumed for producing packaging materials). It is thus very important to address the weight, materials and characteristics of packaging in the Ecolabel criteria for this product group in order to minimize its environmental impact.

**Calculation of Weight/Content Relationship (WCR)**

Discussions of the 1st AHWG meeting and written feedback received from stakeholders addressed the issue which materials and parameters should be included in the calculation. Different aspects have been considered: refilling systems, recycled material, renewable sourced materials and biodegradability.

**Refilling systems** (i.e. where two kinds of packaging, refillable and refill, exist for a product) allow for important packaging material reduction, so it is important to include them in the Ecolabel criteria. Some soap products have the option of refilling or reusable package, where the refill package is usually lighter that the conventional one. It is quite usual in hand-soaps where refillable package has a dispenser and refill package is a simpler bottle. There exist also some other soap products with refill packaging such as body liquid soap. Among all liquid soap products of the European market, 10% have refilling systems[150]. For shampoos, only 26 products have been found with refilling system (0.02%), and for hair conditioner products – only 2 (0.04%)[151].

Refilling system can provide packaging saving of nearly 80% of weight, which can be converted to approximately 80% of saving of environmental impact of packaging stage[152], as it mainly results from

[150] Mintel GNPD Data Base. Category: liquid soaps, 2012.
[151] Mintel GNPD Data Base.
[152] Data obtained from direct calculation for a refilling product of liquid soap.

raw material consumption. The assessment done shows that environmental impacts are directly proportional to the weight of packaging[153]. For instance, in accordance with the results obtained in the technical analysis, in the case of liquid soaps, by using a refilling system, the total environmental impact of the product decreases by 18% with respect the original soap with non-refill packaging.

Thus, it is considered of high importance to promote through Ecolabel criteria the refill/refilling systems in this product group.

The initial proposal of the revision process was to include refillable and refill packaging in the current formula as follows:

$$WCR = \Sigma(((Wi_{refillable}/r + Wi_{refill)} + Ni)/(Di \times r))$$

Where;

*Di* = the weight in grams of product that the packaging-component contains.

*r* = the Return number, i.e. the number of times the packaging-component i is used for the same purpose through a system of return or refill (by default r = 1 if no reuse occurs).

W*irefillable* = the weight (in grams) of refillable packaging-component i

W*irefill*= the weight (in grams) of refill packaging-component i

If there is not any refillable/refill packaging, then, W*irefillable*= Wi, r=1 and W*irefill*=0
Ni: the weight (in grams) of the packaging component that comes from **virgin and non-renewable material** rather than recycled or renewable sources (this applies to both primary and secondary packaging). If the packaging component does not contain **recycled material or bio based polymer, then Ni = Wi.**

Stakeholders agreed with the need of including refilling packaging in the WRC calculation.
Further feedback received from stakeholder was aimed to improve the proposal presented at the AHWG meeting by considering that in some cases refill and refillable could have different volume capacity, and also the two kinds of packages can have different content of recycled or renewable material. A new formula was proposed where different capacities were considered. The improved formula was evaluated and proposed for discussion in the 2nd AHWG meeting (See the formula proposal at the end of this section).

Moreover some rules for refilling systems were proposed to be taken into consideration:

- The refillable parent pack must be designed to accept refills without incurring waste by spillage and should perform its intended function throughout the designed refill rate.
- To qualify both parent pack and refill must be continuously available to consumers throughout the period of the eco-label award.
- If different refill packaging types / sizes are to be used with the parent pack, a separate calculation should be performed for each size or type.
- When calculating weight of refill, analysis should be made of the actual amount of product delivered into the parent pack by the refill. Product retained in the refill should be excluded.

[153] For details please see the report "Preliminary results from the technical analysis, available at project website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

In existing criteria, the use of **Recycled material** is already included in the formula. It is proposed to maintain this parameter, as the use of recycled material allows to decrease the use of raw materials and to save resources and energy used for producing packaging.

It is further proposed to include **Renewable Packaging material** in weight calculation method in the revised criteria. Renewable material is derived from renewable sources (e.g. wood pulp and paper, and plant based polymers).

Bio-polymers allow using renewable resources instead of non-renewable sourced polymers, so they contribute to reduction in the use of primary raw materials and specifically the use of petroleum-based plastics. It is proposed to consider differentiating this kind of polymers from other polymers in the weight calculation method in the revised criteria.

Bio-based polymers are macromolecules derived from plants, bacteria, algae or other sources that are long chains of molecules linked together through a chemical bond. They are generally able to perform the functions of traditional petroleum-based ingredients. Bio-based plastics can be either biodegradable or non-biodegradable. They are often degradable through microbial processes such as composting, but this depends on how they are produced.

The main bio-polymers used in packaging for cosmetics are: polylactic acid (PLA) obtained mainly through fermentation of dextrose, which is extracted from a starch source material (starch comes from different vegetables sources such as rice, maize, potatoes); and polyhydroxyalkanoates (PHAs), which are polymers synthesized by bacteria from sugars fermentation[154]. PLA is the most common polymer used in this kind of packaging.

Nevertheless, bio-polymers, for which the raw materials are obtained from plants, can have social and ethical implications, as these crops farming for industrial uses compete with food resources supply. Main environmental concerns are related to the amount of non-renewable energy used for their production, water pollution and land use due to the intensifying crop production to meet the demand[155]. Therefore, bio-plastics should be made from resources obtained and managed in a sustainable way to be included in the calculation. “Sustainable biomaterials” can be defined as those that are sourced from sustainably grown and harvested cropland or forests, manufactured without hazardous inputs and impacts[156].

As only bio-polymers that come from sustainable source can be included in the formula calculation, it is thus proposed that a declaration of the manufacturer/supplier with the origin of the bio-polymer and a declaration that sustainable crop principles are accomplished in the entire supply-chain are required. These sustainable crop principles should follow those defined by the Common Agriculture Policy (CAP) of Europe[157] and the FAO[158]. Cardboard and wood fibre derived packaging should also come from sustainable managing forests (as described later in respective sub-section).



[154] Envase sostenible para la industria cosmetic, available online at: http://marketingcosmeticaperfumeria.wordpress.com/2011/03/22/envase-sostenible-para-la-industria-cosmetica/.

[155] BIO Intelligence Service, AEA Technology, Institute for European Environmental Policy for DG Environment, Plastic waste in the environment, Final report, April 2011, available online at: http://ec.europa.eu/environment/waste/studies/pdf/plastics.pdf.

156 http://www.sustainablebiomaterials.org.

[157] Common Agriculture Policy (CAP) http://ec.europa.eu/agriculture/index_en.htm.

[158] Biobased Materials: Essential for the Next Generation of Products, available online at: http://www.fao.org/agriculture/crops/core-themes/theme/spi/en/.

The proposal of including bio-based materials is coherent with the policy initiated by the DG Enterprise and drive six lead markets[159] bringing together the European Commission, Member States and industry. Of particular interest from plastics perspective are the bio-based products and recycling markets.

**Biodegradable and degradable plastics** were proposed in feedback received from some stakeholders to be included as a parameter in the calculation formula. About this proposal, some information has been gathered to see if it is suitable and feasible in this revision process

It should be differentiated among different kinds of "degradable" plastics:

- Biodegradable (compostable) plastic: Biodegradable polymers are often bio-based but they can also be petroleum-based (e.g. polycaprolactone). Some biodegradable plastics even contain a mixture of petroleum-based polymers and bio-polymers. They meet scientific standards for biodegradability and compostability of plastics and plastic products. According to definition of EN 13432[160] biodegradable plastics can be completely broken down by micro-organisms in the environment into non-toxic compounds (water, $CO_2$ and biomass under aerobic conditions, as well as methane under anaerobic conditions). Biodegradable plastics could be preferable than conventional recyclable plastic for some specific uses, but only if they can be treated as organic waste, i.e. through composting.
- Degradable plastics: for instance, degradable plastic with special additives and oxo-biodegradable plastics. They are often non-renewable plastics which are degradable due to addition of some substances that catalyse the degradation of the polymer in the environment producing smaller plastic fragments and $CO_2$. This kind of plastics does no meet biodegradability or compostability standards and there is no certification for oxo-/UV-degradability in Europe yet[161]. They do not present environmental benefits unless they are treated by a specific treatment under conditions that allow their degradability.

Biodegradable plastics could present environmental benefits only if they have the appropriate treatment (composting), as biodegradability is not predictable and dependent on appropriate degradation conditions. The behaviour of biodegradable plastic waste depends on the treatment they have as packaging waste, which can not, nevertheless, be guaranteed in the current situation. According to the information collected[162], currently around 58% of plastic waste packaging is treated by recycling and valorisation (thermal treatment) and 42% by landfilling (data for the EU in 2008). There is no collection scheme for biodegradable / degradable plastics and they can even cause difficulties to conventional plastic recycling systems. The use of biodegradable or degradable plastics may have implications for the recycled plastics industry, as it could potentially lead to the contamination of recycled plastics, affecting the quality and physical integrity of the resulting material. Investment may be needed in sorting technology to deal with this challenge.

[159] The Lead Market Initiative is the European policy for 6 important sectors that are supported by actions to lower barriers to bring new products or services onto the market, for more details see the website: http://ec.europa.eu/enterprise/policies/innovation/policy/lead-market-initiative.

[160] EN 13432 - Packaging - Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging.

[161] BIO Intelligence Service, AEA Technology, Institute for European Environmental Policy for DG Environment, Plastic waste in the environmenta, Final report, April 2011, available online at: http://ec.europa.eu/environment/waste/studies/pdf/plastics.pdf.

[162] PlasticsEurope, EuPC, EuPR, EPRO and Consultic (2009) *The Compelling Facts about Plastics - An analysis of European plastics production, demand and recovery for 2008*.

Biodegradable and degradable plastics can present higher environmental impacts (e.g. with regard to green house gas emissions) if they are disposed of in uncontrolled landfills. The Landfill Directive 1999/31/EC[163] sets intermediate and long-term targets for the phased reduction of biodegradable waste going to landfill, which will limit the disposal of biodegradable plastics in landfills as well. In terms of energy recovery via incineration, there is lack of data on the gross calorific values (GCV) of biodegradable plastics.

As conclusion, it is considered that at present the Ecolabel scheme shall promote recycling as the best treatment for packaging plastic, according to the hierarchy defined in the Waste Framework Directive, 2008/98/EC[164] and Packaging Waste Directive 94/62/EC[165]. The full life cycle impacts of biodegradable plastics are still an important topic of research. It seems important that for biodegradable and degradable polymers waste streams the necessary infrastructure (e.g. design of landfills, separate collection centres for recycling, recycling systems) needs to be adjusted. As the current waste treatment for packaging can not guarantee the final destination of packaging, it has been decided not to promote biodegradable and degradable polymers for this criteria revision process. This issue is nevertheless proposed to be considered and investigated further in the later revision, when more evidence and information is available.

Some stakeholder proposed to set **impact factors for different materials** in the formula based on the LCA outcomes. However, the LCA conducted is a generic one and should serve to give the overall picture regarding the environmental performance of an average product along its life cycle. Setting such material weighting factors needs specific and detailed investigation of each packaging material types (needs a detailed full LCA on packaging), this proposal could not be incorporated in the current calculation formula. Other stakeholders supported that the choice of materials is indeed an issue worth considering. Nevertheless, it was also stated that suggesting or restricting materials would need more thorough LCA analysis, which is likely to be too complex for eco-labels. Thus, the focus on material weight reduction was considered the best option to avoid complexity of the criteria.

Regarding the **scope of the formula**, it was proposed to maintain the current scope, where primary and secondary packaging is included. Tertiary packaging is excluded from calculation, as this will be specific to individual business customer requirements such as order quantity, stock control and shipping methods. The major part of stakeholders agreed with this proposal.

As the above mentioned terms are open to interpretation and different published definitions exist, it was proposed that Ecolabel criteria follow the definitions given in Article 3 of the EU Directive on Packaging and Packaging Waste 94/62/EC. These definitions are as follows:

(a) Sales packaging or primary packaging, i. e. packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase;
(b) Grouped packaging or secondary packaging, i. e. packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold

[163] Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0031:EN:NOT.
[164] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0098:EN:NOT.
[165] European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0062:EN:NOT.

as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale; it can be removed from the product without affecting its characteristics;

(c) Transport packaging or tertiary packaging, i. e. packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packaging in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship and air containers

Finally, as the new formula has been extended and other parameters apart of the weight are taken into account (Packaging weight / content ratio, renewable, recycled and refillable packaging), it is proposed to rename the formula (called so far "Weight/Content Ratio") as **"Packaging Impact Ratio" PIR**.

With all considerations explained above, the final proposal for the formula is:

**PIR= Sum (Wi + (Wirefill x F) + Ni + (Nirefill x F)) / (D + (Drefill x F))**

Where:

| | |
|---|---|
| Wi | – weight of packaging (Primary + proportion of secondary per SKU[166]) |
| Wirefill | – weight of refill packaging (Primary + proportion of secondary per SKU) |
| Ni | – weight of non-renewable + non-recycled packaging (Primary + proportion of secondary per SKU) |
| Nirefill | – weight of Non renewable and non recycled refill packaging (Primary + proportion of secondary per SKU) |
| D | – weight of product contained by the "parent" pack |
| Drefill | – weight of product delivered by the refill |
| F | – number of refills required to meet the total refillable quantity, calculated as follows: **F = V x R / Vrefill** |

Where:

| | |
|---|---|
| V | – volume capacity of the parent pack |
| Vrefill | – volume capacity of the refill pack |
| R | – the refillable quantity. This is the number of times that the parent pack can be refilled. Where F is not a whole number it should be rounded up to the next whole number**.** |

NOTE: A new criterion has to be set for determining R. In the current criteria R was set to 20 for plastics and 10 for corrugated board unless the applicant can document a higher number. Comparing this factor with other Ecolabels, it appears to be too high.

It is proposed that manufacturer should provide the number of foreseen refillings. Is could be proposed that R=5 for plastics and R=2 for cardboard is set as default values.

This proposal will be discussed during the 2nd AHWG meeting.

[166] SKU – Stock Keeping Unit.

**Setting more strict limit for WRC (now PIR)**

Impact of packaging is directly related to its **amount,** as the main environmental impacts result from material used. Initiatives that reduce the amount of raw material used, such as refilling systems and recycling processes, allow minimizing the environmental impact of packaging, and as a result, the environmental impact of the entire product.

The current weight/content ratio limit is 0.3 g of packaging for 1 g of product. In 2006 it was determined that the average ratio amounted below 0.1 g packaging/g product[167]. According to Ecoembes[168], weight packaging for packaged products in Spain has decreased by 6% from 2006 to 2010. It is thus assumed that packaging for product group of soaps, shampoos and hair conditioners at European level also follows this trend and the current average weight is lower than the weight from 2006. Ecolabelled products should not have unnecessary packaging, so packaging should be as light as possible, but of course fulfilling the intended function. They should be different (i.e. better performing from the environmental point of view) from average marketed product in terms of formulations, but also in packaging.

Due to lack of information on the average weight/content ratio stakeholders were consulted to comprehend the information. 57 ecolabelled products were analyzed based on the feedback received[169]. The data from the report of the development of EU Ecolabel criteria for soaps, shampoos and hair conditioners[170] was also included. Industry also provided data of some products which indicated that non-refilling packaging average weight/content ratio for these products were 0,25; whereas for refilling products the average ratio was 0,17. Nevertheless, It was found that in general current limit on WCR is higher that the values for average product (see next table), which indicates that it may be appropriate to propose stricter WCR limits. Moreover, the use of recycled or renewable materials and refilling systems will allow obtaining lower values.

**Table 30. WCR average values and current limits**

| PRODUCT | WCR (average 2012) (g packaging/ g product) | | WCR (average 2006)[171] (g packaging/ g product) | | Current limit (g packaging/ g product) |
|---|---|---|---|---|---|
| | **Average** | Range | **Average** | Range | |
| **LIQUID SOAP HAIR CONDITIONER SOLID SOAP** | **0,19** | 0,03-0,29 | **0,15** | **0,1-0,2** | **0,3** |

Sources: own work based on information from reports indicated in footnote and stakeholders 'information sent to the EC

Based on these results, the following PIR limits are proposed for discussion for the revised criteria. Nevertheless, the industrial stakeholders are still testing the new proposed formula and further feedback will be submitted and presented at the 2nd AHWG meeting.

[167] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E. May 2006.
[168] www.ecoembes.com.
[169] For further details see annex IV: Summary of data.
[170] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., May 2006.
[171] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., May 2006.

**Proposed PIR:**

**- for all packaging except of metal aerosol packaging: < 0,2 (g packaging/g product)** – For discussion

**- for metal aerosol packaging: < x (g packaging/g product)** – For discussion if it is necessary at to set it?

**Disposable toiletries (not refillable)**

After the AHWG meeting and according to the criterion number 19 about **Disposable Products** of the Commission decision establishing the ecological criteria for tourist accommodation services[172]: "***unless required by law, disposable toiletries (not refillable) such as shampoo and soap, and other products (not reusable), such as shower caps, brushes, nail files, etc. shall not be used. Where such disposable products are requested by law the applicant shall offer to guests both solutions and encourage them with appropriate communication to use the non-disposable products***".

Based on the above-written, some stakeholders proposed aligning the requirements in the criteria for tourist accommodation services and those of soaps, shampoos and hair conditioners in this respect. It is thus proposed, if stakeholders agree in the 2nd AHWG to be in line with the tourist accommodation criteria, to set restriction on the use of disposable toiletries (not refillable) for products such as shampoos, soaps and hair conditioners.

The term "single use products" are proposed instead of "disposable toiletries" as the later covers also other products, e.g. shower caps, brushes, nail files. Further it is suggested to refer to the number of washing actions as used and defined in the life cycle assessment part. A practical way to apply such a type of restriction is to set a minimum net weight content for the products that are sold without the option of refilling. Products of low weight correspond to a low number of washing actions and expresses better what is understood as "disposable toiletries" in the EU Ecolabel criteria for tourist accommodation (as described above). The following proposal is made:

"Products that are intended for very limited number of washing actions, approximately 4 or less and sold without the option of refilling shall not be awarded the EU Ecolabel. Therefore, a minimum product net weight of 50 ml for liquid soaps, hair conditioners and shampoos and a minimum product net weight of 10 g for solid soaps are required."

Stakeholders are asked for their feedback in this respect, as this issue was not proposed for the 1st AHWG meeting. Furthermore, if this restriction is agreed to be kept it shall be discussed whether to include it in the scope section of the criteria (as exclusion from the scope of the EU Ecolabel).

[172] Commission decision 2009/578/EC of 09 July 2009 establishing the ecological criteria for the award of the Community eco-label for tourism accommodation service, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:198:0057:0079:EN:PDF.

**Sustainable sourcing of packaging materials**

Secondary packaging and primary packaging for some products such as solid soaps is usually made of cardboard material.

For virgin paper and cardboard packaging made of wood fibres it is important to guarantee sustainable origin along the supply chain. Natural forests throughout the world are threatened by global demand for forest products. Much of the world's remaining natural forests still suffer from illegal exploitation, poor management and conversion to other land uses, commonly resulting in severe degradation or complete destruction. In some countries as much as 80% of the timber is harvested illegally, often involving the violation of human rights and destruction of protected forests[173].

The main forest products certification is FSC (Forest Stewardship Council) and PEFC (The Programme for Endorsement of Forest Certification Schemes). FSC[173] is an independent, non-governmental, not-for-profit organization established to promote the responsible management of the world's forests. FSC *certification* provides a credible link between responsible production and consumption of forest products. Currently there are 147 102 231 ha of certified exploitation in 80 countries and a total amount of 1114 licences[173]. FSC in cosmetic packaging is increasing and there are lots of examples available in the market. PEFC[174] is a non-governmental organization established in order to support sustainable forest management. It functions as a global umbrella organisation for the assessment and mutual recognition of national forest certification schemes. Currently there are 243 million ha of certified forests.

It is proposed to set a criterion for cardboard packaging to guarantee that the material comes from forestry which is managed in a sustainable way. Materials made of wood fibres used for packaging should be demonstrated to be produced from forest managed according to the principles of Sustainable Forestry Management (SFM). A definition of SFM was developed by the Ministerial Conference on the Protection of Forests in Europe (MCPFE)[175], and has since been adopted by the Food and Agriculture Organization (FAO). It defines sustainable forest management as:

*"The stewardship and use of forests and forest lands in a way, and at a rate, that maintains their biodiversity, productivity, regeneration capacity, vitality and their potential to fulfil, now and in the future, relevant ecological, economic and social functions, at local, national, and global levels, and that does not cause damage to other ecosystems".*

Outside Europe they shall at least correspond to the United Nations Conference on Environment and Development (UNCED) Forest Principles (Rio de Janeiro, June 1992)[176] and, where applicable, to the criteria or guidelines for sustainable forest management as adopted under the respective international and regional initiatives (ITTO, Montreal Process, Tarapoto Process, UNEP/FAO Dry-Zone Africa Initiative).

[173] Fores Stewardship Council website: http://www.fsc.org.
[174] Programme for the Endorsement of Forest Certification website: http://www.pefc.org/.
[175] European Operational Level Guidelines for Sustainable Forest Management, as endorsed by the Lisbon Ministerial Conference on the Protection of Forests in Europe (2 to 4 June 1998).
[176] Report of the United Nations Conference on Environment and Development, available online at: http://www.un.org/documents/ga/conf151/aconf15126-3annex3.htm/.

Verification should follow the same scheme than other product category groups of Ecolabel, for instance the Furniture[177]. Manufacturers should provide documentation to prove that forests are managed according to Sustainable Forest Management principles. For verification, certificates of chain of custody for the wood fibers certified as FSC, PEFC or any other sustainable forest management official standard will be accepted as proof of compliance.

Regarding the bleaching processes used for paper packaging the requirement set in the currently valid criteria document is proposed to be kept (see below the section on specific requirements for paper/cardboard packaging).

**Requirements on substances used in packaging material**

In the current EU Ecolabel criteria for this product group a number of requirements addressing restriction on substances is already set. Following the provisions of article 6.6 and 6.7 of the EU Ecolabel Regulation 66/2010 requirements on substances were described in the section 6.3.7.

- One option would be thus to apply the same requirements also on substances used in the packaging material. The formulation would be then:

"The packaging must not contain substances which do not fulfil criterion 3b and 3c.

Assessment and verification: The applicant shall provide completed and signed declaration of compliance. Copies of the Safety Data Sheets shall be provided for all ingredients used in the packaging material (whether substances or preparations) together with a signed declaration prepared by the manufacturer of packaging material showing compliance with this criterion".

This would ensure that the user is in general prevented from being exposed to substances classified as hazardous (as they will not be used) and would simplify and reduce the number of criteria. However, manufacturers may face difficulties as the packaging material is not produced by them but it is only purchased. Therefore they have limited control and information on which substances are used in the different packaging materials. Manufacturer stakeholders have been asked to provide feedback explaining the difficulties of applying this option. As in general the stakeholder asked to reduce the administrative burden, the second option is therefore proposed here, as it is considered more practical.

- Another option is to exempt the packaging material from criterion 6.3.7 and to set a list of specific requirements on substances used in packaging using as main reference the current criteria. This latter option is described below and proposed in the current draft revised criteria (see Chapter 7).

| Stakeholders are asked to provide feedback regarding which option is more appropriate to be adopted. |
|---|

[177] Commission Decision of 30 November 2009 on establishing the ecological criteria for the award of the Community eco-label for wooden furniture, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:320:0023:0032:EN:PDF.

**Substances included in the candidate list of Substances of Very High Concern for authorization in packaging materials**

During the discussions conducted at the 1st AHWG meeting the proposal to set a restriction on the substances placed at the candidate list of Substances of Very High Concern (SVHC) was supported. Some common substances of concern used in plastic materials are indicated in Table 31. No information and feedback have been received whether these substances are used in packaging of the product group under study; nevertheless, there were no objections against setting such a requirement and it is proposed in the revised criteria document.

**Table 31. Substances at the Candidate List contained in plastic materials**

| Name of substance | Plastics involved | EC number | CAS number | Reason for inclusion in Candidate List |
|---|---|---|---|---|
| 2,4-Dinitrotoluene | Monomer | 204-450-0 | 121-14-2 | Carcinogenic (article 57a) |
| 4,4'- Diaminodiphenylmethane (MDA) | Monomer | 202-974-4 | 101-77-9 | Carcinogenic (article 57a) |
| Acrylamide | PA Monomer | 201-173-7 | 79-06-1 | Carcinogenic and mutagenic (articles 57 a and 57 b) |
| Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins) | PVC | 287-476-5 | 85535-84-8 | PBT and vPvB (articles 57 d and 57 e) |
| Benzyl butyl phthalate (BBP) | PVC PP catalysts | 201-622-7 | 85-68-7 | Toxic for reproduction (article 57c) |
| Bis (2-ethylhexyl)phthalate (DEHP) | PVC PP catalysts | 204-211-0 | 117-81-7 | Toxic for reproduction (article 57c) |
| Chromium trioxide | HDPE catalysts | 215-607-8 | 1333-82-0 | CMR |
| Dibutyl phthalate (DBP) | PVC PP catalysts | 201-557-4 | 84-74-2 | Toxic for reproduction (article 57c) |
| Diisobutyl phthalate | PVC PP catalysts | 201-553-2 | 84-69-5 | Toxic for reproduction (article 57c) |
| Hexabromocyclododecane (HBCDD) and all major diastereoisomers | Flame Retardant EPS, XPS | 247-148-4 221-695-9 | 25637-99-4 | PBT (article 57d) |
| Lead chromate | Pigment | 231-846-0 | 7758-97-6 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c) |
| Lead chromate molybdate sulphate red (C.I. Pigment Red 104) | Pigment | 235-759-9 | 12656-85-8 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c) |
| Lead sulfochromate yellow (C.I. Pigment Yellow 34) | Pigment | 215-693-7 | 1344-37-2 | Carcinogenic and toxic for reproduction (art. 57 a and 57 c) |
| Tris(2-chloroethyl)phosphate | Flame Retardant, plasticiser | 204-118-5 | 115-96-8 | Toxic for reproduction (article 57c) |

Source: Website of PlasticsEurope: http://www.plasticseurope.org/plastics-sustainability/consumer-protection/reach.aspx

**Specific packaging requirements for each kind of material used**

Different materials are used for packaging of cosmetic products under study. For liquid soaps, shampoos and hair conditioners, packaging is usually made of different kinds of plastics. For all plastic materials impacts come mainly from energy use in its manufacturing. For solid soaps, packaging is usually made of paper or cardboard. Criteria on packaging material (i.e. on the kind of material restricted or excluded) are not proposed in this document. Restrictions are proposed regarding the weight and substances used in the packaging materials.

