EUROPEAN
COMMISSION

Brussels, XXX
[…](2013) XXX draft

COMMISSION DECISION

of XXX

establishing the ecological criteria for the award of the EU Ecolabel for absorbent hygiene products

(Text with EEA relevance)

COMMISSION DECISION

of XXX

establishing the ecological criteria for the award of the EU Ecolabel for absorbent hygiene products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel[1], and in particular Article 8(2) thereof,

After consulting the European Union Eco-labelling Board,

Whereas:

(1) Under Regulation (EC) No 66/2010, the EU Ecolabel may be awarded to products which have a reduced environmental impact during their entire life cycle.

(2) Regulation (EC) No 66/2010 provides that specific EU Ecolabel criteria are to be established according to product groups.

(3) The criteria, as well as the related assessment and verification requirements should be valid for four years from the date of adoption of this Decision, taking into account the innovation cycle for this product group. These criteria aim at using of materials produced in a more sustainable way (considering a life cycle analysis approach), limiting the use of hazardous compounds, the levels of hazardous residues and the contribution of mattresses to indoor air pollution and promoting a durable and high-quality product that is easy to repair and disassembly.

(4) Since consumption of materials can contribute significantly to the overall environmental impacts of absorbent hygiene products, it is appropriate to establish EU Ecolabel criteria for this product group. The criteria should, in particular, promote material-efficient, high-quality products which fit-for-use and are design in an environmentally conscious way.

Comment [MC1]: To be revised

(5) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 16 of Regulation (EC) No 66/2010,

[1] OJ L 27, 30.1.2010, p. 1.

HAS ADOPTED THIS DECISION:

Article 1

1. The product group “adsorbent hygiene products” shall include products which:
   a. Are used for the physical and direct collection of human body waste streams and
   b. Are composed of a mix of natural fibres and polymers, with the fibre content lower than 90% by weight and
   c. Are disposable.
2. The product group shall comprise:
   a. all types of baby diapers
   b. all types of feminine care pads (e.g. sanitary pads/napkins and panty liners)
   c. all types of tampons
   d. breast pads

3 The product group shall not comprise incontinence products and any other type of products falling under the scope of the Council Directive 93/42/EEC 14 June 1993 concerning medical devices[2].

Article 2

For the purpose of this Decision, the following definitions shall apply:

(1) 'Cellulose pulp' means a fibrous material obtained from the treatment of lignocellulosic materials (wood or other agricultural fiber sources) with one or more aqueous solutions of pulping and/or bleaching chemicals. This is composed of cellulose, hemi-cellulose, lignin, and other minor components. The relative amounts of these components depend on the extent of the pulping and bleaching processes.

(2) 'Plastic materials', also referred to as 'Plastics', means synthetic polymers to which additives or other substances may have been added which can be moulded and used as main structural component of final materials and articles.

(3) 'Synthetic polymers' means macromolecular substances other than cellulose pulp intentionally obtained either by:
   (1) A polymerisation process such as poly-addition or poly-condensation, or by any other similar process of monomers and other starting substances;
   (2) Chemical modification of natural or synthetic macromolecules;
   (3) Microbial fermentation.

(4) 'Super absorbent polymers (SAP)' means synthetic polymers designed for absorbing and retaining large amounts of liquid compared to their own mass.

Article 3

In order to be awarded the EU Ecolabel under Regulation (EC) No 66/2010, a product shall fall within the product group "absorbent hygiene products" as defined in Article 1 of this

[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

Decision and shall comply with the criteria as well as the related assessment and verification requirements set out in the Annex.

Article 4

The criteria for the product group "absorbent hygiene products", as well as the related assessment and verification requirements, shall be valid for four years from the date of adoption of this Decision.

Comment [MC2]: correct?

Article 5

For administrative purposes, the code number assigned to the product group "absorbent hygiene products" shall be "XX".

Article 6

This Decision shall apply from [*Please fill in with the date of two months after the adoption]*. Applications shall be evaluated in accordance with the criteria on which they are based..