The following requirements regarding packaging materials were proposed for consideration during the AHWG:

- **Plastic (but also in general packaging materials):** shall not contain the substances included in the candidate list of Substances of Very High Concern (SVHC) for authorization.
- **Paper/cardboard packaging**: Chlorine shall not be used to bleach. Chlorine gas is classified as H400 (very toxic to aquatic life), H315 (causes skin irritation), H319 (causes serious eye irritation), H331 (toxic if inhaled) and H335 (may cause respiratory irritation). Chlorine bleaching process produces highly toxic and persistent organochlorines such as dioxins. Dioxins are recognized as persistent environmental pollutants, regulated internationally by the Stockholm Convention on Persistent Organic Pollutants[178]. In the EU Ecolabel criteria for tissue paper[179] and for copying and graphic paper[180] it is required that chlorine gas shall not be used as a bleaching agent and the same requirement is proposed for the product group under study.
- **Metals**

  Finally, at first a criterion limiting the use of metal packaging for aerosol was considered, but it has been changed and it is now proposed to limit aerosol propellants (see the later section on specific requirements for shaving products packaging).

  It is proposed for discussion not to restrict metal packaging material as such, as, although in general primary metals have higher impacts than plastics due to higher demand of energy and raw materials consumption; they have also some advantages, e.g. metals can be recycled more easily than plastic packaging.

**Recyclability**

Recyclability of waste packaging is of high importance. From life cycle perspective, it would generally be favourable to increase the amount of recycled material entering new life cycles in order to minimize the impact coming from new materials, since the production impacts of virgin materials (and the related intermediates) can be decreased by substituting some of the virgin material with recycled material.

[178] Listing of POPs in the Stockholm Convention – Annexes, available online at: http://chm.pops.int/Convention/ThePOPs/ListingofPOPs/tabid/2509/Default.aspx.

[179] Commission Decision 2009/568/EC of 9 July 2009 establishing the ecological criteria for the award of the Community Eco-label for tissue paper, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:197:0087:0095:EN:PDF.

[180] Commission Decision 2011/332/EU of 7 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for copying and graphic paper, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:149:0012:0024:EN:PDF.

Recycling rate is higher for paper and cardboard packaging waste than for plastic packaging waste. Among packaging plastics, PET is the polymer with higher recycling rate, whereas PVC is the polymer less recyclable (nevertheless, used in low amounts for this product group).

EU Ecolabel criteria should try to ensure the **recyclability** of various components of packaging. The best case is mono-material packaging. For packaging made of different materials, all materials in the packaging should be separable by hand (paper, cardboard, plastic, metal, glass) for sorting or should be suitable for recycling. Packaging elements such as caps or labels also have to be considered to ensure that these elements do not pose difficulties in recycling processes.

Some stakeholder argued that in some cases it may be better to stay with multiple materials in case this allows for material reduction, especially in countries with low waste recycling rates and lack of recycling facilities. Nevertheless, it is agreed that Ecolabel should promote recycling as the best waste treatment and it is considered appropriate to set a requirement to guarantee recyclability of packaging.

**Aerosols containing hydrocarbon propellants**

As it is proposed to extend the scope to shaving products, e.g. foams and/or gels, it is important to set additional requirements concerning their packaging, since today high percentage of those products is still sold in aerosols containers. This packaging is also to certain extent different than the packaging of products currently covered by the scope of the product group under study.

The materials and types of packaging used for each kind of shaving preparation were analysed. The results of this analysis are given in below table:

**Table 32. Kind of packaging and materials used in shaving preparations**

| TOTAL | | Plated Steel | Plated aluminium | Plastic (PE, multilaminated, PP, PET) | Glass |
|---|---|---|---|---|---|
| | **TOTAL** | **36,0%** | **36,0%** | **27,0%** | **1,0%** |
| **Aerosol** | **65%** | 35,2% | 30,0% | 0,0% | 0,0% |
| **Tube** | **24%** | 0,4% | 4,4% | 19,1% | 0,0% |
| **Bottle** | **8%** | 0,0% | 0,9% | 6,2% | 0,9% |
| **Can** | **1%** | 0,4% | 0,6% | 0,0% | 0,0% |
| **Jar** | **1%** | 0,0% | 0,0% | 0,7% | 0,1% |
| **Others** | **1%** | 0,0% | 0,2% | 1,0% | 0,0% |

Source: Based on GNPD (Global Database of New Products) results from 2011

In general, it has been found that:

- 72% of shaving preparations are sold in metal packaging, where:
  - ✓ 65,2% are sold using aerosol containers,
  - ✓ 6,9% are sold in different kind of packaging other than aerosol container (tube, bottle, can and others),
- 27% of shaving preparations are sold in plastic packaging,
- 1% of shaving preparations are sold in glass packaging.

The majority of shaving foams and gels are sold in aerosol containers, while shaving soaps and creams are sold in various kinds of plastic packaging. The most common packaging materials used for foams and gels is metal packaging – plated steel and aluminium. For shaving gels also plastics are used, although to a lower extent than metals. Shaving creams are also sold (but less commonly) in aluminium tubes. While for shaving soaps different kinds of packaging are used.

In general, if kinds of packaging and materials used for all shaving preparations are analysed together, it can be seen that plated steel, plated aluminium (see table above) and various plastics are the main materials used, while aerosol container, followed by a tube and, to a much lower extent, bottle are the most common types of packaging.

Shaving foams and gels usually contain **aerosol propellants** to support the fitness for use of the product design. Chloroflurocarbons (CFCs) are not longer used in aerosols as they are prohibited since 1987 by the Montreal Protocol on Substances that Deplete the Ozone Layer[181], but hydrocarbon propellant such as propane and butane are applied instead. These hydrocarbon propellants contribute to formation of low level ozone, although it should be added that aerosol packaging is not the most important source for the formation of low level ozone. Nevertheless, these emissions should be prevented as they contribute to acid rains and to the greenhouse effect. Moreover, ozone can contribute to lung tissue damage and create high incidences of asthma and allergenic reactions in humans.

According to the **Aerosol Dispensers Directive (ADD)[182]**, aerosol dispensers are defined as "non-reusable containers made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state".

According to the current criterion regarding packaging set in the Commission decision for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners[183]: "***sprays containing propellants must not be used***". It is proposed to consider it also for the new concerned products in the product group under study, i.e. to extend the current criterion formulation by the following requirement: "**aerosols containing hydrocarbon propellants must not be used".**

There are alternatives available in the market for foams and sprays, which substitute these hydrocarbon propellants[184] using other propellant such as compressed air. In general stakeholders agreed to set a special requirement about aerosols if shaving products are included in the scope.

Further, some feedback on the potential restrictions of hydrocarbon propellants has been received already from industrial stakeholders along the consultation process. The main points are summarised below:

[181] The Montreal Protocol on Substances that Deplete the Ozone Layer, available online at: http://ozone.unep.org/pdfs/Montreal-Protocol2000.pdf.

[182] Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers, available online at: http://ec.europa.eu/enterprise/sectors/pressure-and-gas/documents/add/index_en.htm.

[183] Commission Decision 2011/383/EU of 28 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:169:0052:0064:EN:PDF.

[184] See e.g. article "AirOpack, a green alternative to aerosol dispensers", available online at: http://www.premiumbeautynews.com/en/AirOpack-a-green-alternative-to,2123?checklang=1.

"Hydrocarbon propellants are VOCs[185]. Different types of VOCs make differing contributions to tropospheric ozone formation. The VOCs used in aerosols have a low potential to create ground-level ozone. VOCs contribute only indirectly to climate change and do not contribute to acid rains. Hydrocarbon propellants in shaving products only present a very minor environmental impact: the potential to create ground-level ozone is low and the total quantity is negligible because the propellant is only present at 5 % w/w.

Furthermore, it must be remembered that an aerosol dispenser may not be refilled (by law). Metal packaging is broadly recycled, but not always specifically into the same packaging. So talking about a minimum recycled content in an aerosol container could be not relevant except if the metal recycling rate could be considered as equivalent to the recycled content.

The EU Ecolabel should not foster innovation in a single direction and thus create market distortions. Simply excluding hydrocarbon propellants will not achieve any significant environmental improvement. It is though proposed to consider e.g. maximum technically feasible % of hydrocarbon propellants to foster innovation. Aerosol dispensers represent the majority of shaving products; excluding hydrocarbon propellants would definitely deter attraction to the EU Ecolabel for this category."

Further feedback on this area is expected and additional information will be collected.
The proposed formulation for discussion is given in Chapter 7, nevertheless additional comments of stakeholders are particularly invited prior to the AHWG meeting.

### 6.3.9 CRITERION 10: Fitness for use

The current formulation of this criterion is as follows:

The product's fitness for use must be demonstrated either through laboratory test(s) or a consumer test.

The test must be in conformity with the guidelines in Appendix I for testing of product efficiency.

***Assessment and verification***:

Report from a laboratory test or consumer test documenting satisfactory efficiency.

**Appendix I**

**Guidelines for performance test**

The product's efficiency of performance can be demonstrated either through a laboratory test or a consumer test. If a laboratory test is employed the producer's own test shall be acceptable. The applicant must, however, demonstrate that the test gives a measure of the product's performance.

If a consumer test is employed the following guidelines must be followed:

[185] Volatile Organic Compounds

A consumer test must include as minimum of 10 people. The consumers must be asked about the product's efficiency compared to a market-leading product. The questions to the consumers must cover at least the following aspects:

1. How well does the product perform in comparison with the market-leading product?

2. How easy is it to apply the desired dosage of the product in comparison with the market-leading product?

3. How easy is it to apply the product to the hair and/or skin in comparison with the market-leading product?

At least 80 % of the consumers must be at least as satisfied with the product as with the market-leading product.

During the 1st AHWG meeting the proposal to consider a more stringent consumer testing was discussed. The criterion on fitness for use addresses currently the aspects of performance, dosage and application. Regarding the issue of dosage found in the current criteria under packaging criterion 9 c) it is now proposed to shift it in the fitness for use criterion within the performance test requirements. A respective amendment is given in the proposal.

Environmental assessment conducted in this study has showed that high percentage of total environmental impact of products is due to the use phase (on average 20.5% of contribution to the overall environmental impact for all investigated products), coming from the consumption of water during the washing action. Some characteristics of the product, such as the ease for being rinsed-off or long-lasting results, would contribute to saving the amount of water consumed during the use phase, minimizing the overall environmental impact of the products. If energy needed to heat the water is included in the studied system, the use stage is responsible for82% of the total environmental impact of the product (for the case of liquid soap, and in similar extent for other products).

The quality of products awarded with the EU Ecolabel is one of important aspects of the scheme, which must be considered in order to prevent creating the image that ecolabelled products are "environmentally friendlier but poor in performance/inefficient". For that reason performance tests should address all important characteristics and functions of the product.

It was discussed whether a more stringent consumer test addressing additionally the below indicated aspects should be required for this product group in the revised criteria set:

- How easy is it to rinse-off the product in comparison with the market-leading product?
- If the product does not cause to consumers any sensitising effects in use and/or after use.

Further issues for consideration were as follows:

- Should a consumer test be different for professional use soaps and household soaps?
- Should the number of people tested be increased (currently 10 people)?
- When a laboratory performance test is provided, manufacturer shall also prove the ease of dosage and application.
- Should, apart from the main function of the product, the performance test make reference to the characteristics with which each product is sold/marketed, i.e. claims (hydrating, moisturizing, softening, etc.)?

In the framework of the consultation process it was discussed that industry does already a lot of tests of their products in order to manufacture competitive and good quality goods. There exist industry guidelines and also common criteria for tests claims including best practices available, which could be used as a support for the EU Ecolabel criteria. Also consumer organisations conduct consumer tests. Nevertheless, there lack EU harmonised testing procedures or methods.

The existing "Practical guidance on methodology for cosmetic claim substantiation"[186] developed and published by Cosmetics Europe (former COLIPA) aims to help "*the cosmetics industry to comply with the applicable European regulations for the efficacy evaluation of cosmetic products*". The document provides an overview of established testing methodologies in the area of cosmetic claims. Various guidelines published are also useful in this area, e.g. EEMCO[187] guidelines relative to instrumental clinical techniques, international guidelines (e.g. ISO, CNE, ICH, etc.).

According to the practical guidance by Cosmetics Europe, different types of experimental studies can be used to provide data on the performance of cosmetic products:

- The sensorial approach (sight, touch, olfaction) by consumers or experts,
- The instrumental approach which favours specific criteria measured using in vivo, ex-vivo or in vitro approaches, which do not reproduce normal conditions of the use of products but allow objective analysis of specific activities.

Due to the absence of harmonized tests, user tests are often used. A consumer test must include a minimum of 10 people and compare efficiency with a referenced market-leading product. At least 80% of the consumers must be satisfied with the product as with the market-leading product.

The use tests by consumers evaluate the consumers' perception of product efficacy and cosmetic properties based on parameters they can observe or feel. There are two main types of use tests[188]:

- Blind use test: Tests without providing any information such as brand, decor, communication which could influence the consumers´ judgement and alter their perception of the effect of the product alone.
- Concept use tests: Product tests combined with elements of communication that help to check whether the concept, the communication and the effect of the product as perceived by the consumers match; information from concept use tests are used to complement that contained in the product efficacy dossier.

However, experimental studies are not restrictive and do not exclude other experimental approaches which must, nevertheless, satisfy the general principles applicable to all scientific procedures described below:

- Methods must be reliable and reproducible.
- The studies should follow a well-designed and scientifically valid methodology according to good practices.
- The criteria used for evaluation of product performances should be defined with accuracy and chosen in compliance with the aim of the test. For example, shampoo test must include at least cleaning performance and usability (dosage and how easy is it to apply the product ).
- Studies conducted on volunteers should respect ethical rules and products tested should have previously undergone a safety investigation.
- Human studies should be conducted on the target population when necessary, defined by strict inclusion/exclusion criteria.

[186] Practical guidance on methodology for cosmetic claim substantiation, Cosmetics Europe, May 2008.
[187] EEMCO Group – European Group for Efficacy Measurements on Cosmetics and Other Topical Products.
[188] Practical guidance on methodology for cosmetic claim substantiation, Cosmetics Europe, May 2008.

- Ex vivo/in vitro tests must be conducted under standardized conditions and their protocols must refer to published and/or "in house" validated methods. Clear descriptions of the methodology should be documented, as well as the statistical analysis of the data. These tests should be conducted in a controlled environment.
- A study protocol must be drawn up, monitored and validated in order to ensure that the operating procedures are correctly followed.
- The test laboratories must have standardized operating procedures. The person conducting the study must:
    - Have the appropriate qualifications,
    - Have the training and experience in the proposed study,
    - Respect for ethical quality and professional integrity.
- Data processing and the interpretation of results must be fair and should not overstep the limits of the test´s significance.

The guideline provided by Cosmetics Europe advice also which information should be included in the test protocols and test reports[189], e.g. information that can assure the reliability of the study.

**Testing requirements (test protocols)**

- General information:
    - Study objective,
    - Product tested and reference product (if used): type of product, quantity of product applied, product to be tested and reference product (s) (if used),
    - Test procedure: timetable and study location,
    - Data management – Data processing – Analysis of results: Calculations carried out and statistical analysis used must be specified. Statistical methods (statistical tests chosen, alpha risk and software used) should be indicated,
    - Equipments and reagents: Description, specification and identification of equipment, usage conditions and relevance of the measurement.
- Specific Information:
    - Evaluation on human volunteers
        - Product tested,
        - Volunteers: Inclusion and exclusion criteria, number of subjects, training and trained panellists for sensorial evaluation tests by experts,
        - Methodology.
    - Ex vivo/ in vitro tests
        - Substrate,
        - Methodology: the number of subjects and tests must be specified. The test planning should be explained with timetable defined.

**Documentation requirements (test reports)**

- General Information:
    - Identification: the sponsor of the study, organisation in charge and address of the laboratories where the tests take place, person responsible for testing (if

[189] The following indications given below are not exhaustive and might not all be relevant depending the test under consideration.

appropriate other investigators involved), product tested (type of product, formula number, batch number or code etc.) and issue date of the report.
- Objective of the test,
- Test schedule: Starting and finishing date,
- Methodology,
- Statistics: Definition of method employed, outcome of statistical analysis and if not stated in the report, justification,
- Results,
- Discussion,
- Conclusion,
- Signatures of the persons responsible for testing: technician, investigator, quality assurance and person responsible for the statistical analysis,
- Summary of the report.

- Specific information:
  - Evaluation on human volunteers: justification of panel choice with regard to specific effects' assessment and demographic criteria,
  - Use tests by consumers: socio-demographic criteria (panel) and presentation of results,
  - Sensorial evaluation tests by trained expert panels: Presentation of results (choice of presentation of results), analysis of the inter-variability of the panel and list of criteria assessed,
  - Evaluation by a professional expert and Instrumental tests: Presentation of results: quantitative data (number of subjects, median, standard deviation, percentages), qualitative data (absolute or relative frequency), method used to assess the observed effect and interpretation of results,
  - Ex Vivo/ In Vitro tests: Presentation of results.

The Cosmetics Europe´s guidelines state also that verification of cosmetic claims should be a component of product development and tests shall address the properties based on which the product is marketed. It is also the background of the Nordic Ecolabelling´s requirements in this respect. The applicant must be able to document that the performance of the product has been evaluated and documented in a relevant manner. Tests should also include the functions for which the product is marketed. This will avoid misguiding information. In accordance with the requirement to include claim substantiation in the cosmetic product information package, a short summary of the technical data supporting the effect claimed should be accessible to the control authorities.

The new Regulation 1223/2009 on cosmetic products[190] introduces a number of important changes to the way cosmetic products are regulated in the EU. The Regulation may restrict the ability of cosmetics companies to use certain claims of their products. The following guidelines apply:

- The labelling and advertising of cosmetic products "shall not be used to imply that products have characteristics or functions which they do not have".
- The Regulation requires the European Commission, in cooperation with the EU Member States, to set up an action plan related to claims, to adopt a list of common criteria for claims. The content of that list may provide restrictions on product claims.

[190] Regulation EC 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:EN:PDF.

- By July 11, 2016, the Commission shall report to the European Parliament on the use of claims on the basis of the common criteria and shall report to the European Parliament on the use of claims on the basis of common criteria and shall take appropriate measures to ensure compliance with those criteria[191].

There was an agreement in the consultation process that if there were claims on the products they should be tested. However, the companies and the Competent Bodies should be given flexibility how to prove and control the compliance with the criterion on fitness for use. The criterion is considered very important for the customers, nevertheless, it must be remembered that of highest importance is that an Ecolabelled product should be distinguished from other products available on the market due to their very good performance from the environmental point of view. The product's quality should be ensured, but is not of primary importance.

The stakeholders discussed also the issue of the link between the performance requirements and the CDV value. The lack of synergy between these concepts was mentioned. It was emphasized that it would be good to have a criterion integrating these issues; nevertheless such a formula has not been developed yet. This issue could be considered further in the next revision of the criteria.

The final revised criteria formulation and the related verification and assessment proposed are given in Chapter 7.

### 6.3.10 CRITERION 11: Information appearing on the eco-label

The current criterion formulation is as follows:

According to Annex III of Regulation (EC) No 1980/2000, Box 2 of the eco-label shall contain the following text:
* Minimal impact on aquatic ecosystems
* Fulfils strict biodegradability requirements
* Limits packaging waste

***Assessment and verification***:
The applicant shall provide a sample of the product packaging showing the label, together with a declaration of compliance with this criterion.

According to Article 8 (3b) of the EU Ecolabel Regulation 66/2010, for each product group, three key environmental characteristics of the ecolabelled product may be displayed in the optional label with text box. The guidelines for the use of the optional label with text box can be found in the "Guidelines for the use of the EU Ecolabel logo" on the website:

http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf.

Depending on the final formulation of the revised criteria, the optional label with text box could contain one or both of the following texts:

- **Fulfils strict environmental requirements on the use of substances, or**
- **Minimized use of substances harmful to the environment**

[191] The progress of these developments should be observed and taken into account in the next criteria revision process.

Due to the fact that few people are aware that consumer products have an environmental impact, some stakeholders agree to reformulate the text with the objective that the customer really feels he does something good for the environment. Based on this idea and to influence consumer behaviour by additional information text on the product packaging, some possible texts could be:

- **"To minimize the environmental impacts of this product apply proper dosage of the product and rationally consume water, in particular hot water"**

This issue will be decided at the 2nd AHWG meeting in Brussels when the final shape of the revised criteria will be discussed and agreed.

## 6.4 ADDITIONAL ISSUES CONSIDERED IN CRITERIA REVISION PROCESS

### 6.4.1 ADDRESSING NANOMATERIALS

One discussion area regarding new requirements for this product group refers to the use of nanomaterials/nanoparticles in the product group under study. Several stakeholders confirmed their interest on this aspect in the 1st AHWG meeting and numerous have explicitly asked in their written feedback to undertake analysis on this issue and evaluate its relevance for the product group under study. The results of this analysis and some general information about nanomaterials/particles and their use in the concerned products are given below.

In accordance with the report "Nanomaterials in consumer products, Availability on the European market and adequacy of the regulatory framework"[192] some materials intentionally manufactured for use as nanoforms are used in cosmetic products.

**Definition of nanomaterials**

In general the term 'nanomaterial' usually refers to 'materials with external dimensions, or an internal structure, measured in nanometres that exhibit additional or different properties and behaviour compared with coarser materials with the same chemical composition[193].

The new Regulation 1223/2009 on cosmetic products give the following definition: 'nanomaterial' means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.

The European Commission[194] defined recently the term nanomaterials as: *a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.*

*In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.*

[192] Nanomaterials in consumer products, Availability on the European market and adequacy of the regulatory framework RIVM/SIR Advisory 11014 (IP/A/ENVI/IC/2006-193), available online at: http://static.sdu.dk/mediafiles//Files/Om_SDU/Fakulteterne/Teknik/NANO/4%20nanomaterials%20in%20consumer%20products_2006.pdf.

[193] Loevestam, G. et al., Considerations on a Definition of Nanomaterial for Regulatory Purposes, European Commission, JointResearch Centre, EUR 24403 EN (2010).

[194] Commission Recommendation of 18 October 2011 On The Definition of Nanomaterial (2011/696/EU), available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF.

*By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.*

The purpose of the definition is to provide unambiguous criteria to identify materials for which specific considerations in their risk assessment must be taken into account. The risks posed by the nanomaterials to the environment and human health should be assessed using the existing risk assessment approach in the EU. Only the results of the risk assessment will determine whether the nanomaterial is hazardous. However, based on the conclusions from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[195], there is still scientific uncertainty about the safety of nanomaterials in many aspects.

In general nanomaterials can be grouped in three categories[196]:

a) Materials that are nanostructured in the bulk of the product
   - One-phase materials (solid product),
   - Multi-phase materials (solid packaging with a liquid product inside).

b) Materials that have nanostructure on the product surface
   - One-phase materials structured on the nanoscale at the surface,
   - Nanoscale thick unpatterned films on a substrate of different material,
   - Patterned films of nanoscale thickness or a surface having nanoscale dimensions.

c) As particles
   - Surface-bound nanomaterials,
   - Nanoparticles suspended in liquids,
   - Nanoparticles suspended in solids,
   - Free airborne particles.

On the basis of available information, soaps, shampoos and hair conditioners can be assigned to the third category.

It is important to mention that the nanomaterials, when used in a product, could be differentiated based on their physical state as embedded to substrate ones and free nanomaterials. This difference is important when exposure to consumers is considered. The consumers are exposed to nano in case of free nanomaterials whereas are not or less exposed in case of embedded nano-ingredients[197]. However, even embedded forms may become free, for example by manipulations or erosion. Therefore, it is critically important to take into account life cycle perspective. One prominent example may be carbon nanotubes, which are mainly embedded in composites and, therefore, exposure during manufacturing and potentially during subsequent manipulation such as recycling may be the principal concern.

[195] SCENIHR (Scientific Committee on Emerging and Newly-Identified Health Risks), The appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials, 21-22 June 2007.

[196] Wijnhoven, S.W.P. et al, Development of an inventory for consumer products containing nanomaterials, final report 070307/2010/580587/SER/D3.

[197] Poland, C.A. et al., Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study, *Nature Nanotechnology* 3, 423 (2008).

The location of the nanomaterial is related with the following exposure categories:

a) **Expected to cause exposure**: when consumers are in direct contact with the products (relevant e.g. for "nanoparticles in liquids" and "airborne particles").

b) **May cause exposure**: Although the nanoparticles in the product are not considered to be released intentionally, they may be released from the product because of wear and tear, e.g. "surface bound nanoparticles".

c) **No expected exposure to the consumer**: Negligible exposure is expected when nanoparticles are encapsulated in the product.

In cosmetic products, nanoparticles can also be divided into two groups[198]:

1) **Soluble and/or biodegradable**: nanoparticles disintegrates upon application to skin into their molecular components (e.g. liposomes, nanoemulsions)

2) **Insoluble particles**: For example $TiO_2$ and/or fullerenes.

**Use of nanomaterials**

Several of the consumer end-products available today use nanomaterials. Examples of applications with end-products containing nanomaterials are:

- Cosmetics and personal care products
- Paints and coatings
- Household products, e.g. for cleaning
- Catalysts and lubricants
- Sports products
- Textiles
- Food and nutrients
- Food packaging and kitchenware
- Consumer electronics

Considering the information available[199], the most important product categories in Europe where nanomaterials are used are expected to be motor vehicles and electronics and computers.

Nanomaterials are developed and used because they have specific physic-chemical properties (such as improved electromagnetic, catalytic, pharmacokinetic and targeting properties, strength, stiffness, stability, etc.) compared to the same material without nano-scale features. In the specific case of personal care products, nanoparticles are claimed to enhance the direct effect on skin and hair, e.g. moisturizing or anti-aging formulations, make-ups, hair conditioners, protection of skin (e.g. UV-filters in sunscreens) or to have antibacterial properties. Nanomaterials used in cosmetics (in sunscreens, skin care and toothpaste) are, in essence, nanoemulsions and nanopigments[200]. Nanoemulsions are macroscopic preparations containing oil and water droplets to increase the content of nutritious oils while preserving the transparency and the lightness of the formulas.

[198] SCCP (Scientific Committee on Consumer Products), 18 December 2007, Safety of nanomaterials in cosmetic products.

[199] Nanomaterials in consumer products, Availability on the European market and adequacy of the regulatory framework RIVM/SIR Advisory 11014 (IP/A/ENVI/IC/2006-193): http://static.sdu.dk/mediafiles//Files/Om_SDU/Fakulteterne/Teknik/NANO/4%20nanomaterials%20in%20consumer%20products_2006.pdf.

[200] Cosmetics Europe website: http://www.colipa.eu/safety-a-science-colipa-the-european-cosmetic-cosmetics-association/products-and-ingredients/nanotechnology-.html.

Some nano-specific product databases, listing products containing nanoforms, are indicated below:

- **Woodrow Wilson database** (The project on Emerging Nanotechnologies): The American Woodrow Wilson database was the first publicly available on-line inventory (since 2005) of nanotechnology-based consumer products supported from US EPA. The database is free of charge and available on the website:

  http://www.nanotechproject.org/inventories/consumer/.

- **ANEC-BEUC 2010 inventory**. The ANEC/BEUC[201] 2010 inventory is a European inventory of products available to consumers with a claim of containing nanomaterials. The inventory is a Microsoft Excel table available free of charge on: www.beuc.org.

- **Online database of German Environmental NGO 'BUND'**. This product database focuses on consumer products claimed to contain nanomaterials in Germany. It is accessible on the BUND website free of charge:

  http://www.bund.net/nc/themen_und_projekte/nanotechnologie/nanoprodukt datenbank/produktsuche/.

Products containing nanomaterials are already in use and it is expected that their sales will grow by 2015[202]. However, it is not possible to obtain a complete overview of all consumer products containing nanomaterials since:

- There are products with the claim "nano" on the market that do not contain nanomaterials.
- Not all producers advertise their products as such, as at present there is no legal obligation to inform consumers or label products that contain nanomaterials. With the New Regulation 1223/2009/EC any nanomaterial present in the cosmetic products should be named on the ingredient list, with "(nano)" after the ingredient name.
- The list of products containing nanomaterials is fast growing.

Therefore, the below table probably does not contain all personal care products available on the market but only includes products which contain nanomaterials based on the information obtained from databases or internet sites.

**Table 33. Examples of personal care products containing nanomaterials**

| CATEGORY | SUB CATEGORY | EXAMPLES OF PRODUCTS CONTAINING NANOMATERIALS |
|---|---|---|
| **PERSONAL CARE** | SUN COSMETICS | *Sunscreen lotions, sunscreen creams, sunscreen oils*, sunscreen powder, hair protection spray |
| | BABY CARE PRODUCTS | Baby sunscreen, pacifiers |
| | HAIR CARE | **Shampoo, conditioner**, hair gel/styling products, hair regrowth products |
| | SKIN CARE | *Razors, facial masks*, facial steamers, *skin creams/lotions/oils/sprays/powders*, deodorant, whitening lotions, *fragrances*, wet wipes, **soaps**, body |

[201] ANEC: European Association for the Coordination of Consumer Representation in Standardisation, BEUC: Bureau Européen des Unions de Consommateurs.
[202] http://ec.europa.eu/environment/chemicals/nanotech/index.htm.

| | | |
|---|---|---|
| | | wash, shower gels, foot care, **shaving soap**, etc. |
| | ORAL HYGIENE | *Toothpaste*, mouth wash, teeth cleaner, tooth brush |
| | MAKE-UP AND NAIL CARE | Make-up instruments and brushes, make-up removal and cleaning products, lipstick, eye shadow, mascara, make-up base and foundations, blush |
| | OVER THE COUNTER HEALTH PRODUCTS | *(Sticking)plasters, home pregnancy tests*, thermal patches, joint and muscle pain relief cream, *condoms*, mosquito repellent |

Source: Nanomaterials in consumer products, Availability on the European market and adequacy of the regulatory framework RIVM/SIR Advisory 11014 (IP/A/ENVI/IC/2006-193)

It is very difficult to gain a good overview about nanomaterials used in consumer products due to lack of information as manufacturers of consumer products containing nanomaterials until now were not obligated to label or notify if their products contain nanomaterials[203]. Industrial association also states that no information on the extent of use of nanoforms in this particular product group is available. Studies were conducted for the entire cosmetic product group, but the results obtained cannot be linked to specific product categories.

However, based on the data collected in the RIVM/SIR project[204], in the following table several nanomaterials known to be used in cosmetics and personal care products are indicated.

**Table 34. Nanomaterials known to be used in cosmetics and personal care products**

| NANOMATERIAL | EXAMPLES OF CONSUMER PRODUCTS |
|---|---|
| **METAL OXIDES** | |
| **Titanium dioxide ($TiO_2$)** | Sunscreen |
| **Zinc dioxide ($TiO_2$)** | Sunscreen/Tanning oil, lip treatment, lipstick |
| **Iron oxides ($FeO$, $Fe_2O_3$, $Fe_3O_4$)** | Lipstick |
| **METALS** | |
| **Gold (Au)** | Home pregnancy test, catalytic applications |
| **Nickel (Ni)** | Wound dressings |
| **ORGANIC NANOMATERIALS** | |
| **Nano-vitamins** | Bronzer or highlighter, eye shadow, glitter, acne treatment, facial cleanser, facial moisturizer, sunscreen or tanning oil |
| **Fullerenes (e.g $C_{60}$)** | Anti-aging, facial moisturizer and around-eye cream. |
| **Nanospheres, nanosomes, liposomes, delivery systems and capsules filled with e.g arnica, barley-germ, wheat-germ, germal ii, lyphazome, retinol, alpha-bisabolol, calendula, centella asiatica, ginseng, witch hazel, sodium lactate, urea, hyaluronic acid, fulvic acid, vitamins (pro-vitamin b5, vitamin a, vitamin e)** | Around-eye cream, facial anti-aging, moisturizing products, nail treatment products, body firming lotion, anti-itch or rash cream, skin fading or lighting products, hair-loss treatment, body wash, sunscreen and tanning oil and after sun products. |

Source: RIVM/SIR, 2007[204]

[203] With the New Regulation 1223/2009/EC any nanomaterial present in the cosmetic products should be named on the ingredient list, with "(nano)" after the ingredient name.

[204] Nanomaterials in consumer products, Availability on the European market and adequacy of the regulatory framework RIVM/SIR Advisory 11014 (IP/A/ENVI/IC/2006-193), 2007.

Some other nanomaterials, such as nanosilver, are also known to be used in consumer products including cosmetics and soaps due to their antibacterial properties[205].

**Concerns related to nanomaterials**

In a nutshell the concerns related to nanomaterials are linked to the so called "nanomaterials paradox", i.e. desired effects versus unexpected hazardous impact on health. The very same properties that are desirable and potentially useful from a technological perspective, such as the high degree of surface reactivity, are also the properties that may give rise to unexpected and undesired effects. It can be noted, however, that the nanomaterials paradox is not unique to nanomaterials as this principle applies also to pharmaceuticals.

Cosmetic products are in direct contact with humans and, consequently, the main route for exposure to nanomaterials in cosmetics is via the skin. According to the opinion of the Scientific Committee on Consumer Products (SCCP)[206], and their later work released recently in 2012[207] there is insufficient knowledge on: hazard identification, exposure, uptake, absorption and transport across membranes, accumulation in secondary target organs, possible health effects, translocation of nanoparticles via the placenta to the foetus and in vitro and in vivo test methods validated or optimized for nanomaterials. The current methods used in REACH to assess the toxicological and ecotoxicological risk may not be adequate to evaluate the risks related to nanomaterials. Consequently, there is a lack of knowledge regarding the damage nanomaterials may cause.

However, European Chemical Agency is working on this issue and developments are expected in the future (see also the section below). As a general rule, it has been discussed avoiding treating the nanomaterials as hazardous a priori, but to investigate them case by case using the same approach as for all other chemical substances (e.g. risk assessment). When dealing with nanomaterials in other EU Ecolabel product group, another problem -relevant also for this product group- we were confronted with was the lack of legislative obligations to evaluate substances put on the market in very low quantity. The compromise found to overcome this barrier is the request, in the product criteria, to prove that substances in the products do not meet the criteria for being classified on the basis, as a minimum, of information requested by Annex VII of REACH.

**Legislative framework**

REACH is the legislation applicable to the manufacturer and/or importer, placing on the market and using substances on their own, in preparations or in articles. Currently, nanomaterials are covered by the definition of a “substance” under REACH, although there is no explicit reference to nanomaterials and the same REACH provisions apply to all chemical substances. REACH places responsibility on industry to manage the risks that chemicals may pose to human health and environment, as well as to provide safety information that should be passed down the supply chain.

[205] ANEC/BEUC inventory of products claiming to contain nano-silver particles available on the EU market, June 2012.
[206] Scientific Committee on Consumer Safety, Guidance on the safety of nanomaterials in cosmetics, June 2012, available online at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_005.pdf
[207] Scientific Committee on Consumer Products (SCCP), 18 December 2007, Safety of nanomaterials in cosmetic products.

Until recently ECHA[208] has not given any specific guidance concerning nanomaterials. In 2009 the Commission launched a REACH Implementation Project on Nanomaterials (RIPoN) to provide advice on key aspects of REACH with regard to nanomaterials concerning Information Requirements (RIPoN 2) and Chemical Safety Assessment (RIPoN 3)[209]. Based on the results, on 30 April 2012 ECHA published three new appendices updating Chapters R. 7a, R. 7b and R. 7C of the Guidance on Information Requirements and Chemical Safety Assessment. These three new appendices are recommendations for registering nanomaterials and the adequacy of test methods. Consequently at the end of this year and in advance of the next registration deadline, i.e. 30 May 2013, ECHA plans to update the guidance for registration of substances in nanoform and proposal for additional specific for nanomaterials information requirements. A third report of the RIPoN project relates to Substance Identity but it was not possible to reach consensus amongst the expert on the recommendations. Some adjustments are still needed in REACH legislation to assess and control the risks of nanomaterials.

As a result, manufactured nanomaterials are expected to undergo similar tests like other chemicals. Therefore, assuming that they are not classified with the restricted risk phrases, they will then fulfil the requirements of the new Ecolabel criterion on the use of hazardous substances (the criterion which is based on article 6.6 and 6.7 of Ecolabel Regulation 66/2012) and would be allowed.

Apart from the previously mentioned issues, works are being conducted with regard to the evaluation of the legislative framework for controlling and appropriate disposal of nanomaterials at the end of life phase. A recent study of MILIEU and Amec[210] examined the legislative framework for controlling nanomaterial release. It was noted that limitations in both exposure and hazard data for specific nanomaterials cause difficulties in assessment of the potential risks which nanomaterials can cause. The precautionary principle for the control of nanomaterials was emphasized by the authors. Another study[211] suggests that more data collection and research should be done in the area of waste disposal for nanotechnology to ensure that appropriate means of control are in place.

Nanomaterials in cosmetic products are addressed in Article 16 of the New Cosmetic Regulation 1223/2009/EC[212]. The Regulation takes into account the latest technological developments, including the possible use of nanomaterials. The Article 16 of the Regulation refers explicitly to Nanomaterials. Due to its relevance its text is given below:

Article 16 Nanomaterials

1. For every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured.
2. The provisions of this Article do not apply to nanomaterials used as colorants, UV-filters

[208] ECHA, European Chemical Agency: http://echa.europa.eu/.

[209] Specific Advice on Fulfilling Information Requirements for Nanomaterials under REACH (RIP-On 2) – Final Project Report, Hankin S.M., Peters S.A.K., Poland C.A., Foss Hansen S., Holmqvist J., Ross B.L., Varet J. and Aitken R.J, 01 July 2011. For further details see: http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon2.pdf and Specific Advice on Exposure Assessment and Hazard/Risk Characterisation for Nanomaterials under REACH (RIP-On 3) – Final Project Report. Aitken, R.A, Bassan, A., Friedrichs, S., Hankin, S.M., Hansen, S.F., Holmqvist, J., Peters, S.A.K., Poland, C.A., Tran, C.L. 7 July 2011. For further details see: http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon3.pdf.

[210] Review of Environmental Legislation for the Regulatory Control of Nanomaterials, Amec, September 2011, available online at: http://ec.europa.eu/environment/chemicals/nanotech/pdf/review_legislation.pdf.

[211] BIO Intelligence Service (2011), Study on coherence of waste legislation, Final report for the EU (DG ENV), 2011

[212] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF.

or preservatives regulated under Article 14, unless expressly specified.

3. In addition to the notification under Article 13, cosmetic products containing nanomaterials shall be notified to the Commission by the responsible person by electronic means six months prior to being placed on the market, except where they have already been placed on the market by the same responsible person before 11 January 2013.

   In the latter case, cosmetic products containing nanomaterials placed on the market shall be notified to the Commission by the responsible person between 11 January 2013 and 11 July 2013 by electronic means, in addition to the notification in Article 13.

   The first and the second subparagraphs shall not apply to cosmetic products containing nanomaterials that are in conformity with the requirements set out in Annex III.

   The information notified to the Commission shall contain at least the following:

   (a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI;

   (b) the specification of the nanomaterial including size of particles, physical and chemical properties;

   (c) an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year;

   (d) the toxicological profile of the nanomaterial;

   (e) the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products;

   (f) the reasonably foreseeable exposure conditions.

   The responsible person may designate another legal or natural person by written mandate for the notification of nanomaterials and shall inform the Commission thereof.

   The Commission shall provide a reference number for the submission of the toxicological profile, which may substitute the information to be notified under point (d).

4. In the event that the Commission has concerns regarding the safety of a nanomaterial, the Commission shall, without delay, request the SCCS to give its opinion on the safety of such nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable exposure conditions. The Commission shall make this information public. The SCCS shall deliver its opinion within six months of the Commission's request. Where the SCCS finds that any necessary data is lacking, the Commission shall request the responsible person to provide such data within an explicitly stated reasonable time, which shall not be extended. The SCCS shall deliver its final opinion within six months of submission of additional data. The opinion of the SCCS shall be made publicly available.

5. The Commission may, at any time, invoke the procedure in paragraph 4 where it has any safety concerns, for example due to new information supplied by a third party.

6. Taking into account the opinion of the SCCS, and where there is a potential risk to

human health, including when there is insufficient data, the Commission may amend Annexes II and III.

7. The Commission may, taking into account technical and scientific progress, amend paragraph 3 by adding requirements.

8. The measures, referred to in paragraphs 6 and 7, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

9. On imperative grounds of urgency the Commission may use the procedure referred to in Article 32(4).

10. The following information shall be made available by the Commission:

(a) By 11 January 2014, the Commission shall make available a catalogue of all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. This catalogue shall be regularly updated thereafter and be made publicly available.

(b) The Commission shall submit to the European Parliament and the Council an annual status report, which will give information on developments in the use of nanomaterials in cosmetic products within the Community, including those used as colorants, UV-filters and preservatives in a separate section. The first report shall be presented by 11 July 2014 The report update shall summarise, in particular, the new nanomaterials in new categories of cosmetic products, the number of notifications, the progress made in developing nano-specific assessment methods and safety assessment guides, and information on international cooperation programmes.

11. The Commission shall regularly review the provisions of this Regulation concerning nanomaterials in the light of scientific progress and shall, where necessary, propose suitable amendments to those provisions.

The first review shall be undertaken by 11 July 2018.

Further, Article 30 of the Regulation states that "At present, there is inadequate information on the risks associated with nanomaterials. In order to better assess their safety the SCCS should provide guidance in cooperation with relevant bodies on test methodologies which take into account specific characteristics of nanomaterials." Further, in Article 31 it is indicated that "The Commission should regularly review the provisions on nanomaterials in the light of scientific progress."

According to Article 19, any nanomaterial present in the cosmetic products should be named on the ingredient list with “(nano)” after the ingredient name and the responsible person should notify to the Commission six months before placing their product on the market, except where they have already been placed on the market by the same responsible person before 11 January 2013.

The Cosmetic Products Notification Portal (CPNP)[213] is the on-line notification system created to implement Articles 13 and 16 of Regulation 1223/2009 on cosmetic products. It comprises:

- Information on whether the cosmetic product contains nanomaterial and the potential exposure conditions;
- Detailed information on the nanomaterials used in the product. This information is only available to the European Commission. In case that the Commission has concerns regarding the safety of a nanomaterial, the Scientific Committee on Consumer Safety (SCCS) will be requested to give its opinion on the safety of such nanomaterial for use in the cosmetic product.

From January 2012, cosmetic products responsible person have the possibility to notify through CPNP. From July 2013, the use of CPNP will become mandatory for cosmetic products responsible persons and distributors.

It can be seen that the issue of nanomaterials used in cosmetic products is addressed in the current legislation; nevertheless, also the lack of scientific evidence regarding their use and related impacts is indicated.

**Input from stakeholders**

The issue of using nanomaterials is a difficult subject to assess due to lack of sufficient evidence and knowledge. Although they are already in use for several years, still a lot of research is necessary to build firm position towards their application, particularly from the environmental and health impact point of view. Therefore also during the AHWG meeting this issue was discussed and many stakeholders' comments have been received as written feedback. Some stakeholders opted for treating nanomaterials/particles as any other chemicals and set requirements based on hazardous properties. In this case, only nanomaterials that have been risk assessed according to REACH would be allowed. Other stakeholders proposed to exclude nanomaterials in the EU Ecolabel based on the precautionary principle and as long as compliance with the general safety requirements on chemicals cannot be proven. There were also requests to exclude at all nanomaterials/particles insoluble or biopersistent, due to the fact that at present the regulatory requirements are not sufficient for the voluntary labelling scheme and secondly nanomaterials are not adequately regulated by REACH (it is documented among others in the reports published of the REACH Implementation Project on Nanomaterials (RIPoNs)).
It was also pointed out that several definitions of the term “nanomaterial” are available in the EU (e.g. in the Cosmetics Regulation, the Biocidal Products Directive, the Food Labelling Directive and other) and emphasized that a criterion restricting nanomaterials would, therefore, be difficult to set and that checking its compliance would "pose considerable practical difficulties as no harmonized and easy to use methods are available to quantify the presence of nanomaterials in complex matrices like cosmetic products".

In accordance with information collected very low percentage of products under study contains nanomaterials (see below table).

[213] Cosmetic Products Notification Portal: http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/cpnp_user_manual_en.pdf.

**Table 35. Number of products analysed containing nanomaterials**

| Product group | Number of products analysed | % of products containing nanomaterials | Type of nanomaterials | Function |
|---|---|---|---|---|
| Liquid soap | **20 362** | **0,01%** | - Nano-lactysome<br>- Unknown | Unknown<br>Antibacterial protection |
| Solid soap | **4 183** | **0,02%** | - Nano gold | Nanotechnology which enables micro elements of natural silk to penetrate in deep skin layers |
| Shampoo | **13 188** | **0,02%** | - Nano-hydrasphere<br>- Nano particles | Hydration volumizing<br>Restore and repair hair damaged by colouring or heat styling |
| Hair conditioner | **5 327** | **0,02%** | - Nano-hydrasphere | Nano-hydration for dry and damaged hair |
| Shaving products | **1 965** | **0%** | - | - |

Source: Elaborated based on GNPD (Global Database of New Products) results for 2011

Based on the current lack of evidence regarding the potential impacts of nanomaterials there are split views among the stakeholders regarding setting any restrictions. It should be further emphasized that the products in which are used intentionally manufactured nanomaterials constitute very low share of the market and there is no trend identified for vast increase in the coming years, which reduces the relevance of this issue in the current criteria revision. The focus should be given to the main environmental concerns.

Sharing the concerns of the stakeholders it is proposed that in the revised criteria (see p. 6 of the decision draft[214]) the full formulation of the product should be given indicating the form of the ingredients contained, regardless of the concentration; which will cover also the ingredients in nano-forms. As the new Cosmetics Regulation requires already indicating the presence of ingredients in nano-forms on the label of the product since 2013, it is considered redundant to set additional requirements regarding user information in the Ecolabel. What could be proposed is that the applicant shall provide to the Competent Bodies all the information required in the new Cosmetics Regulation (as given above in this section) in order to complete the information of the product dossier.

[214] "The full formulation indicating trade name, chemical name, CAS no. and INCI designations, DID no., the ingoing quantity including and excluding water, the function and the form of all organic and inorganic ingredients (regardless of concentration) in the product must be submitted to the competent body".

Summarising, due to very low percentage of products containing nanomaterials in this product category, this issue does not seem to be of high importance for this product group; nevertheless, the new developments should be followed, and if necessary, further restrictions can be proposed if more evidence is available and testing methods are established. It is proposed that research on this area should be undertaken in the next criteria revision process.

### 6.4.2 ENERGY CONSUMPTION IN MANUFACTURING

Another issue proposed in a first stage of the revision process for consideration is a new requirement referred to applying limit values for energy consumption in product's manufacturing phase. Manufacturing of cosmetic products is an important part of their life cycle, although it should be mentioned, that it has lower contribution to the overall environmental impacts than other stages such as use, disposal to water or packaging. According to the LCA carried out in the technical analysis of this revision process, it accounts for an average 11.5% of the total environmental impact of the products under study. Manufacturing impacts are generated mainly due to energy consumption during manufacturing processes.

In the document "Good sustainability practice (GSP) for the cosmetics industry" [215] some good practices have been identified to improve energy efficiency of the manufacturing processes (among others in cosmetic industry). Among them there are the following practices:

- Reducing temperature during manufacturing or filling by application of new technologies such as cold emulsification technology,
- Exploring options for optimisation of cleaning procedures with the aim of using less washing water and/or reducing its temperature,
- Considering insulation measures for buildings (walls, windows) to reduce energy consumption for heating and air conditioning; the same refers hot water piping systems,
- Exploring options for optimisation of production planning, e.g. sequence of batches produced using same equipment ( improved sequence may save some washing steps),
- Considering replacement of old equipment by new, energy efficient electrical devices (e.g. pumps, extruders),
- Considering 'energy recycling' from hot waste water or air.

According to the sustainability reports of individual companies, many initiatives have been already developed and undertaken to reduce environmental impact of manufacturing, mainly in terms of water and energy consumption. Some manufacturers publish each year their energy consumption values in these reports. Data gathered show that these companies have cut their energy consumption in production processes and consequently the greenhouse gases emissions due to this consumption. Some examples of manufacturers which have reached energy savings in production phase are given in Table 36. From the reports analysed it can be seen that the main manufacturers achieved energy and $CO_2$ emissions reduction of around 20% in the last years.

Nevertheless, these reports refer to companies and they do not give separate data regarding different products, so it is not possible to analyse specific data for soaps, shampoos and hair conditioners production processes. For establishing limit values in Ecolabel criteria, data on energy consumption for manufacturing of each kind of product would be needed.

[215] Good sustainability practice (GSP) for the cosmetics Industry, Cosmetics Europe (former COLIPA), available online at: colipa.eu/downloads/3704.html.

**Table 36. Energy consumption and energy saving in manufacturing process**

| COMPANY | Energy GJ/tonne production | | | Greenhouse gases kg CO2/t production | | |
|---|---|---|---|---|---|---|
| | **2011** | **2010** | **Reduction achieved** | **2011** | **2010** | **Reduction achieved** |
| Unilever | 1.71 | 1.72 | | 117.4 | 133.6 | |
| P&G | - | - | -16% of energy consumption from 2007 to 2011 | - | - | -12% of $CO_2$ emissions from 2007 to 2011 |
| L'Oreal | - | - | Total energy consumption –decreased of 8.1% between 2010 and 2011<br><br>Energy use per finished product: 18% decrease (2006-2011) | - | - | 29,8% absolute reduction in $CO_2$ emissions since 2005 |
| Colgate-Palmolive | - | - | -8.6% of energy consumption achieved from 2002 to 2010 | - | - | Reduced per-ton manufacturing-related greenhouse gas emissions by 21% from 2002 to 2010 |
| Beiersdorf | - | - | Reduction of energy consumption of 32% from 2005 to 2011 | - | - | Reduction of indirect $CO_2$ emissions of 25% from 2005 to 2011 |

Sources: own work based on information from reports indicated in footnote[216]

In the first proposal sent out (1st questionnaire) only 35% of the stakeholders consulted agreed on this proposed requirement on energy consumption. General comments were that such requirement was very difficult to set up (especially for small companies) and it would increase complexity for little added value, because the energy consumption in production is very limited compared to the use phase. In the LCA conducted in the revision process[217], it was shown that if energy needed for heating water during use phase was included in the analysis of liquid soaps, the use stage accounts for 82% of the total impact of the liquid soaps and the main impacts are related to non-renewable energy use and global warming.