Formatted: Indent: Left: 0 cm

Article 8

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission

Janez POTOČNIK

Member of the Commission

ANNEX

EU ECOLABEL CRITERIA

Criteria for awarding the EU Ecolabel to bed mattresses:

1. Product description
2. Fluff pulp
3. Man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate)
4. Cotton and other natural cellulosic seed fibres
5. Plastic materials and super absorbent polymers
6. Other materials
7. Excluded or limited substances or mixtures
8. Material efficiency in the manufacturing
9. Guidance on the product disposal
10. Fitness for use and quality of the product
11. Information appearing on the EU Ecolabel
12. Social aspects

The specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant or his supplier or both.

Where possible, the testing shall be performed by laboratories that meet the general requirements of European Standard EN ISO 17025[3] or equivalent.

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

As pre-requisite, the product must meet all respective legal requirements of the country (countries) in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement.

Comment [MC3]: To be revised

1. Product description

A description of product and packaging shall be provided (product name, classification, functionalities) together with information on:

- the total weight of the product,
- the materials and additives used in the product with their respective weights and, whenever applicable, their respective CAS numbers.

Information on the weight shall be also displayed in the packaging.

Assessment and verification:

[3] ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

The applicant shall provide a sample of the product and a report including the technical description and the weight of the product and of each material used.

2. Fluff pulp

2.1 Sourcing

All pulp fibres shall be covered by valid sustainable forest management and chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

A minimum of 25% pulp fibres shall be manufactured from wood that has been grown according to the principles of Sustainable Forestry Management as defined by the UN FAO.

The remaining proportion of pulp fibres shall be from wood that is sourced from legal forestry and plantations.

Assessment and verification:

The applicant shall provide valid, independently certified chain of custody certificates from the pulp supplier(s) demonstrating that pulp fibres have been grown according to Sustainable Forestry Management principles and/or are from legal sources.

FSC, PEFC and PEFC endorsed schemes shall be accepted as independent certification.

The pulp manufacturer shall demonstrate that due diligence processes have been followed as specified in Regulation (EC) 995/2010 in order to ensure that timber has been legally harvested. Valid FLEGT (Forest Law Enforcement, Governance and Trade) or CITES (Convention on International Trade in Endangered Species) licenses or third party certification shall be accepted as evidence of legal sourcing.

2.2 Bleaching

The pulp used in the product shall not be bleached with the use chlorine gas. The total amount of AOX emissions from pulp manufacturing shall not exceed 0.17 kg/ADT.

Assessment and verification:

The applicant shall provide a declaration from the pulp supplier that chlorine gas is not used and a test report showing compliance with the AOX limit value. ISO 9562 or the equivalent EPA 9562 shall be accepted as test methods and detailed calculations shall be included in the test report, together with related supporting documentation.

The supporting documentation shall include an indication of the measurement frequency. AOX shall only be measured in processes where chlorine compounds are used for the bleaching of the pulp.

2.3 Optical brighteners and colouring agents

Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the pulp.

Assessment and verification*:*

The applicant shall provide a declaration from the supplier that the requirements have been fulfilled

2.4 Emission of COD and phosphorous (P) to water and sulphur (S) compounds and NOx to air from production

The emissions to air and/or water from the pulp production shall be expressed in terms of points (P_{COD}, P_S, P_{NOx}, P_P). Points are calculated by dividing actual emission by the reference values reported below.

- None of the individual points P_{COD}, P_S, P_{NOx}, P_P shall exceed 1.5.
- The total number of points (P total = $P_{COD} + P_S + P_{NOx} + P_P$) shall not exceed 4.0.

Pulp grade	**Reference values (kg/ADT)**			
	COD_{ref}	**S_{ref}**	**NOx_{refe}**	**P_{ref}**
Bleached chemical pulp (others than sulphite)	18.0	0.6	1.6	0.045 (*)
Bleached chemical pulp (sulphite)	25.0	0.6	1.6	0.045
CTMP	15.0	0.2	0.3	0.005
(*) Net emissions of P are considered in the calculation. The P naturally contained in wood raw materials and in water can be subtracted from the total emissions of P. Reductions up to 0.010 kg/ADT shall be accepted.				

In case of a co-generation of heat and electricity at the same plant, the emissions of S and NOx resulting from electricity generation shall be subtracted from the total amount.