During the 1st AHWG meeting, the industry indicated that it would be very difficult to set requirements on the production processes of specific products. Other stakeholders mentioned also that such a criterion would be difficult with respect to proving the compliance, particularly for small producers. In general there was an agreement that verification would be problematic, also for competent bodies. As it has been demonstrated that the industry is already active in reducing the energy and water consumption (as they are important for them cost factors), thus, it has been

[216] Cosmetics Europe website: http://www.cosmeticseurope.eu/about-cosmetics-europe/cosmetics-europe-membership/active-corporate-members.html.
UNILEVER website: http://www.unilever.com/sustainable-living/greenhousegases/performance/index.aspx.
LOREAL website: http://www.sustainabledevelopment.loreal.com/DD/media/pdf/LOrealRDD2011_GRI_Environment.pdf.
COLGATE website: http://www.colgate.com/Colgate/US/Corp_v2/LivingOurValues/Sustainability_v2/Sustainability_Report_2011.pdf#page=7
BEIERSDORF website: http://www.beiersdorf.com/Sustainability/Our_Commitment/GRI_Index.html.

[217] For details see the revised version of the Technical Background report, available online at: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

proposed to agreed on other criteria areas, which can be better addresses through Ecolabel criteria for this product group.

As conclusion, a criterion regarding energy consumption in manufacturing processes is not proposed to be set in this revision. Saving impact potential in not very elevated and it would be difficult for manufacturers to prove the compliance with the requirement (especially for small companies) as well for competent bodies to verify it.

### 6.4.3 SUSTAINABLE RENEWABLE-SOURCED INGREDIENTS

A future criterion regarding use of renewable ingredients in order to limit the use of fossil fuel based ingredients and to promote vegetable based ingredients was in a first stage proposed for consideration. This proposal was discussed with stakeholders during the 1st AHWG meeting.

During last years environmental concerns related to the use of fossil based ingredients versus vegetable based ingredients has arisen. This issue is relevant considering the future limitations on fossil fuels and the concern of global warming, related directly to the use and the combustion of fossil fuels.

Nevertheless, as discussions and different studies about possibilities of substitution of non-renewable ingredients indicate, some issues on economic and ecological impacts of vegetable ingredients' production have to be taken into consideration in this respect.

In accordance with a study conducted by Procter & Gamble for the case of surfactants, comparisons between synthetic and petrochemical surfactants have been done, and it has been found that a total substitution of petrochemical by oleochemical may be not recommended for several reasons given below[218]:

- The wide range in consumer needs (wash conditions) would be more difficult to be met with oleochemical surfactants alone.
- Data from biodegradation, removal by sewage treatment, toxicity and LCA studies show that petrochemical and oleochemical surfactants are of comparable environmental quality.
- Replacement of petrochemical by oleochemical surfactants would not lead to any significant reductions in water or air emissions, nor would it reduce energy consumption across the life cycle of the surfactants.

In the revision of the Nordic Ecolabel for cosmetic products of 2011[219], the possibility of limiting the amount of non-renewable materials was discussed. But finally it was decided not to set general requirements regarding renewable raw materials, only a voluntary requirement was set. It was concluded that many aspects need to be considered, e.g. energy consumption during production of the raw materials, comparison between the extraction and transportation of renewable and non-renewable materials. Moreover, the difficulty of ingredients traceability was emphasized by manufacturers. Consumers and licensees indicated a wish for Nordic Ecolabelling to expand this area and consider the issue of renewable raw materials in the future, but it was concluded that it was necessary to investigate the matter further ahead of future revisions**.**

[218] Procter & Gamble, Natural and Synthetic Surfactants - Which one is better?, available online at: http://www.scienceinthebox.com/en_UK/programs/natural_synthetic_en.html.
[219] Nordic Ecolabelling Cosmetic products 090 Background document – 16 February 2011.

There is currently not much experience with promoting renewable raw materials within the EU ecolabelling of chemical products. In the EU Ecolabel criteria for Lubricants[220] there is a requirement regarding the amount of renewable oil. As verification the applicant shall provide the competent body with a declaration of compliance with this criterion.

In other EU Ecolabel product groups' revisions decided not to set this kind of criteria. It was stated that for renewable raw materials, sustainability requirements are expected to be difficult for many manufacturers to fulfil due to challenges of procurement of relevant documentation, especially since raw materials are often mixtures of substances originating from different sources.

One of the challenges businesses are facing in terms of actual using sustainable palm oil in products is the complexity and lack of transparency in the supply chain. This difficulty could lead to increase in use of non-renewable raw materials compared to the situation today, which is not desirable from an environmental point of view[221].

Similarly, from some stakeholders' written feedback received after the 1st AHWG meeting it has been concluded that promoting vegetable based ingredients and limiting the use of fossil fuel based ingredients is not feasible at the moment. They stated that this proposal should be deeply driven by scientific based arguments like Sustainable and Life Cycle approaches. This is the purpose of some projects such as ERASM LCA project, which will update some previous exercises carried out in 1995[222] that showed no differences between oleo-based surfactants and petrochemical surfactants.

As conclusion, **criterion promoting vegetable-based ingredients against the use of fossil-based ingredients** is not proposed to be set in this revision process, as environmental advantages of these ingredients along their Life Cycle are not proved in many cases and it need further scientific-based investigation. Moreover the compliance of this criterion will be difficult to prove and to verify.
But it is an issue that Ecolabel should take into consideration for future revisions following the advances in LCA related studies.

**Sustainable sourcing of vegetable oil/palm oil**

Although no specific criteria promoting vegetable-based ingredients are proposed, in the product group studied, high percentage of products uses already ingredients derived from vegetable oils.

During the 1st AHWG meeting some stakeholders expressed their concern on the issue of sustainable management in this area, especially for palm oil plant based ingredients, which is the most commonly used oil in this product group. Discussions were held about the feasibility of setting a criterion on sustainable sourcing of materials to guarantee that vegetable oil ingredients used in the product come from sustainable managed plantations. Some stakeholders supported the proposal of having a criterion on sustainable sourcing of palm oil and mentioned the voluntary move in the industry towards sustainable sourcing of palm oil, as this subject gains more and more customer

[220] Commission Decision 2011/381/EU of 24 June 2011on establishing the ecological criteria for the award of the EU Ecolabel to lubricants, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:169:0028:0039:EN:PDF.
[221] Revision of Ecolabel Criteria for Laundry Detergents 2008-2010, Background report, available online at: http://ec.europa.eu/environment/ecolabel/ecolabelled_products/categories/pdf/laundry/final_draft.pdf .
[222] Stallmans M. et al, European Life Cycle Inventory for Detergent Surfactants Production, Tenside Surf. Det. 32 (1995) 2, available online at: http://www.lasinfo.org/reports/eu_life_cycle_inv_deterg_surfact_prod.pdf.

interest and concern. Other stakeholders added that there are many issues which should be taken into account in this respect and it could be a good impulse for the Ecolabel to start addressing ethical issues in the scheme. Nevertheless, it was also said that setting requirements for renewable raw materials, which are difficult to meet and to document, could result in unintended promotion of synthetically produced ingredients. As conclusion further information was requested in the view of the new proposal to be discussed in the second AHWG meeting.

Some European regulations and schemes have started to set criteria in this area. For example the Nordic Ecolabel considered the "Possibility to set obligatory requirements in respect of sustainability and sourcing of raw materials from renewable sources – certified raw materials and certified organic raw materials". No obligatory requirement is set though, as it was considered that more research is needed.

In the European Union, under the Renewable Energy Directive (RED)[223], only those vegetable oils that have been verifiably certified as sustainable can receive state support for energy use and may be counted towards national renewable energy targets.

Vegetable Oil is an expressed oil of vegetable origin consisting primarily of triglycerides of fatty acids. In cosmetics and personal care products, Vegetable Oil and Hydrogenated Vegetable Oil are used in the formulation of bath products, cleansing products, eye makeup, fragrances, foot powders, facial makeup, personal cleanliness products, suntan products, and other skin products. Driven by the increasing global demand for edible oils, in the past few decades there have been observed rapid expansion in the production of two major edible oils; soy oil in South America and palm oil throughout the tropics and stretching into the sub-tropics.

Compared with the other major oil crops – rapeseed, soy and sunflowers – the palm oil is the highest-yielding provider of vegetable oil worldwide[224]. Elaeis Guineensis (Palm) Oil, Elaies Guineensis (Palm) Kernel Oil, Hydrogenated Palm Oil and Hydrogenated Palm Kernel Oil are oils obtained from the palm tree, *Elaeis guineensis*. In cosmetics and personal care products, these palm oil ingredients are used in the formulation of skin care products, makeup and suntan products. Elaeis Guineensis (Palm) Oil, Elaies Guineensis (Palm) Oil, Hydrogenated Palm Oil and Hydrogenated Palm Kernel Oil are primarily used as skin conditioning agents - occlusive. The Hydrogenated Palm Oil ingredients may also be used as viscosity increasing agents[225]. Several ingredients used for soaps, shampoos and conditioners such as elaeis guineensis, sodium lauryl sulphate, cetyl alcohol, stearic acid, isopropyl and other palmitates, steareth-2, steareth-20 and fatty alcohol sulphates, may be derived from palm oil.

According to the Roundtable on Sustainable Palm Oil (RSPO) information, between 1990 and nowadays, the area under palm-oil cultivation has increased by about 43% – most of this increase being in Malaysia and Indonesia. This fact caused the conversion of large areas of forests with high ecological value threatening the rich biodiversity of these ecosystems.

Palm oil cultivation can generate positive effects on the income and livelihood of farming families and hence on development in rural areas. Despite these favourable characteristics, it can contribute

[223] Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC.

[224] Palm Oil – sustainability is possible! Promotion and certification of smallholders helps sustainable palm oil production. Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. http://www.giz.de/Themen/de/SID-77EE5142-FCBBA49E/dokumente/2011giz-en-sustainable-palm-oil-production.pdf.

[225] http://www.cosmeticsinfo.org/ingredient_details.php?ingredient_id=293.

to negative impacts such as destruction of rainforests, extinction of endangered species, displacement of small farmers and giant monoculture plantations. So palm oil has environmental benefits provided it is produced sustainably.

Regarding certification, RSPO is the main scheme of initiatives that aims to promote the growth and use of sustainable vegetable oils. Similar initiatives regarding other renewable products, e.g. soya beans (Round Table on Responsible Soy (RTRS)) and sugar cane, are currently being developed. Some producer countries are being developing their own certificates for palm oil such as Malaysia Sustainable Palm Oil (MSPO) certification and the mandatory Indonesian Sustainable Palm Oil (ISPO) certification. All accepted certifications should prove compliance with the ISO Guide 65/66.

The Roundtable on Sustainable Palm Oil is the most important international initiative on sustainably certified palm oil. RSPO is a not-for-profit association that unites stakeholders from seven sectors of the palm oil industry - oil palm producers, palm oil processors or traders, consumer goods manufacturers, retailers, banks and investors, environmental or nature conservation NGOs and social or developmental NGOs - to develop and implement global standards for sustainable palm oil. The members of the RSPO account for roughly 50% of global palm oil production and also include the most important buyers and the processing industry. In July 2010 there were already two million tonnes of RSPO-certified palm oil available on the world market, with an upward trend. These data indicate that the availability of certified palm oil is sufficient and it is expected to be increased in the following years thanks to the commitment of industry and the consumers' demand. In fact, concerns exist that the market demand for certified palm oil is not as high as expected. Without a market demand, producers are unlikely to undertake certification. RSPO figures for 2010 show that the situation has improved, showing that 56% of available certified palm oil was purchased[226].

In a recent study "Review of policy options relating to sustainable palm oil procurement"[226] elaborated by Defra in 2011 in UK, it was stated that sourcing RSPO certified palm oil and its related products is currently possible, and available in volumes sufficient to cover the UK's consumption.

The main limitation could be the availability of certified palm derivatives such as surfactants, glycerine and emulsifiers from sustainable sources. Significant changes towards sustainable palm oil supply now depend on the manufacturers developing the availability of certified oleochemical derivatives.

If a criterion regarding sustainable sourced palm oil is proposed in the EU Ecolabel scheme, manufacturers should provide evidence that the product originates from a certified, well managed source, and verify that products are not mixed with products from uncertified sources at any point in the supply chain.

Sustainable palm oil production is comprised of legal, economically viable, environmentally appropriate and socially beneficial management and operations. The set of principles and criteria for the RSPO certification are available in the document *RSPO Principles and Criteria for Sustainable Palm Oil Production*[227].

RSPO certification is based on economic, social and ecological criteria:

[226] Defra, Review of policy options relating to sustainable palm oil procurement, 2011, available online at: http://www.proforest.net/proforest-news/defra-palm-oil-report/defra-report-on-uk-palm-oil-consumption-and-sustainable-policy-options-published.

[227] *RSPO Principles and Criteria for Sustainable Palm Oil Production* , available online at: http://www.rspo.org/file/RSPO%20Criteria%20Final%20Guidance%20with%20NI%20Document.pdf

- Economic criterion: continuous efficiency improvements; documentation on the improvement of production conditions and continuous increases in yield which lead to work and employment
- Ecological criterion: rainforest or other areas of high conservation value may not be destroyed to make way for new plantations
- Social criterion: working conditions must be consistent with industry standards and minimum wages must be paid. The RSPO also addresses health and safety at work.

The RSPO certification scheme has both production and chain of custody certificates being issued. There are four main routes by which the RSPO's supply chain requirements can be met[228]:

- Identity Preserved (IP): This methodology assures 100% of the physical product originates from a specific estate or plantation. However, the costs associated with such strict control mean that it is expensive and so it is not expected to be used except in exceptional or extremely high volume circumstances where the economics of scale could offset the costs.
- Fully Segregated: A fully segregated supply chain will ensure that various different CSPO sources are mixed together, but kept separate from non-certified palm oil. Thus, a new commodity grade will be created.
- Mass Balance (MB): The controlled mixing of certified & non-certified palm oil is the hallmark of a mass balance system.
- Book and Claim: In a comparable manner to carbon trading, book and claim operates through a system of parallel certificate trading between buyers and sellers.

**As conclusion**, criterion promoting vegetable-based ingredients against fossil-based ingredients is not proposed, as advantages of these ingredients are not proved in many cases. Nevertheless, viewed the important use of derived palm oil ingredients used in this category group and the environmental and social impacts that this can cause, it would be desirable to set a new criterion to guarantee that palm oil derived ingredient come from sustainable plantations. Nevertheless, some problems still exist on setting this criterion, e.g. the difficulty for manufacturers to get supply-chain traceability and certified palm oil derivates as well as difficulties for verifying the compliance.

**The future criteria formulation could comprise the following requisites:**

Vegetable ingredients made of palm oil should be made of oil coming from sustainable managed source according to the principle of sustainability for economic, social and environmental aspects.

Manufacturers should provide supply-chain-evidence that the product originates from a certified and well managed source and that products are not mixed with products from uncertified sources at any

[228] Defra, Review of policy options relating to sustainable palm oil procurement, 2011, available online at: http://www.proforest.net/proforest-news/defra-palm-oil-report/defra-report-on-uk-palm-oil-consumption-and-sustainable-policy-options-published.

point in the supply chain. Discussion should be maintained to decide which mechanisms included in RSPO certification are accepted (inclusion of mass balance and book and claim).

Certification RSPO would be accepted as evidence, as well as other official certifications if is considered sure enough and it is in conformance with ISO Guide 65/66.

## 7. REVISED CRITERIA PROPOSAL

**Please see a separate document – draft criteria proposal (after finalisation, its content will be incorporated here).**

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*Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern*: http://echa.europa.eu/documents/10162/d60da5c8-85de-4cb2-b95a-fada9451373b

*Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern*: http://echa.europa.eu/documents/10162/d418f8b0-ba93-402a-97fd-1e340d22c541

*Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern*: http://echa.europa.eu/documents/10162/5196d655-7b11-41b2-acba-c8709064fac8

*Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern*: http://echa.europa.eu/documents/10162/19fd114d-eb69-4012-a107-8ceb97787733

*Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern*: http://echa.europa.eu/documents/10162/b8395d41-b6d5-427c-8294-d46997e8835d.

*The appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials.* SCENIHR (Scientific Committee on Emerging and Newly-Identified Health Risks), 21-22 June 2007

*The Compelling Facts about Plastics - An analysis of European plastics production, demand and recovery for 2008*.PlasticsEurope, EuPC, EuPR, EPRO and Consultic (2009)

*The International Fragrance Association (IFRA): Code of Practice*, December 2006, available online at: http://www.ifraorg.org/en-us/code_of_practice_1

*The scientific committee on cosmetic products and non-food products intended for consumers opinion concerning fragrance allergy in consumers a review of the problem analysis of the need for appropriate consumer information and identification of consumer allergens,* December 1999, available online at: http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf

- **Databases used:**

**Mintel Global New Products Database** (GNPD): www.gnpd.com

Mintel is a provider of world-leading market intelligence. The Global New Products Database monitors product innovation and retail success in consumer packaged goods markets, worldwide. The GNPD offers coverage of new product activity. Over 20,000 new products are added every month, from 49 countries worldwide.

Mintel GNPD is used by a multitude of different types of companies worldwide. GNPD can be used to monitor new product launches and to study new product trends. The tool allows analysing global design strategies, identifying innovative designs, analysing market launches.

**Eurostat:** http://epp.eurostat.ec.europa.eu/

Eurostat is the statistical office of the European Union which provides the statistics at European level.

## 9. APPENDIX I: SCOPE OF THE PRODUCT GROUP

The existing definition of soaps, shampoos and hair conditioners product group has been analysed to determine if it shall be amended, e.g. if other cleaning products, which could be covered by the Ecolabel criteria for this group, exist and should be included in the current revision process .

Products with a certain degree of similarity, for example a common function or way of application or with similar chemical composition should be taken into account. Other rinse-off cosmetic products for similar purposes have been discussed for their inclusion, e.g. shaving products or toothpaste. The possible inclusion of products with similar purposes for animals, especially pets, as well as leave-on products like wet wipes and cleansing and remover make-up products, have also be discussed.

With this aim, the typical ingredients of each new considered product group have been analyzed and compared with the composition of soaps, shampoos and hair conditioners. The analysis covered products like:

- shaving-foam, -cream, -gel, -soap,
- toothpaste,
- shampoo for animals,
- wet wipes,
- cleansing and remover make-up products.

In order to assess the extension of the product scope, a brief description on the products which could potentially be included in the current product group has been prepared. The analysis includes:

- formulation (information about typical ingredients used in each product category),
- basic market information,
- brief environmental information obtained from existing studies,

First, the formulation of products covered by the current criteria document is briefly presented and afterwards the potential new product groups are given. The information regarding the formulation was obtained from the following sources:

**A. Cosmetics Europe (former Colipa) frame formulations**[229]

Article 7(3) of the Cosmetics Directive 76/768/EEC[230] specifies that Member States may require the provision of safety information to the competent authority (in the majority of cases: Poison Centres) for products marketed in the EU. The purpose of this is to enable the correct medical treatment to be given promptly in the event of an accident, such as a child consuming a cosmetic product.

The Frame Formulations[231] are based on a system developed jointly by the UK Cosmetic, Toiletry and Perfumery Trade Association (CTPA) with the National Poisons Information Service (London) and detail the type of ingredients and their maximum concentration

[229] COLIPA GUIDELINES. Cosmetic Frame Formulations. Guidelines realized in collaboration with the European Association of Poison Centres and Clinical Toxicologists (EAPCCT). January 2000.

[230] Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetics products (76/768/EEC) (OJL 262, 27.9.1976,P.169): http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1976L0768:20100301:en:PDF.

[231] COLIPA GUIDELINES. Cosmetic Frame Formulations. Guidelines realized in collaboration with the European Association of Poison Centres and Clinical Toxicologists (EAPCCT). January 2000.

(qualitative and quantitative information) for most cosmetic products available on the European market. If a product fits the Frame Formulation, then only basic information needs to be provided to the competent authorities at national level. More information should be given to the Poison Centres upon request.

Formulations used in the study have been defined based on Cosmetics Europe frame formulations, from where the main ingredients for each product have been defined.

**B. Mintel GNPD database (the Global New Products Database)[232]**

The Global New Products Database monitors product innovation and retail success in consumer packaged goods markets, worldwide. The GNPD offers coverage of new product activity for competitor monitoring, category awareness and new product idea generation.
GNPD is used to research current consumer markets and latest ingredient usage to develop new product ideas and concepts.
GNPD searches product formulations globally and allows searching and analysing ingredients trends in new consumer packaged goods. Whether searching for a specific emerging ingredient or for an overarching trend in ingredients, GNPD ingredients help to understand activities going on in the local market or on an international scale.
Mintel GNPD is used to understand how brands evolve and change based on global trends: ingredient trends, packaging trends and a forecast prediction for the category.
GNPD database contains more than 300.000 new products, as well as editorial and expert analysis on global trends.

Information on the characteristics of different products existing on the market has been gathered using the GNPD in order to do a preliminary analysis of the most common substances and materials used (both for product content and packaging) for the products under study.

Representativeness has been taken into account, so that different kinds of products included in the category has been studied: standard products, ecolabelled products, baby products, professional and household products.
The number of products analyzed for each kind of product (liquid soap, solid soap, shampoo and hair conditioner) is presented below:

**Table 37. Number of products analysed**

| Product group | Number of products analysed |
|---|---|
| Liquid soap | **20 362** |
| Solid soap | **4 183** |
| Shampoo | **13 188** |
| Hair conditioner | **5 327** |

Source: Elaborated based on GNPD (Global Database of New Products) results for 2011

[232] Source Mintel GNPD Data Base. For details see the database website: http://www.gnpd.com/.

The formulation of the products covered currently by the product group under study, i.e. liquid soaps, shampoos, solid soaps and hair conditioners is presented below.

### 9.1 LIQUID SOAPS

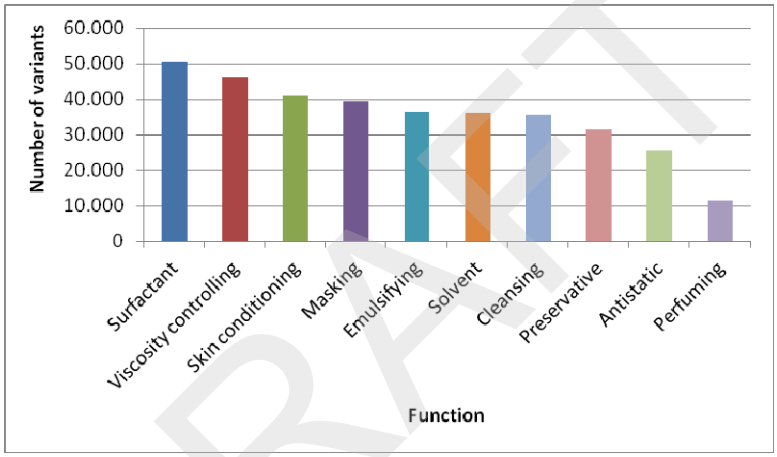
FORMULATION

**20 362** products (liquid soaps) have been found in GNPD and analyzed.

**Raw materials**

The top ingredients present in liquid soaps are presented in Figure 1:

**Figure 6. Top ingredients present in liquid soaps**




**Number of variants:** Number of different substances that perform the same function

Source: Elaborated based on GNPD (Global Database of New Products) results for 2011

Based on the Cosmetics Europe report "Cosmetic frame formulations"[233] the average composition of liquid soap products is given in the below table:

**Table 38. Average composition of liquid soaps**

| SOAP | |
|---|---|
| **LIQUID SOAP** | |
| Ingredients | Maximum levels (% w/w) |
| Anionic / amphoteric surfactants (e.g. laureth sulfates, betaines) | 40 |
| Non-ionic surfactants (e.g. glucose derivatives) | 40 |
| Soaps (sodium, potassium or triethanolamine) | 20 |
| Emollients (e.g. *PEG-7*, *glyceryl cocoate*) | 20 |
| Humectants (e.g. *glycerin*, *propylene glycol*, *sorbitol*) | 10 |
| Viscosity controlling agents (e.g. *sodium chloride*, | 5 |

[233] COLIPA GUIDELINES. Cosmetic Frame Formulations. Guidelines realized in collaboration with the European Association of Poison Centres and Clinical Toxicologists (EAPCCT). January 2000.

| | |
|---|---|
| hydroxycellulose derivatives) | |
| Additional ingredients (e.g. plant extracts) | 5 |
| Pearlescent agents (e.g. *glycol distearate*, *glycol stearate*) | 5 |
| Skin conditioning agents (e.g. cationic cellulose) | 5 |
| *Perfume* | 2 |
| Preservatives, antimicrobials | 2 |
| Cosmetic colorants | 1 |
| Aqua | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations.

### 9.2 SOLID SOAPS

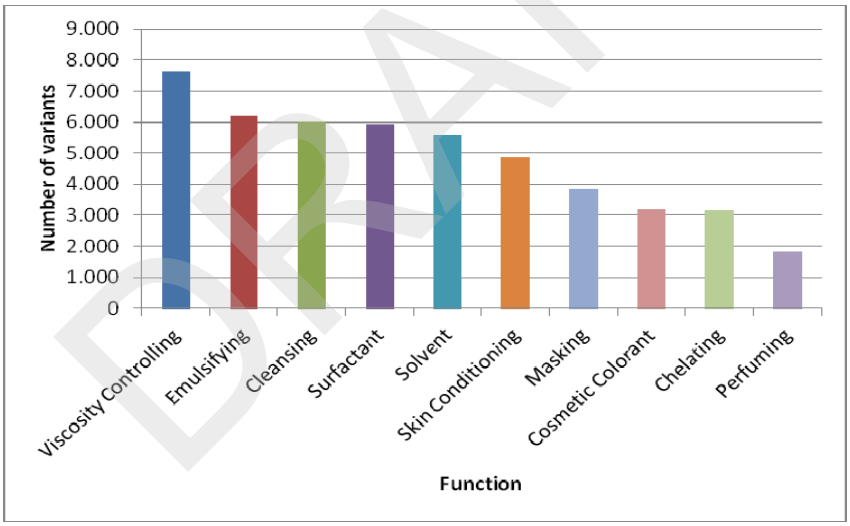
FORMULATION

**4 183 products** (solid soaps) have been found and analyzed.

**Raw materials**

The top ingredients present in solid soaps are given in Figure 2:

**Figure 7. Top ingredients present in solid soaps.**




Number of variants: Number of different substances that perform the same function
Source: Bases on GNPD (Global Database of New Products) results from 2011

Based on the Cosmetics Europe report "Cosmetic frame formulations"[234] the average composition of solid soaps products is given in the below table:

[234] COLIPA GUIDELINES. Cosmetic Frame Formulations. Guidelines realized in collaboration with the European Association of Poison Centres and Clinical Toxicologists (EAPCCT). January 2000.

**Table 39. Average composition of solid soaps**

| SOAP | |
|---|---|
| **SOAP - TOILET** | |
| Ingredients | Maximum levels (% w/w) |
| Soap (based on tallow, palm oil and coconut oil fatty acids) | 99 |
| *Glycerin* | 20 |
| Emolients, humectants (e.g. *lanolin*) | 10 |
| Amphoteric /anionic surfactants (e.g. *cocamidopropyl betaine*) | 5 |
| Mineral and/or vegetable oils (e.g. palm oil) | 5 |
| *Perfume* | 5 |
| Cosmetic colorants | 2.5 |
| *Titanium dioxide* | 2 |
| Skin conditioning agents (e.g. *polyquaternium-7*) | 2 |
| Additional ingredients (e.g. plant extracts, optical brighteners) | 2 |
| Preservatives, antimicrobials, antioxidants, chelating agents | 1 |
| Aqua | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

### 9.3 SHAMPOOS

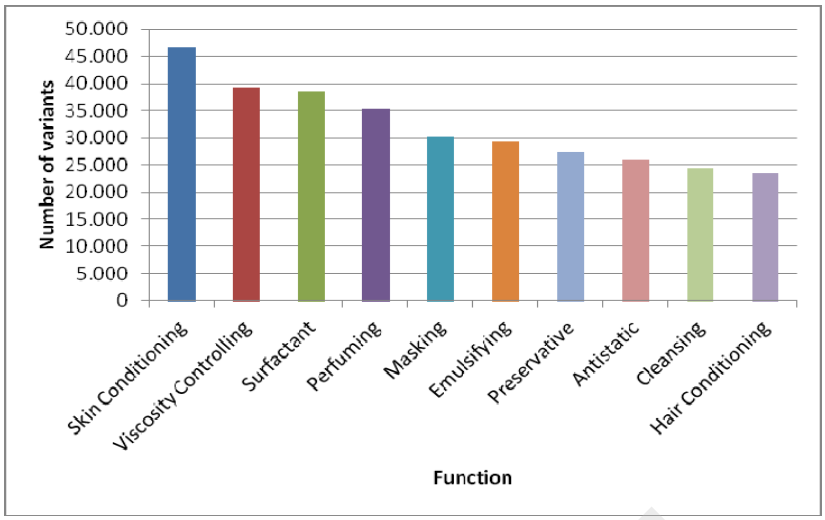
FORMULATION

**13 188** products (shampoos) has been found and analyzed.

**Raw materials**

The top ingredients present in shampoos are given in Figure 3:

**Figure 8. Top ingredients present in shampoos**




Number of variants: Number of different substances that perform the same function
Source: Based on GNPD (Global Database of New Products) results from 2011

Based on the Cosmetics Europe report "Cosmetic frame formulations[235]" the average composition of shampoo products is given in the below table:

**Table 40. Average composition of shampoos**

| HAIR PRODUCTS | |
|---|---|
| **SHAMPOO - LIQUID AND CREAM** | |
| Ingredients | Maximum levels (% w/w) |
| Anionic surfactants (e.g. sodium/ammonium/TEA lauryl sulfates, sodium/ammonium/TEA laureth sulfates) | 30 |
| Amphoteric surfactants (e.g. betaine derivatives) | 20 |
| Non-ionic surfactants (e.g fatty alkanolamides) | 15 |
| Viscosity controlling agents (e.g. *propylene glycol*, PEG) | 10 |
| Cationic surfactants C12 (e.g. *stearamidopropyl dimethylamine*, *distearyldimonium chloride*) | 5 |
| Hair conditioning agents (e.g. silicone derivatives, cysteine derivatives, cellulose derivatives, fatty acid esters) | *each up to* 5 |
| Additional ingredients (e.g. UV filters, pearlescent agents, opacifying agents) | *each up to* 5 |
| Preservatives, antimicrobials | 1 |
| Chelating agents (e.g. *disodium EDTA*) | 0.5 |
| *Aqua* | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

### 9.4 HAIR CONDITIONERS

FORMULATION

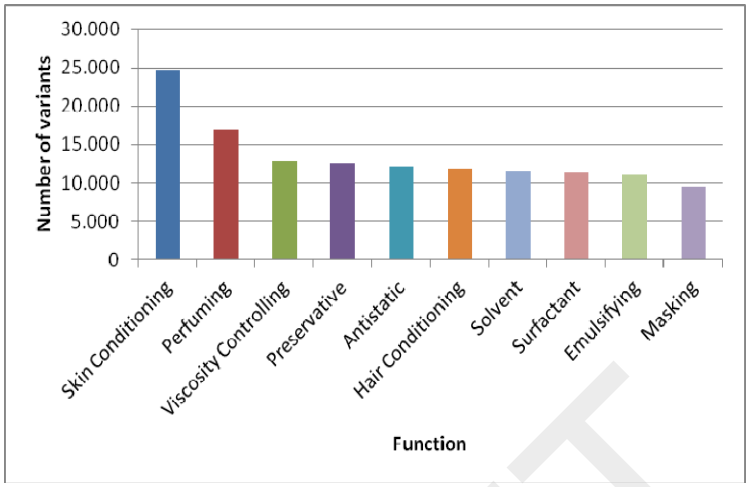
**5 327** products (hair conditioners) has been found and analyzed.

[235] COLIPA GUIDELINES. Cosmetic Frame Formulations. Guidelines realized in collaboration with the European Association of Poison Centres and Clinical Toxicologists (EAPCCT). January 2000.

**Raw materials**

The top ingredients present in hair conditioners are given below:

**Figure 9. Top ingredients present in hair conditioners**




Number of variants: Number of different substances that perform the same function
Source: Based on GNPD (Global Database of New Products) results from 2011

Based on the Cosmetics Europe report "Cosmetic frame formulations"[236] the average composition of hair conditioners products is given in the below tables:

**Table 41. Average composition of hair conditioners**

| HAIR PRODUCTS | |
|---|---|
| **HAIR CONDITIONER** | |
| Ingredients | Maximum levels (% w/w) |
| Oils, waxes (mineral and vegetable), silicones and fatty alcohols (e.g. *petrolatum*, *triticum vulgare*, *amodimethicone*, *cetearyl alcohol*) | 20 |
| Ethanol (*alcohol, alcohol denat.*) | 15 |
| Emulsifying agents (e.g. *ceteth-30*, *cetyl alcohol*) | 10 |
| Amphoteric surfactants (e.g. betaines derivatives) | 10 |
| Additional ingredients (e.g. proteins, chelating agents, pearlescent agents) | 10 |
| Cationic surfactants C12 (e.g. *cetrimonium chloride*) | 5 |
| Emollients, humectants (e.g. *glycerin*, *propylene glycol*) | 5 |
| Viscosity controlling agents (e.g. *carbomer*, *hydroxyethylcellulose*) | 5 |
| Polymers, resins (e.g. *polyquaternium-10*, *polyquaternium-11*, *butyl ester of PVM/MA copolymer*) | 5 |
| *Perfume* | 3 |
| UV filters | 1 |
| Preservatives, antimicrobials | 1 |
| Cosmetic colorants | 1 |
| *Aqua* | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

[236] COLIPA GUIDELINES. Cosmetic Frame Formulations. Guidelines realized in collaboration with the European Association of Poison Centres and Clinical Toxicologists (EAPCCT). January 2000.

**Table 42. Average composition of silicone based hair conditioners**

| HAIR PRODUCTS | |
|---|---|
| **HAIR CONDITIONER (SILICONE BASED)** | |
| Ingredients | Maximum levels (% w/w) |
| Silicones and volatile silicones (e.g. *cyclomethicone*) | 99 |
| Additional ingredients (e.g. UV filters, polymers) | 10 |
| Emulsifying agents (e.g. ethoxylated fatty alcohols) | 6 |
| Ethanol (*alcohol, alcohol denat.*) | 5 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

If we compare all the ingredients present in soaps, shampoos and hair conditioners, we will found the following differences (see below table):

- The main difference between bar and liquid soaps is the alkali used to saponify the oils. In bar soap the alkali used is sodium hydroxide while in liquid soaps it is potassium hydroxide.
- The difference between soaps and shampoos are mainly the shares of the oils.
- Shampoos and hair conditioners are quite different from each other. Firstly, they differ in their purpose. Shampoos are used to clean (remove oil, dust, dirt pollutants and dead skin cells) the hair. On the other hand, conditioners are hair care products that are used to soften the texture of the hair, making them softer and easier to comb after washing. For this reason, the components used to manufacture shampoos and conditioners are also different. Conditioners contain moisturizers to help make the hair more manageable and also proteins and glossers to help strengthen and shine the hair. Shampoos contain ingredients that are found in soaps. Another difference is the pH, while in shampoos is slightly acidic, in conditioners it is more acidic than in shampoos because it helps to promote the development of amino acids and to help keratin to bond onto the hair. Although the composition of shampoos and hair conditioners is different, both fall within the same product group of soaps, shampoos and hair conditioners complying with the same ecological criteria set in the respective Commission Decision.

**Table 43. Comparative table of ingredients in soaps, shampoos and hair conditioners**

| SOAPS, SHAMPOOS AND HAIR CONDITIONERS | | | | |
|---|---|---|---|---|
| **Ingredients** | **LIQUID SOAP** | **SOLID SOAP** | **SHAMPOOS** | **HAIR CONDITIONERS** |
| Soap (based on tallow, palm oil and coconut oil fatty acids) | | ■ | | |
| Oils, waxes (mineral and vegetable), silicones and fatty alcohols (e.g. *petrolatum*, *triticum vulgare*, *amodimethicone*, *cetearyl alcohol*) | | | | ■ |
| Anionic / amphoteric surfactants (e.g. laureth sulfates, betaines) | ■ | ■ | ■ | ■ |
| Cationic surfactants C12 (e.g. *stearamidopropyl dimethylamine*, *distearyldimonium chloride*) | | | ■ | ■ |
| Non-ionic surfactants (e.g. glucose derivatives) | ■ | | ■ | |
| Soaps (sodium, potassium or triethanolamine) | ■ | | | |
| Emollients (e.g. *PEG-7*, *glyceryl cocoate, glycerin*) | ■ | ■ | | ■ |
| Ethanol (*alcohol, alcohol denat.*) | | | | ■ |
| Emulsifying agents (e.g. *ceteth-30*, *cetyl alcohol*) | | | | ■ |
| Humectants (e.g. *glycerin*, *propylene glycol*, *sorbitol*) | ■ | ■ | | ■ |
| Viscosity controlling agents (e.g. *sodium chloride*, hydroxycellulose derivatives) | ■ | | ■ | ■ |
| Additional ingredients (e.g. plant extracts, proteins, optical brighteners, opacifying agents) | ■ | ■ | ■ | ■ |
| Mineral and/or vegetable oils (e.g. palm oil) | | ■ | | |
| Pearlescent agents (e.g. *glycol distearate*, *glycol stearate*) | ■ | | ■ | ■ |
| Skin conditioning agents (e.g. cationic cellulose) | ■ | ■ | | |
| *Titanium dioxide* | | ■ | | |
| Chelating agents (e.g. *disodium EDTA*) | | ■ | ■ | ■ |
| Polymers, resins (e.g. *polyquaternium-10*, *polyquaternium-11*, *butyl ester of PVM/MA copolymer*) | | | | ■ |
| *Perfume* | ■ | ■ | | ■ |
| Preservatives, antimicrobials | ■ | ■ | ■ | ■ |
| Cosmetic colorants | ■ | ■ | | ■ |
| Hair conditioning agents (e.g. silicone derivatives, cysteine derivatives, cellulose derivatives, fatty acid esters) | | | ■ | |
| UV filters | | | ■ | ■ |
| Aqua | ■ | ■ | ■ | ■ |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulation

## 9.5 SHAVING PRODUCTS

In the section below, the first group of products which has been considered for the potential scope extension is presented. Shaving products are preparations used to carry out shaving. There are two types:

- Products used before shaving
- Products used after shaving

In this report, only preparations **before shaving** have been analysed. They include:

- **Shaving cream and brushless shaving cream (soap based and brushless)**: The cream is applied to the hair face, to provide lubrication and avoid skin irritation from shaving. Shaving cream can be bought in a spray can or it can be purchased in tubes. Shaving cream in can is commonly dispensed as foam or a gel. The cream itself commonly consists of a mixture of soaps, oil, surfactants and water or alcohol, under a proper pH.

- **Shaving gel**: is a lubricating product designed to soften the hair being shaved, preventing the skin irritation. Shaving gel is packed in tubs as well as in cans, and is usually designed to foam into a thick, dense lather. Many of the basic ingredients are the same as shaving cream.

- **Shaving gel (post foaming):** Shaving gel will foam when it is agitated in the hands or on the face.

- **Shaving foam aerosol:** These products usually contain aerosol propellants to help use the product. Hydrocarbon propellants like butane or propane are used. These substances present the greatest concern about the environmental impact for shaving preparations.

- **Shaving soap/stick:** Using a shaving brush, soap is whipped into a lather which provides lubrication and protection for the skin irritation. It is less used in comparison with shaving foam or gel. The composition is similar to normal bath soap but oriented to produce a stable lather. In this case, potassium hydroxide and sodium hydroxide are used as saponification agents rather than just sodium hydroxide.



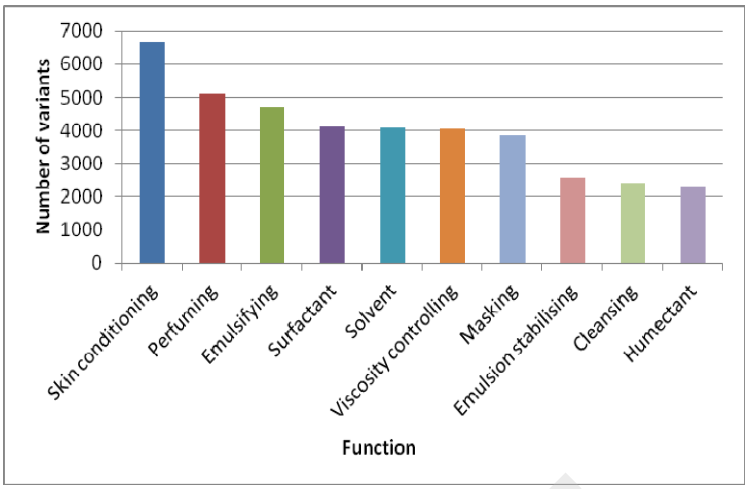
### FORMULATION

**1 965** products has been found and analyzed in GNPD Database.

#### Raw materials

The top ingredients present in shaving preparations are below:

**Figure 10. Top ingredients present in shaving preparations**




Number of variants: Number of different substances that perform the same function
Source: Based on GNPD (Global Database of New Products) results from 2011

Based on the Cosmetics Europe report "Cosmetic frame formulations"[237] the average composition of shaving products is given in the below table:

**Table 44. Average composition of shaving cream and brushless shaving cream – soap based**

| SHAVING PRODUCTS | |
|---|---|
| **SHAVING CREAM AND BRUSHLESS SHAVING CREAM /SOAP BASED** | |
| Ingredients | Maximum levels (% w/w) |
| Soaps (e.g. mixed sodium and potassium stearates, laurates and cocoates) | 60 |
| Humectants (e.g. *glycerin*, *propylene glycol*) | 30 |
| Viscosity controlling agents, emulsifying agents (e.g. fatty acid glycol esters, fatty alcohols) | 15 |
| Emollients (e.g. lanolin derivatives, oils, fatty acid esters) | 15 |
| Silicones (e.g. *dimethicone*) | 10 |
| Synthetic surfactants (e.g. anionic such as *sodium laureth sulfate*) | 5 |
| *Perfume* | 2 |
| Additional ingredients (e.g. viscosity controlling agents, vitamins) | 2 |
| Opacifying agents (e.g. *titanium dioxide*) | 1 |
| *Menthol* | 1 |
| Anticorrosives (e.g. *sodium metasilicate*) | 0.5 |
| *Sodium borate* | 0.5 |
| Chelating agents | 0.5 |
| Antioxidants | 0.1 |
| *Aqua* | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

[237] COLIPA GUIDELINES. Cosmetic Frame Formulations. Guidelines realized in collaboration with the European Association of Poison Centres and Clinical Toxicologists (EAPCCT). January 2000.

**Table 45. Average composition of shaving cream and brushless shaving cream – brushless**

| SHAVING PRODUCTS | |
|---|---|
| **SHAVING CREAM AND BRUSHLESS SHAVING CREAM / BRUSHLESS** | |
| Ingredients | Maximum levels (% w/w) |
| Fatty acids | 40 |
| Oils (e.g. mineral oil, lanolin oil) | 20 |
| Soaps (e.g. *Tea-stearate* and *TEA-laurate*) | 10 |
| Silicones (e.g. *dimethicone*) | 10 |
| Additional ingredients (e.g. vitamins, plant extracts) | 2 |
| *Perfume* | 2 |
| Antioxidants, chelating agents | 0.5 |
| *Aqua* | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

**Table 46. Average composition of shaving gel**

| SHAVING PRODUCTS | |
|---|---|
| **SHAVING GEL** | |
| Ingredients | Maximum levels (% w/w) |
| Film forming agents (e.g. *glyceryl polymethacrylate*) | 10 |
| Silicones (e.g. *dimethicone*) | 5 |
| Viscosity controlling agents (e.g. *hydroxyethylcellulose*) | 3 |
| Emulsifying agents, surfactants (e.g. *sodium laureth sulfate*) | 3 |
| Additional ingredients (e.g. vitamins, plant extracts) | 2 |
| *Perfume* | 1 |
| Cosmetic colorants | 1 |
| Preservatives, antimicrobials | 1 |
| *Aqua* | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

**Table 47. Average composition of shaving gel (post foaming)**

| SHAVING PRODUCTS | |
|---|---|
| **SHAVING GEL (POST FOAMING)** | |
| Ingredients | Maximum levels (% w/w) |
| Soaps (e.g. potassium salts of fatty acids, triethanolamine salts of fatty acids) | 30 |
| Humectants (e.g. glycerin) | 15 |
| Emulsifying agents, surfactants (e.g. PEG-150 distearate) | 10 |
| Additional ingredients (e.g. vitamins, plant extracts) | 5 |
| Post foaming agents (e.g. hydrocarbon) | 5 |
| Viscosity controlling agents (e.g. cellulose derivatives) | 2 |
| Silicones (e.g. dimethicone) | 2 |
| Parfum | 2 |
| Skin conditioning agents (e.g. polyquaternium-7) | 2 |
| Cosmetic colorants | 1 |
| Preservatives, antimicrobials | 0.2 |
| Menthol | 0.2 |

| SHAVING PRODUCTS | |
|---|---|
| **SHAVING GEL (POST FOAMING)** | |
| Ingredients | Maximum levels (% w/w) |
| Aqua | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

**Table 48. Average composition of shaving foam aerosol**

| SHAVING PRODUCTS | |
|---|---|
| **SHAVING FOAM AEROSOL** | |
| Ingredients | Maximum levels (% w/w) |
| Mixed alkanolamine / sodium / potassium soaps | 30 |
| Humectants (e.g. glycerin) | 15 |
| Propellants (e.g. hydrocarbons) | 15 |
| Emollients (e.g. waxes, lanolin, silicone derivatives) | 10 |
| Anionic surfactants (e.g. sodium laureth sulfate) | 10 |
| Non-ionic surfactants (e.g. lauramide DEA) | 10 |
| Emulsifying agents (e.g. PEG derivatives) | 5 |
| Additional ingredients (e.g. proteins, vitamins) | 2 |
| Parfum | 1 |
| Preservatives, antimicrobials | 1 |
| Viscosity controlling agents (e.g. cellulose derivatives) | 1 |
| Menthol | 0.5 |
| Aqua to | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

**Table 49. Average composition of shaving soap / stick**

| SHAVING PRODUCTS | |
|---|---|
| **SHAVING SOAP / STICK** | |
| Ingredients | Maximum levels (% w/w) |
| Mixed sodium and potassium stearates and laurates | 90 |
| Humectants (e.g. glycerin) | 15 |
| Non-ionic surfactants (e.g. polysorbates) | 5 |
| Silicones (e.g. dimethicone) | 5 |
| Additional ingredients (e.g. vitamins, plant extracts, chelating agents) | 2 |
| Parfum | 2 |
| Titanium dioxide | 1 |
| Preservatives, antimicrobials | 1 |
| Antioxidants | 0.1 |
| Menthol | 0.1 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

The objective of any shaving preparation is to wet and soften the hair to be shaved, decreasing the effect of the skin irritation.

The main differences between compositions are the quantities in which standard ingredients are used and the choice of substitutes for the few ingredients that are variable. The three major ingredients present in the formula of shaving creams are:

- Water,
- Saturate fatty acid such as stearic acid, one of the main ingredients in soap making,
- Surfactant: for example triethanolamine

Other ingredients that can vary are:

- Emulsifiers such as Lanolin or polyoxyethylene sorbitan monostearate to mix immiscible substances and hold water to the skin,
- Humectant such as glycerine, renders skin softer and more supple. Also acts as a moisturiser and lubricator.

The main differences between formulations are the proportions of ingredients, the variability of some specific ingredients such as emulsifiers and/or perfumes and the manufacturing process. The choice of aerosol propellant is also important for shaving foams. Most common are butane, isobutane and propane.

After comparing the ingredients present in soaps and shaving cream preparations in the table below, it is considered that, although the composition between them is slightly different, shaving products could be included within the same product group of rinse-off products.

**Table 50. Comparative table of ingredients in soaps and shaving cream preparations**

| COMPARATIVE LIQUID/SOLID SOAP AND SHAVING CREAM | | | | |
|---|---|---|---|---|
| **Ingredients** | **LIQUID SOAP** | **SOLID SOAP** | **SHAVING CREAM AND BRUSHLESS SHAVING CREAM /SOAP BASED** | **SHAVING CREAM AND BRUSHLESS SHAVING CREAM / BRUSHLESS** |
| Soap (based on tallow, palm oil and coconut oil fatty acids) | | | | |
| Oils, waxes (mineral and vegetable), silicones and fatty alcohols (e.g. *petrolatum*, *triticum vulgare*, *amodimethicone*, *cetearyl alcohol*) | | | | |
| Anionic / amphoteric surfactants (e.g. laureth sulfates, betaines) | | | | |
| Non-ionic surfactants (e.g. glucose derivatives) | | | | |
| Soaps (sodium, potassium, triethanolamine or mixed sodium and potassium stearates, laureates and cocoates) | | | | |
| Emollients (e.g. *PEG-7*, *glyceryl cocoate, glycerine, lanolin derivatives, oils, fatty acid esters)* | | | | |
| Emulsifying agents (e.g. *ceteth-30*, *cetyl alcohol*) | | | | |
| Humectants (e.g. *glycerin*, *propylene glycol*, *sorbitol*) | | | | |
| Viscosity controlling agents (e.g. *sodium chloride*, hydroxycellulose derivatives) | | | | |
| Additional ingredients (e.g. plant extracts, proteins, optical brighteners, opacifying agents, vitamins) | | | | |
| Mineral and/or vegetable oils (e.g. palm oil) | | | | |
| Pearlescent agents (e.g. *glycol distearate*, *glycol stearate*) | | | | |
| Skin conditioning agents (e.g. cationic cellulose) | | | | |
| *Titanium dioxide* | | | | |
| Chelating agents (e.g. *disodium EDTA*) | | | | |
| *Perfume* | | | | |
| Preservatives, antimicrobials | | | | |
| Cosmetic colorants | | | | |
| Hair conditioning agents (e.g. silicone derivatives, cysteine derivatives, cellulose derivatives, fatty acid esters) | | | | |
| Menthol | | | | |
| Anticorrosives (e.g sodium metasilicate) | | | | |
| Sodium borate | | | | |
| Antioxidants | | | | |
| Aqua | | | | |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

## BASIC MARKET INFORMATION

The main companies producing shaving products in Europe are presented in below:

**Table 51. Main companies for shaving products in Europe**

| Company | Percentage of products (%) |
|---|---|
| Procter & Gamble | 19.7 |
| Beiersdorf | 7.4 |
| Wilkinson Sword | 3.9 |
| L'Oréal | 2.4 |
| Oriflame | 2.0 |
| King of Shaves | 1.9 |
| Sara Lee | 1.6 |
| DM Drogerie Markt | 1.4 |
| Evyap | 1.4 |
| The Body Shop | 1.2 |
| BiC | 1.2 |
| Carrefour | 1.2 |
| Colgate-Palmolive | 1.1 |
| Vichy | 1.1 |
| Parfums Christian Dior | 1.0 |
| Avon | 0.9 |
| Schwarzkopf & Henkel | 0.9 |
| Peggy Sage | 0.8 |
| Rossmann | 0.8 |
| Others | 48.1 |

Source: Based on GNPD (Global Database of New Products) results from 2011

According to Mintel study for shaving and depilatory products[238] the basic information about new product launches and main claims are indicated below:

Market volume and launches:

- New product launches in 2011 fell by 15%.
- Europe remained the most active region with 42% of launches, followed by Latin America with 20% and North America with 18%.
- The most active countries of Europe include: France (14% of European launches), the UK (12%) and Ireland (10%).
- Shaving preparations became the leading Shaving & Depilatories sub-category, accounting for 39% of products (being the 31% Razors and 29% Depilatory Products).

Target and claims:

- The majority (80%) of shaving preparations products were intended for men,
- The leading claims were: botanical/herbal (57%), male (52%), moisturising/hydrating (37%), dermatologically tested (32%) and ease of use (32%).
- Almost one in ten (9%) products featured either the environmentally friendly product or package claim - both seeing a small 1% increase in activity.
- 12% of launches of shaving preparations of this period were paraben-free
- The fragrance-free claim accounted for 7% of total launches of shaving preparations in 2011

[238] Mintel GNPD Category Insight, Shaving & Depilatories , 2011.

## ANALYSIS ON SHAVING PREPARATIONS´PACKAGING

The shares of shaving preparations are given in below table:

**Table 52. Group of shaving preparations**

| | |
|---|---|
| Shaving gel* | 55% |
| Shaving foam | 27% |
| Shaving cream | 16% |
| Shaving soap | 2% |

**All gels (including post foaming gels)*

Source: Based on GNPD (Global Database of New Products) results from 2011

The materials and types of packaging used for each kind of shaving preparation were analysed. The results of this analysis are given in below tables:

**Table 53. Kind of packaging and materials used in shaving foams**

| SHAVING FOAMS | | Plated Steel | Plated aluminium | Plastic (PE, multilaminated, PP, PET) | Glass |
|---|---|---|---|---|---|
| | **TOTAL** | **57,1%** | **37,7%** | **5,2%** | **0,0%** |
| **Aerosol container** | **92%** | 55,6% | 36,6% | 0,0% | 0,0% |
| **Bottle** | **5%** | 0,0% | 0,0% | 4,9% | 0,0% |
| **Can** | **3%** | 1,5% | 1,1% | 0,0% | 0,0% |
| **Tray** | **0,4%** | 0,0% | 0,0% | 0,4% | 0,0% |
| **Tube** | **0%** | 0,0% | 0,0% | 0,0% | 0,0% |

Source: Based on GNPD (Global Database of New Products) results from 2011

*In orange: products using aerosols*
*In yellow: non-aerosol products with metal packaging*
*In green: non-aerosol with non-metal packaging*

**Table 54. Kind of packaging and materials used in shaving gels**

| SHAVING GELS | | Plated Steel | Plated aluminium | Plastic (PE, multilaminated, PP, PET) | Glass |
|---|---|---|---|---|---|
| | **TOTAL** | **50,0%** | **30,0%** | **20,0%** | **0,0%** |
| **Aerosol container** | **78%** | 49,6% | 27,9% | 0,0% | 0,0% |
| **Tube** | **18%** | 0,0% | 0,9% | 16,8% | 0,0% |
| **Bottle** | **4%** | 0,0% | 1,1% | 3,2% | 0,0% |
| **Can** | **1%** | 0,4% | 0,2% | 0,0% | 0,0% |

Source: Based on GNPD (Global Database of New Products) results from 2011

**Table 55. Kind of packaging and materials used in shaving creams**

| SHAVING CREAMS | | Plated Steel | Plated aluminium | Plastic (PE, multilaminated, PP, PET) | Glass |
|---|---|---|---|---|---|
| | **TOTAL** | **6,1%** | **35,2%** | **58,8%** | **0,0%** |
| **Tube** | **76%** | 1,8% | 25,5% | 49,1% | 0,0% |
| **Aerosol container** | **11%** | 3,6% | 7,3% | 0,0% | 0,0% |
| **Jar** | **4%** | 0,0% | 0,0% | 4,2% | 0,0% |
| **Tray** | **4%** | 0,0% | 1,2% | 2,4% | 0,0% |
| **Bottle** | **3%** | 0,0% | 0,0% | 3,0% | 0,0% |
| **Others** | **2%** | 0,6% | 1,2% | 0,0% | 0,0% |

Source: Based on GNPD (Global Database of New Products) results from 2011

**Table 56. Kind of packaging and materials used in shaving soaps**

| SHAVING SOAPS | | Plated Steel | Plated aluminium | Plastic (PE, multilaminated, PP, PET) |
|---|---|---|---|---|
| | **TOTAL** | **10,5%** | **21,1%** | **68,4%** |
| **Flexible** | **37%** | 0,0% | 0,0% | 36,8% |
| **Tube** | **26%** | 10,5% | 0,0% | 15,8% |
| **Aerosol container** | **21%** | 0,0% | 21,1% | 0,0% |
| **Bottle** | **16%** | 0,0% | 0,0% | 15,8% |

Source: Based on GNPD (Global Database of New Products) results from 2011

It can be seen that majority of shaving foams and gels are sold in aerosol containers while shaving soaps and creams are sold mainly in various kinds of plastic packaging. The most common packaging materials used for foams and gels is metal packaging – plated steel and aluminium. For shaving gels also plastics are used, although to lower extent than metals. Shaving creams are also sold (but less commonly) in aluminium tubes. While for shaving soaps different kinds of packaging are used.

In general, if kinds of packaging and materials used for all shaving preparations are analysed together, it can be seen that plated steel, plated aluminium (see table below) and various plastics are the materials used, while aerosol container, followed by a tube and to a much lower extent bottle are the common types of packaging.

**Table 57. Kind of packaging and materials used in shaving preparations**

| TOTAL | | Plated Steel | Plated aluminium | Plastic (PE, multilaminated, PP, PET) | Glass |
|---|---|---|---|---|---|
| | **TOTAL** | **36,0%** | **36,0%** | **27,0%** | **1,0%** |
| **Aerosol** | **65%** | 35,2% | 30,0% | 0,0% | 0,0% |
| **Tube** | **24%** | 0,4% | 4,4% | 19,1% | 0,0% |
| **Bottle** | **8%** | 0,0% | 0,9% | 6,2% | 0,9% |
| **Can** | **1%** | 0,4% | 0,6% | 0,0% | 0,0% |
| **Jar** | **1%** | 0,0% | 0,0% | 0,7% | 0,1% |
| **Others** | **1%** | 0,0% | 0,2% | 1,0% | 0,0% |

Source: Based on GNPD (Global Database of New Products) results from 2011

In general, it has been found that:

- 72% of shaving preparations are sold in metal packaging, where:
  - ✓ 65,2% are sold using aerosol containers,
  - ✓ 6,9% are sold in different kind of packaging other than aerosol container (tube, bottle, can and others),
- 27% of shaving preparations are sold in plastic packaging,
- 1% of shaving preparations are sold in glass packaging.

BASIC ENVIRONMENTAL INFORMATION (REGARDING PACKAGING)

Shaving foams and gels usually contain **aerosol propellants** to help use the product. Chloroflurocarbons (CFCs) are not longer used in aerosols as they are prohibited since 1987 by the Montreal Protocol on Substances that Deplete the Ozone Layer, but hydrocarbon propellant such as propane and butane are applied instead. These hydrocarbon propellants contribute to formation of low level ozone, although it should be added that aerosol packaging is not the biggest source for the formation of low level ozone. Nevertheless, these emissions should be prevented as they contribute to acid rains and to the greenhouse effect. Moreover, ozone can contribute to lung tissue damage and create high incidences of asthma and allergenic reactions in humans.

According to the **Aerosol Dispensers Directive 75/324/EEC (ADD)**[239], aerosol dispensers are defined as "non-reusable containers made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state".

According to the current criterion regarding packaging set in the Commission decision for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners[240]: "***sprays containing propellants must not be used***". It is proposed to consider it also for the new concerned products in the product

[239] Pressure equipment and gas appliances Aerosol Dispensers Directive (ADD): overview, available online at: http://ec.europa.eu/enterprise/sectors/pressure-and-gas/documents/add/index_en.htm.

[240] Commission Decision of 28 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners (2011/383/EU): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:169:0052:0064:EN:PDF.

group under study, i.e. to extend the current criterion formulation by the following requirement: "**aerosols containing hydrocarbon propellants must not be used".**

There are alternatives available in the market for foams and sprays, which substitute these hydrocarbon propellants[241] using other propellant such as compressed air.

Substance of concern

Apart from the issue regarding the packaging of shaving preparations, which should be addressed in the Ecolabel criteria, the review of literature indicated one substance of concern for this kind of products: Triethanolamine[242], which is an ingredient of shaving preparations, may trigger an allergic reaction in some individuals and thus it is considered as an ingredient of concern from the human health point of view. It is not considered an environmental hazard.

## 9.6 TOOTHPASTE

In this section a brief description of information related to toothpaste composition and additionally collected market and environmental data is given.

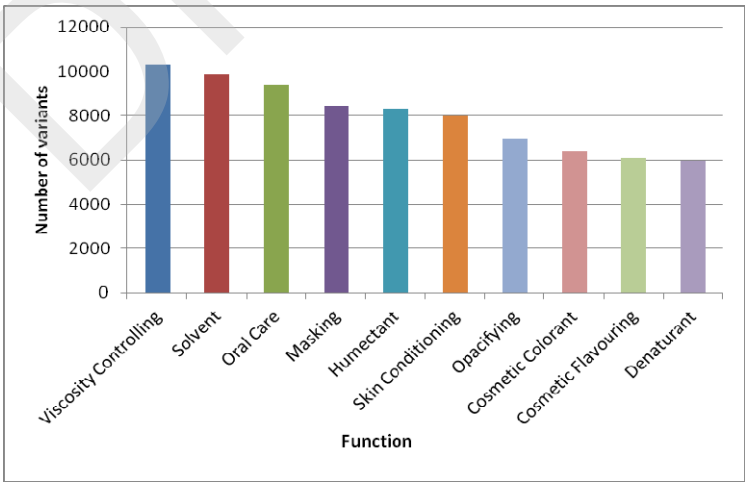
FORMULATION

**4 812** products has been found and analyzed.

**Raw materials**

The top ingredients present in toothpaste are given below:

**Figure 11. Main ingredient groups contained in toothpaste**




Number of variants: Number of different substances that perform the same function
Source: Based on GNPD (Global Database of New Products) results from 2011

[241] See e.g. article "AirOpack, a green alternative to aerosol dispensers", available online at: http://www.premiumbeautynews.com/en/AirOpack-a-green-alternative-to,2123?checklang=1.

[242] Based on information contained in: Dinesen Rogers Ch., Media D., Does Shaving Cream Affect the Environment, available online at: http://greenliving.nationalgeographic.com/shaving-cream-affect-environment-20223.html.

Based on the Cosmetics Europe report "Cosmetic frame formulations"[243] the average composition of toothpaste products is given in the below table:

**Table 58. Average composition of toothpaste**

| TOOTHPASTE | |
|---|---|
| **Ingredients** | **Maximum levels (% w/w)** |
| *Sorbitol* | 70 |
| Abrasives (e.g. *dicalcium phosphate dihydrate* and/or *alumina* and/or *calcium carbonate* and/or *silica* and silicates) | 55 |
| *Glycerin* | 40 |
| Insoluble metaphosphate (IMP) | 35 |
| Ethanol (*alcohol, alcohol denat.*) | 30 |
| Sodium pyrophosphate, potassium pyrophosphate | 15 |
| PEG, PPG | 10 |
| Oral care-protecting agents (e.g. *strontium chloride*) | 10 |
| Anionic surfactants (e.g. *sodium lauryl sulfate*) | 6 |
| Viscosity controlling agents (e.g. cellulose derivatives) | 5 |
| Additional ingredients (e.g. pH stabilisers such as sodium/potassium phosphate) | 5 |
| Flavour (mostly essential oils, e.g. mint) | 3 |
| *Titanium dioxide* | 2 |
| Cosmetic colorants | 1 |
| Oral care-antiplaque (e.g. *zinc citrate*, *bromochlorophene*) | 1 |
| Oral care-sweetening agents (e.g. *saccharin*) | 0.5 |
| Esters of hydroxybenzoic acid | 0.4 |
| *Calcium glycerophosphate* | 0.15 |
| Fluoride compounds (calculated as Fluorine) | 0.15* |

* Actual weight present will depend on molecular weight of fluorine donor, e.g. 0.15% fluorine = 1.14 % MFP (monofluorophosphate) or 0.333 % NaF (*sodium fluoride*)

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

Basically, the most common active ingredients in toothpastes are:

- Fluoride: active ingredient that prevents cavities,
- Antimicrobial agents that fight the bacteria of dental plaque,
- Antitartar agents,
- De-sensitising agents to relieve tooth sensitivity,
- Abrasives,
- Surfactants and foaming agents,
- Other non active ingredients such as humectants, colouring thickeners, flavour, water softeners and sweeteners.

Such type of ingredients is completely different from those that can be found in soaps, shampoos and hair conditioners.

The product group of soaps, shampoos and hair conditioners does not cover products that are specifically marketed for disinfecting or anti-bacterial use. Biocides are only allowed for preservation of the product, in order to avoid products that claim to be biocidal. Triclosan is an antibacterial

[243] COLIPA GUIDELINES. Cosmetic Frame Formulations. Guidelines realized in collaboration with the European Association of Poison Centres and Clinical Toxicologists (EAPCCT). January 2000.

disinfectant used widely in toothpastes. It is classified as an agent that may cause adverse environmental effects[244]:

- H410: very toxic to aquatic life with long lasting effects,
- H315: causes skin irritation and H319: causes serious eye irritation.

Some studies[244] have shown that the use of triclosan in cosmetic products is also a matter of concern from a toxicological point of view. Triclosan has been found in a number of different locations, e.g. in sewage and in waste water from treatment plants indicating that use of triclosan results in exposure in the environment.

After the preliminary analysis conducted, it is proposed not to include toothpaste into the scope of the product group due to the fact that its composition differs very much from the products covered currently by the product group of "soaps, shampoos and hair conditioners".

BASIC MARKET INFORMATION

In accordance with data obtained from the GNPD Mintel Database there were 4812 toothpaste products in the European market in 2011. The five top companies producing toothpaste products are presented below:

**Table 59. Top five companies producing toothpaste**

| Company | Number of toothpaste products |
|---|---|
| Colgate-Palmolive | 779 |
| GlaxoSmithKline | 691 |
| Schwarzkopf & Henkel | 289 |
| Procter & Gamble | 255 |
| Unilever | 220 |

Source: Based on GNPD (Global Database of New Products) results from 2011

Main claims placed on toothpaste products are given in the below table:

**Table 60. Main claims for toothpaste products**

| Claims | Percentage of total products |
|---|---|
| 1. With Vitamins/Minerals | 50% |
| 2.Refreshing | 27% |
| 3.Whitening Action | 24% |
| 4.Non-specified | 19% |
| 5.Anti.bacterian | 12% |
| 6.Children (5-12) | 11% |
| 7.Botánical/Herbal | 11% |
| 8.Calcium Added | 4% |
| 9.Without Additives/Preservatives | 4% |
| 10.Children (0-4) | 3% |

Source: Based on GNPD (Global Database of New Products) results from 2011

[244] Risk assessment on the use of triclosan in cosmetics, Norwegian Scientific Committee for Food Safety, 2005, available online at: http://vkm.no/dav/117573d6c4.pdf.

Toothpaste products have usually two kinds of packaging (primary and secondary):

- a tube made of plastic or aluminium lined with a thin layer of plastic,
- external packaging (cardboard material).

The shares of various packaging materials for this product group and of the different packaging kinds are presented in tables below, where it can be seen that multi-laminated is the main material used, followed by other plastics such as PE and PP. 46% of products have secondary packaging made of cardboard.

**Table 61. Packaging materials used for toothpaste**

| Packaging Materials | |
|---|---|
| Multi-laminated | 63% |
| Plastic non-specified | 24% |
| Plastic PE | 6% |
| Aluminium | 3% |
| Plastic PP | 4% |

Source: Based on GNPD (Global Database of New Products) results from 2011

**Table 62. Shares of different packaging kinds for toothpaste**

| Kind of packaging | |
|---|---|
| Tube | 91% |
| Bottle | 8% |
| Aerosol | 1% |

Source: Based on GNPD (Global Database of New Products) results from 2011

## BASIC ENVIRONMENTAL INFORMATION

Three Life Cycle Analysis and environment evaluation studies have been identified for toothpaste (listed below). The focus was mainly on the packaging material.

- Life Cycle Analysis research project for Unilever for toothpaste category (Enval, 2010). (Document non available),
- Tom's of Main toothpaste packaging: Aluminium vs. Laminate tubes. University of Michigan. 2007[245],
- Existing comparative LCA on toothpaste packaging by SmithKline Beecham (SB)[246].

The main environmental concerns regarding toothpaste are related to some potential problematic chemicals used:

- Triclosan (antibiotic) may become so prevalent that bacteria found in the environment and humans will develop resistance.

[245] A summary of the analysis conducted is available online at: http://www.tomsofmaine.com/TomsOfMaine/en-us/views/images/UniversityMichiganReport.pdf.

[246] The main results of the study are available online at: http://spd.bournemouth.ac.uk/html/lca_toothpaste_and_packaging.html.

- Sodium pyrophosphate (removes minerals and is tartar build-up preventing). It contains phosphorus which contributes to excessive algal growth in waterways.
- Fluoride. Its addition is considered the single most important reason for the developed world's reduced incidence of cavities since then.

Regarding packaging, a study comparing different packaging materials for toothpaste was conducted by SmithKline Beecham[247]. In accordance with the results obtained, it was found that traditional all-aluminium tubes have higher environmental impact compared with plastic tubes (in the study – plastic barrier laminate), mainly due to the issue of raw materials consumption. This may nevertheless change if a very high level of recycling is achieved for aluminium.

## 9.7 PET SHAMPOOS

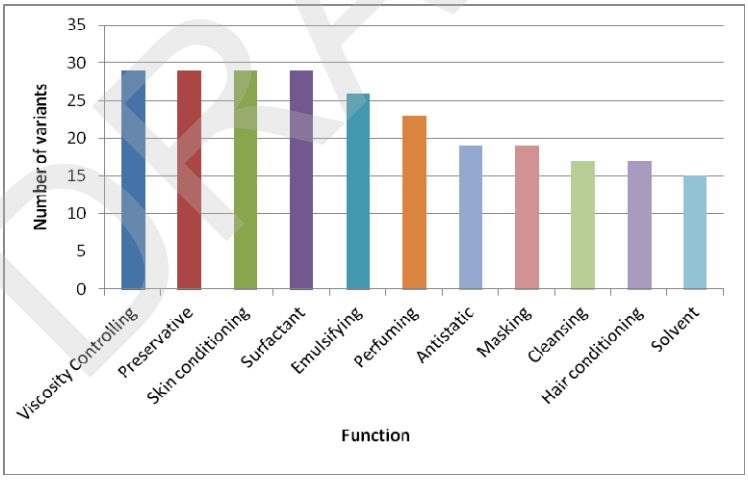
FORMULATION

**201** products has been found and analyzed.

### Raw materials

The top ingredients present in pet shampoos are below:

**Figure 12. Main ingredient groups contained in pet shampoos**




Number of variants: Number of different substances that perform the same function
Source: Based on GNPD (Global Database of New Products) results from 2011

Shampoos that are especially designed to be used for pets, commonly dogs and cats, are usually intended not only to just clean but also to treat skin condition, allergy or to fight against parasite infestations. This is the reason why these shampoo products have special chemical composition and may contain insecticides, antibacterials, antifungals, antiseborrheic or other medications. However, the product group of soaps, shampoos and hair conditioners does not cover products that are

[247] Sustainable Product Development, Case Study 1: Life Cycle Assessment, available online at: http://spd.bournemouth.ac.uk/html/lca_toothpaste_and_packaging.html.

specifically marketed for disinfecting or anti-bacterial use. Antibacterial disinfectant and microbial substances must meet the requirements for preservatives. Biocides in ecolabelled products are only allowed for preservation of the product. Products with biocidal properties are not eligible for Ecolabel since it is not permitted to add biocides other than preservatives.

However pet shampoo designed to be used only to just clean can be suitable to be included within the same group of soaps, shampoos and hair conditioners.

## BASIC MARKET INFORMATION

In accordance with data obtained from the GNPD Mintel Database there were 201 pet shampoos in the European market in 2011. The five top companies producing pet shampoo products are presented below:

**Table 63. Top five companies producing pet shampoos**

| Company | Percentage of pet shampoos |
|---|---|
| Nestlé Purina PetCare | 14% |
| Eight in One Pet Products | 12% |
| Greenfields Pet Products | 5% |
| NVTS Agrovetzashchita | 4% |
| John Paul Mitchell Systems | 4% |

Source: Based on GNPD (Global Database of New Products) results from 2011

Main claims placed on toothpaste products are given in the below table:

**Table 64. Main claims for pet shampoos**

| Claims | Percentage of total products |
|---|---|
| Botanical/Herbal | 29% |
| Ph neutral | 17% |
| With Vitamins/Minerals | 8% |
| Without Additives/Preservatives | 7% |
| Skin disorders | 6% |

Source: Based on GNPD (Global Database of New Products) results from 2011

## ENVIRONMENTAL INFORMATION

Specific environmental studies or life cycle assessment studies on pet shampoos have not been found. However, the environmental performance of these products would be similar to shampoos, as the way of application and the release to environment (through wastewater) is the same in both cases.

Rinse-off products for animals are not covered by the cosmetics directive. Nevertheless, due to similar formulation and environmental fate they could be included in the scope, if stakeholders support this.

Such products are included in the scope of the new Nordic Swan Ecolabel for cosmetics.

## 9.8 WET WIPES

### GENERAL CONSIDERATIONS

There are many different kinds of wipes[248] listed below

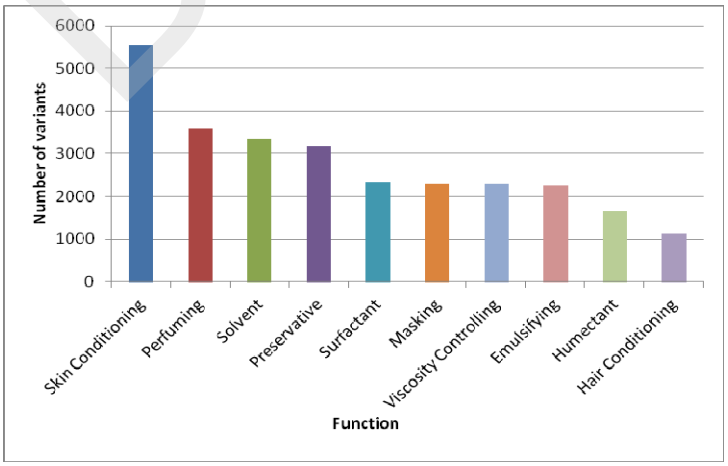
- Baby wipes,
- Facial wipes,
- Cleansing wipes,
- Hand & body wipes,
- Moist towelettes,
- Personal Hygiene wipes,
- Feminine Hygiene wipes,
- Antibacterial wipes,
- Medicated wipes.

Currently the EU Ecolabel criteria for "Sanitary Products" are under development. For this product category, wet wipes were one of the products considered primarily as candidates to fit within the "Sanitary Products" scope. 1st AHWG meeting regarding this development took place in June 2012 but the wipes were not included into this product group's scope.

### FORMULATION

**1 821** cosmetic wipes and **1 860** sanitary wipes have been found and analyzed based on the information from GNPD. The top ingredients used in wet wipes preparations are presented in tables below. The material used as support in wipes is a non-woven fabric similar to the type used in diapers and dryer sheets, containing fibres of silk, cotton, rayon, wool, and similar materials as well as plastic resins like polyester, polyethylene, and polypropylene. Additional ingredients groups used in cosmetic and sanitary wet wipes are given in below figures and table.

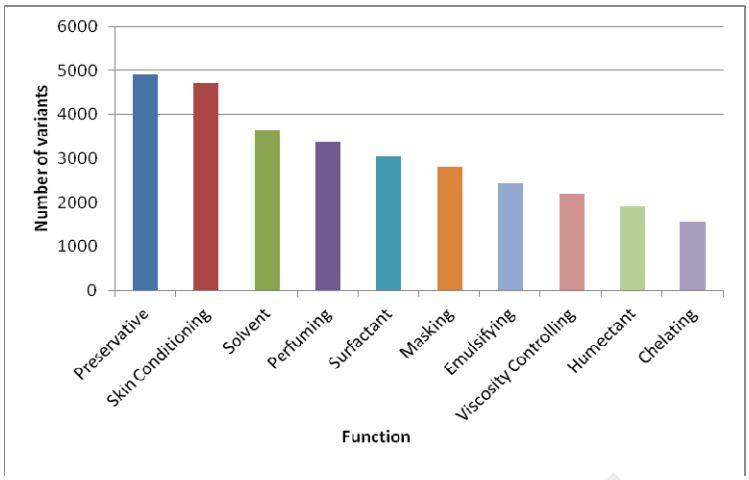
**Figure 13. Main ingredient groups contained in cosmetic wipes**




Number of variants: Number of different substances that perform the same function
Source: Based on GNPD (Global Database of New Products) results from 2011

[248] EDANA – the international association serving the nonwovens and related industries website: http://www.edana.org/ .

**Figure 14. Main ingredient groups contained in sanitary wipes**




Number of variants: Number of different substances that perform the same function
Source: Based on GNPD (Global Database of New Products) results from 2011

Based on the Cosmetics Europe report "Cosmetic frame formulations"[249] the average composition of wet wipe products (excluding the wipe support material) is given in the below table:

**Table 65. Average composition of refreshing wet wipes**

| REFRESHING WET WIPES | |
|---|---|
| **Ingredients** | **Maximum levels (% w/w)** |
| Ethanol (*alcohol, alcohol denat.*) | 30 |
| Humectants, emollients (e.g. *propylene glycol*, *glycerin*) | 10 |
| Anionic surfactants (e.g. *sodium laureth sulfate*) | 5 |
| Non-ionic surfactants, emulsifying agents (e.g. *oleth-20*, *polysorbate 80*)* | 5 |
| Additional ingredients (e.g. plant extracts) | 5 |
| *Perfume* | 2 |
| Preservatives, antimicrobials | 2 |
| *Aqua* | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

*Some baby wipes do contain ethanol (alcohol, alcohol denat.) at 10%.

Based on the ingredients analysis from Colipa and Mintel, wet wipes were found to have a similar composition. Nevertheless, a significant difference constitutes the material used as support. Furthermore, the way of application is different from rinsed-off products and their environmental fate will also be different (i.e. they will be disposed with household waste), thus it was not proposed to include them to the current product group in this revision process.

[249] COLIPA GUIDELINES. Cosmetic Frame Formulations. Guidelines realized in collaboration with the European Association of Poison Centres and Clinical Toxicologists (EAPCCT). January 2000.

## BASIC MARKET INFORMATION

Wipes products in European Market in 2011 (GNPD Database):

- 1799 wipes in the categories of sanitary
- 2300 wipes in the categories of cosmetics

The main companies producing wipes and the main claims put on these products are presented in tables below.

**Table 66. Main companies/brand (percentage of market products) of cosmetic wipes**

| Beiersdorf | L'Oréal | Garnier | Yves Rocher | Johnson & Johnson |
|---|---|---|---|---|
| 15% | 14% | 12% | 12% | 10% |

Source: Based on GNPD (Global Database of New Products) results from 2011

**Table 67. Claims in wet wipes (cosmetic)**

| Claims | Percentage of total products |
|---|---|
| 1. Botanical/Herbal | 19% |
| 2. Dermatological tested | 19% |
| 3. Cleaning | 18% |
| 4. With Vitamins/Minerals | 11% |
| 5. Moisturizing | 10% |
| 6. Sensitive Skin | 6% |
| 7. Quickness to use | 5% |
| 8. Skin Affections | 5% |
| 9. Ophthalmological tested | 4% |
| 10. Anti-Acne | 4% |

Source: Based on GNPD (Global Database of New Products) results from 2011

**Table 68. Claims in wet wipes (sanitary)**

| Claims | Percentage of total products |
|---|---|
| 1. For babies (0-4) | 50% |
| 2. Alcohol free | 28% |
| 3. Botanical/Herbal | 28% |
| 4. Dermatological tested | 28% |
| 5. pH-Neutral | 25% |
| 6. Practical packaging | 16% |
| 7. Hypo-allergenic | 14% |
| 8. Non-specified | 14% |
| 9. To take away | 13% |
| 10. Fragrance free | 11% |
| Others | 46% |

Source: Based on GNPD (Global Database of New Products) results from 2011

## PACKAGING OF WIPES

Most of products have flexible packaging format. Packages are designed to easily dispense single sheets while keeping the towelettes moist until ready for use. Main materials are given in table below. It can be seen that plastics are the main packaging material used for this kind of products.

**Table 69. Main materials used in packaging of wipes**

| Plastics (generic) | Plastic PE | Plastic PP | Multi-laminated | Metal film | Plastic LDPE | Plastic PET | Cardboard |
|---|---|---|---|---|---|---|---|
| 72% | 13% | 5% | 4% | 2% | 2% | 1% | 2% |

Source: Based on GNPD (Global Database of New Products) results from 2011

Furthermore, it is worth mentioning that only 5% of wipe products are packed in refill packs.

## ENVIRONMENTAL INFORMATION

Regarding **raw materials**, wet wipes differs on the chemical composition of the support, which is usually made of a mixture of non-woven polymers and wood pulp. This mixed support is usually not biodegradable. Regarding the support, there are however some examples available on the market of biodegradable wipes, which can minimize the environmental impact of these products[250]. These wipes are made of natural fibres which come from certified sustainable sources.

Single-use products like wipes are often assumed to be worse for the environment than their reusable counterparts. EDANA (the international association serving the nonwovens and related industries) completed a Life Cycle Assessment (LCA) comparing baby wipes, washcloth and cotton balls[251]. The results obtained show that a single-use product does not have more impact on the environment than a reusable product. The study, commissioned by the main producers of baby wipes, shows different environmental impacts of baby wipes versus other cleaning methods, with no superiority on wash cloths and favourable results on the majority of indicators for the use of wipes versus cotton balls. While single-use products have higher impact in terms of use of raw materials and waste, they have lower impacts due to the amount of water, detergents and energy consumption compared to other washing products and reusable towels, which require washing and sometimes drying. The impact of wet wipes during **use** is much lower than of rinse-off products, since no water is needed to use wipes. These results on baby wipes could be extrapolated to cosmetic wipes.

Wipes are non rinse-off products and they are **disposed** as solid waste after use. Regarding waste disposal, the mixture of non-woven polymers mixed with wood pulp of some wipes is not readily biodegradable. In accordance with the information obtained from the Mintel Database only 2% of cosmetic wipes analysed are biodegradable.

[250] For more information please see the website of Kleenex: http://www.kleenex.co.uk/UK/About/Environment.aspx.
[251] The executive summary of this study is available online at the EDANA website: http://www.edana.org/Content/Default.asp?PageID=75&DocID=4482.

Due to different environmental impacts from those of the products currently covered by the EU Ecolabel scope, wet wipes are not proposed for inclusion in the revised product group. Wet wipes for "cosmetic purposes" (such as facial wipes, cleansing wipes, hand&body wipes, moist towelettes) could be included in a new future category grouping non rinse-off products together with cleansing and remover make-up products.

## 9.9 CLEANSING AND REMOVER MAKE-UP PRODUCTS

FORMULATION

**4 142** products have been found and analyzed.

### Raw materials

The top ingredients present in cleansing and make-up remover products are given below:

**Table 70. Main ingredient groups contained in cleansing and remover make-up products**

| | |
|---|---|
| Skin conditioning | Surfactant |
| Solvent | Preservative |
| Perfuming | Emulsifying |
| Viscosity controlling | Humectant |
| Masking | Hair conditioning |

Source: Based on GNPD (Global Database of New Products) results from 2011

Based on the report "Cosmetic frame formulations" from Colipa the average composition of cleansing and make-up remover products is as follows:

**Table 71. Average composition of make-up remover**

| REMOVER MAKE-UP | |
|---|---|
| **Ingredients** | **Maximum levels (% w/w)** |
| Silicones | 50 |
| Additional ingredients (e.g. proteins, vitamins, plant extracts) | 10 |
| Preservatives, antimicrobials | 0.1 |
| Oils (e.g. paraffinum liquidum, oleyl alcohol, isopropyl myristate) | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

**Table 72. Average composition of eye make-up remover**

| EYE REMOVER MAKE-UP | |
|---|---|
| **Ingredients** | **Maximum levels (% w/w)** |
| Oils (e.g. mineral) | 40 |
| Emollients, humectants (e.g. glycerin, propylene glycol) | 15 |
| Non-ionic surfactants (e.g. polysorbate 60) | 6 |
| Emulsifying agents (e.g. cetyl alcohol) | 5 |
| Viscosity controlling agents (e.g. hydroxyethylcellulose) | 5 |
| Amphoteric / cationic surfactants (e.g. betaine derivatives) | 5 |
| Preservatives, antimicrobials | 2 |
| Additional ingredients (e.g. chelating agents, plant extracts, UV filters) | 1 |
| Aqua | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

**Table 73. Average composition of face mask (skin care for cleansing)**

| FACE MASK (SKIN CARE FOR CLEANSING) | |
|---|---|
| **Ingredients** | **Maximum levels (% w/w)** |
| Waxes (e.g. cera alba), oils (mineral and vegetable) and fats | 90 |
| Viscosity controlling agents (e.g. bentonite, carbomer, cellulose) | 60 |
| Humectants (e.g. glycerin, propylene glycol) | 40 |
| Fillers (e.g. starch, zinc oxide, kaolin) | 30 |
| Emulsifying agents, surfactants (e.g. glyceryl stearate, sodium laureth sulfate) | 25 |
| Ethanol (alcohol, alcohol denat.) | 20 |
| Additional ingredients (e.g. plant extracts, UV filters, antioxidants) | 5 |
| Emollients (e.g. isopropyl myristate) | 5 |
| Preservatives, antimicrobials | 2 |
| Parfum | 1 |
| Cosmetic colorants | 1 |
| Chelating agents | 0.5 |
| Aqua | to 100 |

Source: COLIPA GUIDELINES. Cosmetic Frame Formulations

After comparing the composition of the make-up remover, eye make-up remover and face mask with the composition of soaps and shampoos it has been seen that they are different. Additionally, the way of application is different from rinse-off products, which causes that the final environmental fate is different. Therefore, cleansing and remover make-up products are not proposed to be included in the scope of the product group.

## BASIC MARKET INFORMATION

In 2011 there were 6111 make-up removal products available on the European market. The main companies producing these products and main claims placed on the products are indicated in tables below.

**Table 74. Main companies/brand (percentage of market products) of make-up removal products**

| Top 5 Companies | |
|---|---|
| Beiersdorf | 17% |
| Yves Rocher | 14% |
| L'Oréal | 14% |
| Garnier | 12% |
| Johnson & Johnson | 10% |

Source: Based on GNPD (Global Database of New Products) results from 2011

**Table 75. Claims in make-up removal products**

| Claims | Percentage of total products |
|---|---|
| **1.** Botanical/Herbal | 20% |
| **2.** Cleaning | 15% |
| **3.** Dermatological tested | 14% |
| **4.** Moisturizing | 12% |
| **5.** With Vitamins/Minerals | 8% |
| **6.** Sensitive skins | 7% |
| **7.** Ethical/animals | 6% |
| **8.** Without Additives/Preservatives | 6% |
| **9.** Organic / Bio | 6% |
| **10.** Paraben free | 6% |

Source: Based on GNPD (Global Database of New Products) results from 2011

## PACKAGING

Most common packaging for make-up removal products (face and eyes) are given below:

**Table 76. Kind of packaging used for make-up removal products**

| Kind of packaging | |
|---|---|
| Bottle | 51% |
| Tube | 22% |
| Flexible | 14% |
| Flask | 11% |
| Flexible bag | 2% |

Source: Based on GNPD (Global Database of New Products) results from 2011

**Table 77. Main materials used in packaging of make-up removal products**

| Packaging Materials | |
|---|---|
| Plastic non-specified | 38% |
| Plastic PE | 20% |
| Plastic PP | 16% |
| Plastic PET | 13% |
| Glass | 4% |

Source: Based on GNPD (Global Database of New Products) results from 2011

## ENVIRONMENTAL INFORMATION

Non specific studies or LCA reports for make-up removal and cleansing products have been identified.

## 10. APPENDIX II: HAZARD STATEMENTS ACCORDING TO CLP 1272/2008 FOR HAZARDOUS SUBSTANCES

| *Hazard statement according to CLP 1272/2008/EEC* | *Associated risk phrases according to Directive 67/548/EEC* |
|---|---|
| H300 Fatal if swallowed | R28 |
| H301 Toxic if swallowed | R25 |
| H304 May be fatal if swallowed and enters airways | R65 |
| H310 Fatal in contact with skin | R65 |
| H311 Toxic in contact with skin | R65 |
| H330 Fatal if inhaled | R23; R26 |
| H331 Toxic if inhaled | R23 |
| H340 May cause genetic defects | R23 |
| H341 Suspected of causing genetic defects | R68 |
| H350 May cause cancer | R45 |
| H350i May cause cancer by inhalation | R49 |
| H351 Suspected of causing cancer | R40 |
| H360F May damage fertility | R60 |
| H360D May damage the unborn child | R61 |
| H360FD May damage fertility. May damage the unborn child | R60-61 |
| H360Fd May damage fertility. Suspected of damaging the unborn child | R60-63 |
| H360Df May damage the unborn child. Suspected of damaging fertility | R61-62 |
| H361f Suspected of damaging fertility | R62 |
| H361d Suspected of damaging the unborn child | R63 |
| H361fd Suspected of damaging fertility. Suspected of damaging the unborn child | R62-63 |
| H362 May cause harm to breast-fed children | R64 |
| H370 Causes damage to organs | R39/23; R39/24; R39/25; R39/26; R39/27; R39/28 |
| H371 May cause damage to organs | R68/20; R68/21; R68/22 |
| H372 Causes damage to organs through prolonged or repeated exposure | R48/25; R48/24; R48/23 |
| H373 May cause damage to organs through prolonged or repeated exposure | R48/20; R48/21; R48/22 |
| H400 Very toxic to aquatic life | R50 |
| H410 Very toxic to aquatic life with long-lasting effects | R50-53 |
| H411 Toxic to aquatic life with long-lasting effects | R51-53 |
| H412 Harmful to aquatic life with long-lasting effects | R52-53 |
| H413 May cause long-lasting harmful effects to aquatic life | R53 |
| EUH059 Hazardous to the ozone layer | R59 |
| EUH029 Contact with water liberates toxic gas | R29 |
| EUH031 Contact with acids liberates toxic gas | R31 |
| EUH032 Contact with acids liberates very toxic gas | R32 |
| EUH070 Toxic by eye contact | R39-41 |
| H334 May cause allergy or asthma symptons or breathing difficulties if inhaled | R42 |
| H317 May cause allergic skin reaction | R43 |

## 11. APPENDIX III: CONCLUSION ON MAIN ENVIRONMENTAL IMPACTS OF SOAPS, SHAMPOOS AND HAIR CONDITIONERS BASED ON LYFE CYCLE ASSESSMENT

Goal of the LCA studies

**Life cycle assessment** conducted allowed to obtain the **overall environmental profiles** of different kinds of products included in the product group of "soaps, shampoos and hair conditioners", and to identify which life cycle stages have the greatest environmental impacts.

Further, a **sensitivity analysis on key parameters** was undertaken in order to obtain additional information on relevant life cycle stages as well as on the impact of specific substances and materials used in the product and in its packaging. Analysing how the variation of these parameters affects the environmental impacts is an important output of this investigation. However, the particular environmental impact improvement potential, as calculated, can be used mainly as a qualitative parameter, as in most cases data gaps are found.

Limitations of the LCA study

**Limitations** in the life cycle assessment studies have to be taken into consideration. Namely, limitations can be identified in the collection and source of date, in its representativeness and in the availability of specific substances as found in LCA databases. It may also be considered that the commonly used environmental impact assessment methods entail some limitations regarding ecotocixity impact categories.

Functional unit for LCA

The functional unit describes qualitatively and quantitatively the function(s) or the service(s) provided by the product analysed. The functional unit for soaps, shampoos and hair conditioners has been defined as: **A washing action of a part of the body with the main objective of providing hygienic results and aesthetic improvements.**

In order to obtain more comprehensive results from the LCA study, the reference flow for LCA analysis has been based on mass criteria of the whole product, taking as reference the average product unit sold and standard dosages. Reference flow for each kind of product studied is presented in Table 78 below:

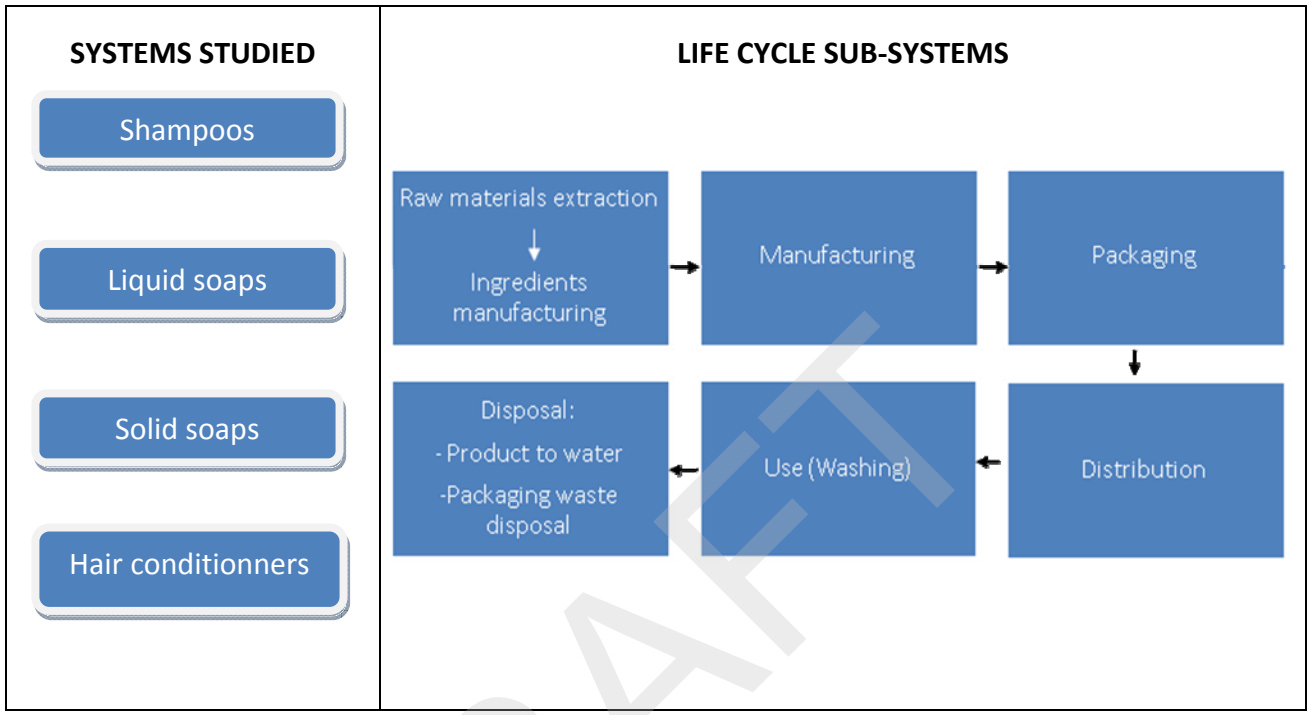
**Table 78. Reference flow for four kinds of products studied**

| Product | Reference flow |
|---|---|
| Liquid soap (shower) | A bottle of 250 ml of liquid soap (containing 255 g of product), with the main function of personal washing and personal care for 20 washing actions |
| Shampoo | A bottle of 250 ml of shampoo (containing 255 g of product), with the main function of personal washing and personal care for 24 washing actions |
| Hair conditioner | A bottle of 250 ml of hair conditioner (containing 255 g of product), with the main function of personal washing and personal care for 18 washing actions |
| Solid soap (hands) | A solid bar soap of 100 g with the function of hands washing and personal care for 50 washing actions |

Systems products definition

LCA from cradle to grave has been done, including all life stages of products: raw materials extraction and ingredients preparation, product manufacturing, packaging, distribution, use and disposal.

**Figure 15. Scope of the systems studied.**



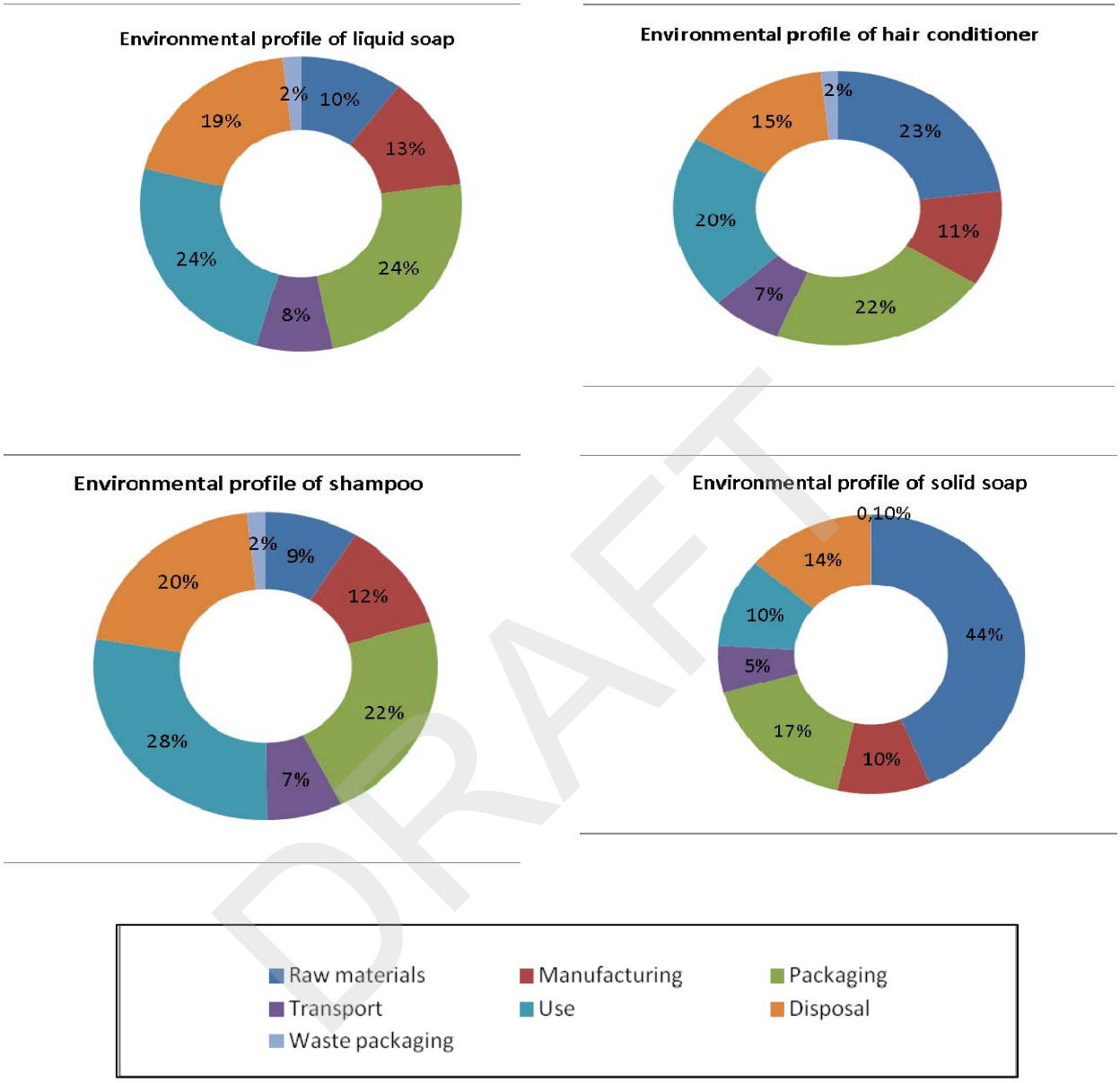

Life Cycle Impact Assessment results

The impact assessment method used is the IMPACT 2002+[252]. The IMPACT 2002+ life cycle impact assessment methodology proposes a feasible implementation of a combined midpoint categories and endpoints (damage approach). For some results, the different impact categories have been aggregated in a single score obtained through weighting processes.

In Figure 16 it can be seen the general environmental impact of the four kinds of products studied: liquid soaps, solid soaps, shampoos and hair conditioners. Midpoints are used for a more specific and detailed analysis, whereas damage endpoints are useful to communicate the results obtained to broader audience. The pre-defined (mathematical) weighting of the different midpoint score within the Impact 2002+ assessment method allow us to come to a single score. However, this should be used more for communication than for analysis, as weighting is not standardised and it is generally considered more relevant for the experts groups to hold discussions in greater detail – on midpoints level. In any case it is useful to have a general picture of the contribution of each life stage related to the overall environmental impact of the whole product life cycle and to identify the environmental hot spots.

[252] Risk and Impact Modeling: IMPACT 2002+ description, available at: http://www.sph.umich.edu/riskcenter/jolliet/impact2002+.htm.

**Figure 16.** Environmental impact distribution by life stage (IMPACT 2002+)






Life cycle assessment of liquid soaps, solid soaps, shampoos and hair conditioners show that **hot spots** among all life stages of these products are related to use stage, disposal to water, packaging and chemicals used. Other stages (manufacturing, distribution and waste packaging treatment) have lower load in the overall environmental impact of these products.

Impact results from life cycle assessment show that an important load of the overall environmental impact of these products comes from the **use phase** (20.5% of the total products impact). Ecolabel criteria cannot easily address action in this stage; contrary to criteria of other product groups (i.e. detergents for which water and energy use depends to a certain extent on the characteristics of the product) – apart from the minimum requirements of the products´ performance regarding the

intended function. In any case it is very important to highlight that user's behaviour has an important role and respective communication to consumers is essential.

**Release to water** stage represents high share in the total environmental impact of the products (between 20 and 14% depending on the kind of product). In this stage the treatment of wastewater generated after use stage has been included. Wastewater is considered to contain water used and the overall product used (as it is rinsed-off). It is assumed that wastewater goes to a household wastewater treatment plant.

Apart from the use phase and release to water stages, **packaging** shows high environmental impact. This high contribution indicates the importance to focus and investigate whether a further limitation of the packaging environmental impact is possible. Initiatives that reduce the amount of raw material used, such as refilling systems and recycling processes, allow minimizing the environmental impact of packaging, hence the environmental impact of the entire product.

It is important to investigate ways which could ensure high recyclability of the used packaging as well as facilitate the use of recycled material, i.e. packaging elements such as caps or labels should not pose difficulties in recycling processes.

Comparisons among plastics show that in general terms, HDPE seems to have lower environmental impact. PET has the highest score in resource depletion whereas PVC is not commonly used in packaging and the additives found in it are considered problematic and are often restricted in Ecolabelled products. Biopolymers can present advantages in waste degradation and the use of renewable resources, although the production of this type of materials is associated with a bit higher economic and energy costs.

Comparison between paper and plastic packaging indicates lower environmental impacts for paper packaging.

Recycling rate is higher for paper and cardboard packaging waste than for plastic packaging waste. Among packaging plastics, PET is the polymer with a higher recycling rate, whereas PVC is the polymer less recyclable. Biopolymer present advantages with regard to waste degradation. It is important to guarantee recyclability of packaging and the use of recycled material, so packaging elements such as caps or labels also have to be considered to ensure that these elements do not pose difficulties in recycling processes. In order to facilitate the recyclability of packaging the materials in the packaging should be easily separable (paper, cardboard, plastic, metal, glass) for sorting.

It is environmentally favourable to increase the amount of recycled material entering other product life cycles in order to minimize the impact coming from materials, since the production impacts of virgin material (and the related intermediates) can be lowered by substituting some of the virgin material with recycled one.

**The preparation and production of chemicals processed and used in the final products** are also associated with significant environmental impacts along the product life cycle. This stage represents 44% of the total environmental impact for solid soaps, 23% of environmental impact of hair conditioners, 9% of the environmental impact of shampoo and 10% of the environment impact of liquid soaps. The impacts with higher values are related to non-renewable energy and land

occupation needed to produce these ingredients, whereas toxicity categories, related to the release of these substances into environmental compartments like water, have lower values, mainly due to limited characterization factor for eco-toxicity.

Regarding **chemicals**, limitations have been found due to the lack of quantification of their impacts in the available LCA impact assessment databases, and some generic or similar substances have been used when needed. LCA impact assessment methods have limitations to assess human toxicity and ecotoxicity of substances. It is considered that complementary investigations regarding the use of substances and their ecotoxicity impacts are necessary because in the current lifecycle impact assessment (LCIA) methods numerous substances found in soaps, shampoos and hair conditioners are not covered. For these substances there is no characterization factor for the calculation of their environmental impacts which results in a potential underestimation and final underrepresentation of the calculated environmental impacts.

**Distribution process** has been not deeply studied in this revision and secondary and literature data has been used in this stage. This stage is responsible for 7% on average of the total impact of products studied, considering average European distribution scenario. Measures of promoting efficiency of transport and improvement in logistics, as well as reduction of products' weight could contribute to reducing this impact.

**Manufacturing of products** (for which data was derived based on average standard processes as found in the European Databases) shows also an important load in the total environmental impact of products (11.5% on average). According to LCA results obtained, impacts from manufacturing process come mainly from the use of non-renewable energy for heating and electricity. The main environmental impacts resulting from this stage are found for the impact categories of global warming and use of non-renewable energy. This stage is considered difficult to be regulated via the Ecolabel scheme and other policy tools may be more relevant and more effective. Nevertheless, this information is important for future actions i.e. indicating the areas in which the industry could contribute to improvement of environmental performance (through increase of efficiency in manufacturing and production processes in plants).

**Treatment of packaging waste** stage represents low share of the total environmental impact of products (2% for bottles and 0,1% for solid soap packaging). The waste treatment scenario has been defined in accordance with the current European statistics. For plastic bottles (liquid soap, shampoo and hair conditioner), 30% of waste is recycled, 27% undergoes energy recovery and 43% goes to landfill. For paper/cardboard packaging (solid soap) 81% of waste is recycled, 8% undergoes energy recovery and 6% goes to landfill. Impacts from recycling have been not included as they are allocated in the manufacturing process of recycled material, out of the scope of the study. Impacts come from landfill and incineration processes.

Introduction of good environmental practices and requirements in the Ecolabel criteria have been analysed in order to estimate and measure the improvement potential and the resulting environmental impact minimization. In the following table 79 a general overview regarding the significant impacts found per life cycle phase and the corresponding action proposed for the Ecolabel is outlined. The following four information elements and their interrelation are presented:

1. main outcomes of the environmental performance analysis of the product group
2. Appropriateness and potential to regulate this area through the policy tool of Ecolabel
3. Good environmental practices /restrictions which are considered
4. The environmental improvement potential indications

**Table 79. Outcomes of life cycle assessment and actions in Ecolabel – a general overview**

| STAGE | Environmental impact | Potential regulation by EU Ecolabel | Good environmental practices /restrictions | Improvement potential |
|---|---|---|---|---|
| Chemicals | 44% of the total environmental impact for solid soaps<br>23% for hair conditioners,<br>9% for shampoo<br>10% for liquid soaps | High | Select for each functional group less harmful substances (Ecotoxicity factors, CLP, biodegradability) | - Improvement of the environmental performance of ingredients used, including during stages of manufacturing, use and release to water.<br>- Minimized potential ecotoxicity effects if products are released to different environmental compartments. |
| | | | Select substances with less energy and non-renewable resources consumption | - Reduced environmental impact of substances from energy and resources used during its manufacturing. |
| Manufacturing | on average 11,5% of the total environmental impact | Moderate | Improvement in manufacturing processes efficiency, mainly in energy use | - Reduction of impacts from manufacturing process, which come mainly from the use of non-renewable energy for heating and electricity.<br>- Minimization of environmental impacts in categories of global warming, use of non-renewable energy. |
| Packaging | 24% of the total environmental impact for liquid soaps,<br>22% for hair conditioners,<br>22% for shampoo ,<br>17% for solid soaps | High | Minimize packaging weight | 70% environmental impact of packaging is due to the material used (the rest is generated by manufacturing of packaging) - Decreases in weight (amount of material) results in direct decreases of environmental impacts. |
| | | | Increase of recycled material sources | - 70% environmental impact of packaging is due to the material used thus the decrease of virgin material results in direct decreases of environmental impact. |

| STAGE | Environmental impact | Potential regulation by EU Ecolabel | Good environmental practices /restrictions | Improvement potential |
|---|---|---|---|---|
| | | | Materials selection:<br>- Use materials with a minor environmental impact | - 70% environmental impact of packaging is due to the material used (, Selecting plastic with low environmental impact along its life cycle (including production phase and recycling phase) and consider potential for reusability and recyclability can bring environmental savings. |
| | | | Refilling systems | - Ensuring refilling system can provide a packaging saving of the 79% of weight and an saving of 18% of the global environmental impact of the product |
| | | | Guarantee recyclability:<br>- Use recyclable materials<br>All parts separable or compatible | - Recycling of waste is in general environmentally preferable than other treatments (energy recovery or landfill), nevertheless it can differ for various materials. Recycling allows producing material which can enter again to the system enabling environmental impacts saving in first stages of life product. |
| Distribution | Average of 7% of total product environmental impact | Low | Improve efficiency in logistic and transport processes.<br>- Decrease weight of packaging (lower weight of transported product) | - Environmental improvement due to saving of fossil fuel use. |
| Use | 28-10% of total product environmental impact depending on each product | Low | Improvements in products performance: dosage, more easily rinse-off. | - Reducing dose/washing action<br>- Reducing water consumed /washing action<br>lead to water and energy saving in the use phase. |
| Release to water | 20-14% of total product environmental impact depending on each product | *Impacts from this stage depend on raw materials and use stage* | Communication and awareness messages to users | - Reducing product and water consumed /washing action can lead to water and energy saving in the use phase and reduction of impacts related to various life cycle stages. |
| | | | Use substances which are not toxic for the environment or the humans. | - Environmental impact minimization coming from wastewater treatment. |

| STAGE | Environmental impact | Potential regulation by EU Ecolabel | Good environmental practices /restrictions | Improvement potential |
|---|---|---|---|---|
| Treatment of packaging waste | 0.1% of the total environmental impact for solid soaps,<br>2% of the total environmental impact of liquid products | *Impacts from this stage depend on packaging stage* | Increase recycling rates in packaging waste.<br>Reduce amount of waste generated by packaging (refilling systems, lower packaging weight) | - In general, recycling of waste is environmentally preferable than other treatments and can use to reduction of impact related e.g. to production of raw materials for packaging. |

Sources: own work based on life cycle results

## 12. APENDIX IV: SUMMARY OF DATA

In order to define suitable thresholds in the revised criteria, competent bodies were asked to provide statistical information on currently ecolabelled products in order to obtain reliable and representative data. The information was asked to all Competent Bodies by e-mail, with condition that data will be treated confidentially.

The values gathered were referred to:

- Critical Dilution Volume.
- AnNBDO and aNBDO values.
- Weight Content values for packaging.

At the end of the process, information of 57 ecolabelled products from 4 different countries was obtained.

Based on the quantitative study of 57 products based on exact formulations, the results for some parameters are given in the table below:

**Table 80. Summary of data**

| Number | TYPE OF PRODUCT | CDV | anNBDO (g/g AC) | aNBDO (g/g AC) | WCR (g packaging/g product) |
|---|---|---|---|---|---|
| 1 | shower gel with refill | 18657,4 | 0,029 | 0,024 | 0,05 |
| 2 | shower gel refill | 18657,4 | 0,029 | 0,024 | 0,12 |
| 3 | hand soap liquid 1 | 16146,3 | 0,016 | 0,016 | In 3 different packagings with a WCR of 0,25 and 0,26 and 0,27 |
| 4 | hand soap liquid 2 | 14608,4 | 0,014 | 0,014 | In 3 different packagings with a WCR of 0,25 and 0,26 and 0,27 |
| 5 | hand soap liquid 3 | 16734,8 | 0,018 | 0,018 | In 3 different packagings with a WCR of 0,26 and 0,26 and 0,27 |
| 6 | hand soap liquid 4 | 16467 | 0,022 | 0,022 | In 3 different packagings with a WCR of 0,25 and 0,26 and 0,27 |
| 7 | hand soap | 14281 | 0 | 0 | In 2 different packagings with a WCR of 0,18 and 0,26 |
| 8 | SHAMPOO 1 | 16066,4 | - | - | 0,22 |
| 9 | SHAMPOO 2 | 14318,8 | - | - | 0,15 |
| 10 | SHOWER GEL | 15785,4 | - | - | 0,25 |

| Number | TYPE OF PRODUCT | CDV | anNBDO (g/g AC) | aNBDO (g/g AC) | WCR (g packaging/g product) |
|---|---|---|---|---|---|
| 11 | SOAP 1 | 12073,0 | - | - | 0,16 |
| 12 | SOAP 2 | 12394,1 | - | - | 0,16 |
| 13 | SOAP 3 | 9825,4 | - | - | 0,10 |
| 14 | SOAP 4 | 19856,2 | - | - | 0,06 |
| 15 | X | - | - | - | 0,11 |
| 16 | X | - | - | - | 0,12 |
| 17 | X | - | - | - | 0,08 |
| 18 | X | - | - | - | 0,09 |
| 19 | | 12043 | 0 | 0 | - |
| 20 | | 15249 | 0,0036 | 0 | 0,10 - 0,03- 0,03 |
| 21 | | 18694 | 0,01 | 0 | 0,29 |
| 22 | liquid soap | 15990 | 0,020 | 0,020 | 0,264 |
| 23 | liquid soap | 19909 | 0,022 | 0,022 | 0,264 |
| 24 | liquid soap | 15025 | 0,025 | 0,025 | 0,093 |
| 25 | liquid soap | 14337 | 0,019 | 0,019 | 0,294 |
| 26 | liquid soap | 14299 | 0,025 | 0,025 | 0,285 |
| 27 | liquid soap | 13941 | <0,025 | <0,03 | 0,189 |
| 28 | liquid soap | 13941 | <0,025 | <0,03 | 0,280 |
| 29 | liquid soap | 10032 | <0,025 | <0,03 | 0,185 |
| 30 | liquid soap | 7342 | 0,003 | 0,003 | 0,257 |
| 31 | liquid soap | 8130 | 0,010 | 0,010 | 0,114 |
| 32 | liquid soap | 19448 | 0,019 | 0,019 | 0,100 |
| 33 | liquid soap | 13967 | 0,016 | 0,016 | 0,263 |

| Number | TYPE OF PRODUCT | CDV | anNBDO (g/g AC) | aNBDO (g/g AC) | WCR (g packaging/g product) |
|---|---|---|---|---|---|
| 34 | liquid soap | 19877 | 0,023 | 0,021 | 0,257 |
| 35 | liquid soap | 14374 | - | - | 0,252 |
| 36 | liquid soap | 8484 | - | 0,011 | 0,263 |
| 37 | Hair conditioner | 4904 | - | 0,048 | 0,252 |
| 38 | Solid soap | 2281 | 0,007 | 0,008 | 0,127 |
| 39 | - | - | - | - | 0,079 |
| 40 | - | - | - | - | 0,295 |
| 41 | - | - | - | - | 0,266 |
| 42 | - | - | - | - | 0,097 |
| 43 | - | - | - | - | 0,094 |
| 44 | - | - | - | - | 0,247 |
| 45 | - | - | - | - | 0,243 |
| 46 | - | - | - | - | 0,279 |
| 47 | - | - | - | - | 0,268 |
| 48 | - | - | - | - | 0,056 |
| 49 | - | - | - | - | 0,291 |
| 50 | - | - | - | - | 0,283 |
| 51 | - | - | - | - | 0,207 |
| 52 | - | - | - | - | 0,105 |
| 53 | - | - | - | - | 0,096 |
| 54 | - | - | - | - | 0,137 |
| 55 | - | - | - | - | 0,162 |
| 56 | - | - | - | - | 0,130 |
| 57 | - | - | - | - | 0,080 |

Source: Stakeholders 'information sent to the EC

## 13. APENDIX V: CANDIDATE LIST OF SUBSTANCES OF VERY HIGH CONCERN

**Table 81. Candidate list Substances of Very High Concern**

| *Substance Name* | *EC Number* | *CAS Number* | *Date of inclusion* | *Reason for inclusion* |
|---|---|---|---|---|
| 4-(1,1,3,3-tetramethylbutyl)phenol | 205-426-2 | 140-66-9 | 2011/12/19 | Equivalent level of concern having probable serious effects to the environment (article 57 f) |
| Dichromium tris(chromate) | 246-356-2 | 24613-89-6 begin_of_the_skype_ highlighting | 2011/12/19 | Carcinogenic (article 57 a) |
| 2-Methoxyaniline; o-Anisidine | 201-963-1 | 90-04-0 | 2011/12/19 | Carcinogenic (article 57 a) |
| Lead styphnate | 239-290-0 | 15245-44-0 begin_of_the_skype_ highlighting | 2011/12/19 | Toxic for reproduction (article 57 c) |
| Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 begin_of_the_skype_highlighting 650-017-00-8 end_of_the_skype_highlighting in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 begin_of_the_skype_highlighting 1272/2008 end_of_the_skype_highlighting of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight | | | 2011/12/19 | Carcinogenic (article 57 a) |
| Zirconia Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 begin_of_the_skype_highlighting 650-017-00-8 end_of_the_skype_highlighting in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 | | | 2011/12/19 | Carcinogenic (article 57 a) |

| *Substance Name* | *EC Number* | *CAS Number* | *Date of inclusion* | *Reason for inclusion* |
|---|---|---|---|---|
| begin_of_the_skype_highlighting 1272/2008 end_of_the_skype_highlighting of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm). c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight | | | | |
| Pentazinc chromate octahydroxide | 256-418-0 | 49663-84-5 begin_of_the_skype_highlighting | 2011/12/19 | Carcinogenic (article 57 a) |
| N,N-dimethylacetamide | 204-826-4 | 127-19-5 | 2011/12/19 | Toxic for reproduction (article 57 c) |
| Bis(2-methoxyethyl) phthalate | 204-212-6 | 117-82-8 | 2011/12/19 | Toxic for reproduction (article 57 c) |
| 1,2-dichloroethane | 203-458-1 | 107-06-2 | 2011/12/19 | Carcinogenic (article 57 a) |
| Phenolphthalein | 201-004-7 | 77-09-8 | 2011/12/19 | Carcinogenic (article 57 a) |
| Arsenic acid | 231-901-9 | 7778-39-4 | 2011/12/19 | Carcinogenic (article 57 a) |
| Lead diazide, Lead azide | 236-542-1 | 13424-46-9 begin_of_the_skype_highlighting | 2011/12/19 | Toxic for reproduction (article 57 c), |
| Potassium hydroxyoctaoxodizincatedichromate | 234-329-8 | 11103-86-9 begin_of_the_skype_highlighting | 2011/12/19 | Carcinogenic (article 57 a) |
| Formaldehyde, oligomeric reaction products with aniline | 500-036-1 | 25214-70-4 begin_of_the_skype_highlighting | 2011/12/19 | Carcinogenic (article 57 a) |
| Lead dipicrate | 229-335-2 | 6477-64-1 | 2011/12/19 | Toxic for reproduction (article 57 c) |
| Trilead diarsenate | 222-979-5 | 3687-31-8 | 2011/12/19 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c) |
| Bis(2-methoxyethyl) ether | 203-924-4 | 111-96-6 | 2011/12/19 | Toxic for reproduction (article 57 c) |
| Calcium arsenate | 231-904-5 | 7778-44-1 | 2011/12/19 | Carcinogenic (article 57 a) |
| 2,2'-dichloro-4,4'-methylenedianiline | 202-918-9 | 101-14-4 | 2011/12/19 | Carcinogenic (article 57 a) |
| Cobalt dichloride | 231-589-4 | 7646-79-9 | 2011/06/20 - | Carcinogenic |

| *Substance Name* | *EC Number* | *CAS Number* | *Date of inclusion* | *Reason for inclusion* |
|---|---|---|---|---|
| | | | 2008/10/28 | and toxic for reproduction (articles 57 a and 57 c) |
| Strontium chromate | 232-142-6 | 7789-06-2 | 2011/06/20 | Carcinogenic (article 57a) |
| 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters | 271-084-6 | 68515-42-4 | 2011/06/20 | Toxic for reproduction (article 57c) |
| 1,2,3-Trichloropropane | 202-486-1 | 96-18-4 | 2011/06/20 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c) |
| 2-Ethoxyethyl acetate | 203-839-2 | 111-15-9 | 2011/06/20 | Toxic for reproduction (article 57c) |
| 1-Methyl-2-pyrrolidone | 212-828-1 | 872-50-4 | 2011/06/20 | Toxic for reproduction (article 57c) |
| 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich | 276-158-1 | 71888-89-6 begin_of_the_skype_highlighting | 2011/06/20 | Toxic for reproduction (article 57c) |
| Hydrazine | 206-114-9 | 302-01-2, 7803-57-8 | 2011/06/20 | Carcinogenic (article 57a) |
| 2-Ethoxyethanol | 203-804-1 | 110-80-5 | 2010/12/15 | Toxic for reproduction (article 57c) |
| Cobalt(II) sulphate | 233-334-2 | 10124-43-3 begin_of_the_skype_highlighting | 2010/12/15 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c) |
| 2-Methoxyethanol | 203-713-7 | 109-86-4 | 2010/12/15 | Toxic for reproduction (article 57c) |
| Acids generated from chromium trioxide and their oligomers. Group containing: Chromic acid, Dichromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid | 231-801-5, 236-881-5 | 7738-94-5, 13530-68-2 begin_of_the_skype_highlighting | 2010/12/15 | Carcinogenic (article 57a) |
| Cobalt(II) diacetate | 200-755-8 | 71-48-7 | 2010/12/15 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c) |
| Cobalt(II) carbonate | 208-169-4 | 513-79-1 | 2010/12/15 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c) |
| Chromium trioxide | 215-607-8 | 1333-82-0 | 2010/12/15 | Carcinogenic and mutagenic (articles 57 a and 57 b) |
| Cobalt(II) dinitrate | 233-402-1 | 10141-05-6 begin_of_the_skype_highlighting | 2010/12/15 | Carcinogenic and toxic for reproduction (articles 57 a |

| *Substance Name* | *EC Number* | *CAS Number* | *Date of inclusion* | *Reason for inclusion* |
|---|---|---|---|---|
| | | | | and 57 c) |
| Boric acid | 233-139-2, 234-343-4 | 10043-35-3 begin_of_the_skype_highlighting end_of_the_skype_highlighting, 11113-50-1 begin_of_the_skype_highlighting | 2010/06/18 | Toxic for reproduction (article 57 c) |
| Disodium tetraborate, anhydrous | 215-540-4 | 1303-96-4, 1330-43-4, 12179-04-3 begin_of_the_skype_highlighting | 2010/06/18 | Toxic for reproduction (article 57 c) |
| Potassium dichromate | 231-906-6 | 7778-50-9 | 2010/06/18 | Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c) |
| Ammonium dichromate | 232-143-1 | 7789-09-5 | 2010/06/18 | Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c) |
| Sodium chromate | 231-889-5 | 7775-11-3 | 2010/06/18 | Carcinogenic, mutagenic and toxic for reproduction (articles 57 a, 57 b and 57 c) |
| Potassium chromate | 232-140-5 | 7789-00-6 | 2010/06/18 | Carcinogenic and mutagenic (articles 57 a and 57 b). |
| Tetraboron disodium heptaoxide, hydrate | 235-541-3 | 12267-73-1 begin_of_the_skype_highlighting | 2010/06/18 | Toxic for reproduction (article 57 c) |
| Trichloroethylene | 201-167-4 | 79-01-6 | 2010/06/18 | Carcinogenic (article 57 a) |
| Acrylamide | 201-173-7 | 79-06-1 | 2010/03/30 | Carcinogenic and mutagenic (articles 57 a and 57 b) |
| Pitch, coal tar, high temp. | 266-028-2 | 65996-93-2 | 2010/01/13 | Carcinogenic, PBT and vPvB (articles 57a, 57d and 57e) |
| Anthracene oil, anthracene paste | 292-603-2 | 90640-81-6 | 2010/01/13 | Carcinogenic[2], mutagenic[3], PBT and vPvB (articles 57a, 57b, 57d and 57e) |
| Anthracene oil, anthracene-low | 292-604-8 | 90640-82-7 | 2010/01/13 | Carcinogenic[2], mutagenic[3], PBT and vPvB (articles 57a, |

| *Substance Name* | *EC Number* | *CAS Number* | *Date of inclusion* | *Reason for inclusion* |
|---|---|---|---|---|
| | | | | 57b, 57d and 57e) |
| Zirconia Aluminosilicate Refractory Ceramic Fibresare fibres covered by index number 650-017-00-8 begin_of_the_skype_highlighting 650-017-00-8 end_of_the_skype_highlighting in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 begin_of_the_skype_highlighting 1272/2008 end_of_the_skype_highlighting of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions:a) Al2O3, SiO2 and ZrO2 are present within the following concentration ranges:Al2O3: 35 – 36 % w/w, and SiO2: 47.5 – 50 % w/w, and ZrO2: 15 - 17 % w/w,b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm). | - | Extracted from Index no. 650-017-00-8 begin_of_the_skype_highlighting | 2010/01/13 | Carcinogenic (article 57a) |
| Aluminosilicate Refractory Ceramic Fibresare fibres covered by index number 650-017-00-8 begin_of_the_skype_highlighting 650-017-00-8 end_of_the_skype_highlighting in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 begin_of_the_skype_highlighting 1272/2008 end_of_the_skype_highlighting of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the two following conditions:a) Al2O3 and SiO2 are present within the following concentration ranges:Al2O3: 43.5 – 47 % w/w, and SiO2: 49.5 – 53.5 % w/w,orAl2O3: 45.5 – 50.5 % w/w, and SiO2: 48.5 – 54 % w/w,b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm). | - | Extracted from Index no.: 650-017-00-8 begin_of_the_skype_highlighting | 2010/01/13 | Carcinogenic (article 57a) |
| Tris(2-chloroethyl)phosphate | 204-118-5 | 115-96-8 | 2010/01/13 | Toxic for reproduction (article 57c) |
| Anthracene oil | 292-602-7 | 90640-80-5 | 2010/01/13 | Carcinogenic[1], PBT and vPvB (articles 57a, 57d and 57e) |
| Anthracene oil, anthracene paste, anthracene fraction | 295-275-9 | 91995-15-2 | 2010/01/13 | Carcinogenic[2], mutagenic[3], |

| *Substance Name* | *EC Number* | *CAS Number* | *Date of inclusion* | *Reason for inclusion* |
|---|---|---|---|---|
| | | | | PBT and vPvB (articles 57a, 57b, 57d and 57e) |
| Lead chromate | 231-846-0 | 7758-97-6 | 2010/01/13 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c) |
| **Diisobutyl phthalate** | 201-553-2 | 84-69-5 | 2010/01/13 | Toxic for reproduction (article 57c) |
| Lead chromate molybdate sulphate red (C.I. Pigment Red 104) | 235-759-9 | 12656-85-8 begin_of_the_skype_ highlighting | 2010/01/13 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c) |
| Anthracene oil, anthracene paste,distn. lights | 295-278-5 | 91995-17-4 | 2010/01/13 | Carcinogenic[2], mutagenic[3], PBT and vPvB (articles 57a, 57b, 57d and 57e) |
| 2,4-Dinitrotoluene | 204-450-0 | 121-14-2 | 2010/01/13 | Carcinogenic (article 57a) |
| Lead sulfochromate yellow (C.I. Pigment Yellow 34) | 215-693-7 | 1344-37-2 | 2010/01/13 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c)) |
| Sodium dichromate | 234-190-3 | 7789-12-0, 10588-01-9 begin_of_the_skype_ highlighting | 2008/10/28 | Carcinogenic, mutagenic and toxic for reproduction (articles 57a, 57b and 57c) |
| Diarsenic trioxide | 215-481-4 | 1327-53-3 | 2008/10/28 | Carcinogenic (article 57a) |
| Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins) | 287-476-5 | 85535-84-8 | 2008/10/28 | PBT and vPvB (articles 57 d and 57 e) |
| **Benzyl butyl phthalate (BBP)** | 201-622-7 | 85-68-7 | 2008/10/28 | Toxic for reproduction (article 57c) |
| Lead hydrogen arsenate | 232-064-2 | 7784-40-9 | 2008/10/28 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c) |
| Triethyl arsenate | 427-700-2 | 15606-95-8 begin_of_the_skype_ highlighting | 2008/10/28 | Carcinogenic (article 57a) |
| Diarsenic pentaoxide | 215-116-9 | 1303-28-2 | 2008/10/28 | Carcinogenic (article 57a) |
| **Dibutyl phthalate (DBP)** | 201-557-4 | 84-74-2 | 2008/10/28 | Toxic for reproduction (article 57c) |
| 4,4'- Diaminodiphenylmethane (MDA) | 202-974-4 | 101-77-9 | 2008/10/28 | Carcinogenic (article 57a) |

| *Substance Name* | *EC Number* | *CAS Number* | *Date of inclusion* | *Reason for inclusion* |
|---|---|---|---|---|
| **5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)** | 201-329-4 | 81-15-2 | 2008/10/28 | vPvB (article 57e) |
| Anthracene | 204-371-1 | 120-12-7 | 2008/10/28 | PBT (article 57d) |
| **Bis (2-ethylhexyl)phthalate (DEHP)** | 204-211-0 | 117-81-7 | 2008/10/28 | Toxic for reproduction (article 57c) |
| Bis(tributyltin)oxide (TBTO) | 200-268-0 | 56-35-9 | 2008/10/28 | PBT (article 57d) |
| Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane | 247-148-4 and 221-695-9 | 25637-99-4 begin_of_the_skype_highlighting end_of_the_skype_highlighting, 3194-55-6 (134237-50-6 begin_of_the_skype_highlighting end_of_the_skype_highlighting) (134237-51-7 begin_of_the_skype_highlighting end_of_the_skype_highlighting) (134237-52-8 begin_of_the_skype_highlighting end_of_the_skype_highlighting) | 2008/10/28 | PBT (article 57d) |

Source: European Chemicals Agency website