The following equation shall be used to calculate the proportion of the emissions resulting from heat generation: $[MWh(heat) – MWh(heat)_{sold}] / [MWh(heat) + 2 \times MWh(electricity)]$

Where,

- MWh(electricity) is the electricity produced at the co-generation plant.
- MWh(heat) is the useful heat produced in a cogeneration process
- $MWh(heat)_{sold}$ is the useful heat that is used outside the pulp manufacturing plant.

Assessment and verification:

The applicant shall provide detailed calculations showing compliance with this criterion, together with related supporting documentation which shall include test reports using the following test methods:

- *COD: ISO 6060, EPA SM 5220D or HACH 8000;*
- *NOx: ISO 11564 or EPA 7E;*
- *S(oxid.): EPA 8;*
- *S(red.): EPA 8 or EPA 16A;*

- *S content in oil: ISO 8754 or EPA 8;*
- *S content in coal: ISO 351 or EPA 8;*
- *P: ISO 6878, SM4500, APAT IRSA CNR 4110 or Dr Lange LCK 349.*

The supporting documentation shall include an indication of the measurement frequency and the calculation of the points for COD, S, NOx and P. It shall include all emissions of S and NOx which occur during the production of pulp, including steam generated outside the production site, except those emissions related to the production of electricity.

Measurements shall include recovery boilers, lime kilns, steam boilers and destructor furnaces for strong smelling gases. Diffuse emissions shall be taken into account.

Reported emission values for S to air shall include both oxidised and reduced S emissions (dimethyl sulphide, methyl mercaptan, hydrogen sulphide and the like). The S emissions related to the heat energy generation from oil, coal and other external fuels with known S content may be calculated instead of measured, and shall be taken into account.

Measurements of emissions to water shall be taken on unfiltered and unsettled samples either after treatment at the plant or after treatment by a public treatment plant.

The measurement period shall be 12 months of production. Measurements for COD and P shall be taken on a monthly basis, measurements for S and NO_x on a yearly basis.

For a new or re-built plant or a change of process at the production plant, measurements shall be done on a weekly basis for a total of 8 consecutive weeks following steady running of the plant. The measurement shall be representative of the respective campaign.

2.5 Emissions of CO_2 from production

CO_2 emissions from non-renewable energy sources shall not exceed 500 kg per tonne of pulp produced. Reference values according to the following table shall be taken into account:

Fuel	**CO_2 fossil emissions (g $CO_{2fossil}$/MJ)**
Coal	95
Crude oil	73
Fuel oil 1	74
Fuel oil 2-5	77
LPG	69
Natural Gas	56
Grid Electricity	400

Assessment and verification:

The applicant shall provide detailed calculations showing compliance with this criterion, together with related supporting documentation.

The applicant shall provide data on the air emissions of carbon dioxide. This shall include all sources of non-renewable fuels during the production of pulp, including the emissions from the production of electricity (whether on-site or off-site).

The measurement period shall be 12 months of production. Measurements shall be done on a yearly basis.

For a new or re-built plant or a change of process at the production plant, measurements shall be done on a weekly basis for a total of 8 consecutive weeks following steady running of the plant. Results have to be shown also after 12 months of production. The measurement shall be representative of the respective campaign.

The amount of energy from renewable sources purchased and used for the production processes will not be considered in the calculation of the CO_2 emissions: appropriate documentation that this kind of energy are actually used at the mill or are externally purchased shall be provided by the applicant.

3. Man-made cellulose fibres (including viscose, modal, lyocell, cupro, triacetate)

3.1 Sourcing

(a) All pulp fibres shall be covered by valid sustainable forest management and chain of custody certificates issued by an independent third party certification scheme such as FSC, PEFC or equivalent.

A minimum of 25% pulp fibres shall be manufactured from wood that has been grown according to the principles of Sustainable Forestry Management as defined by the UN FAO.

The remaining proportion of pulp fibres shall be from wood that is sourced from legal forestry and plantations.

(b) Dissolving pulp produced from cotton linters shall meet with the requirement 4.1 for cotton (sourcing and traceability).

Assessment and verification:

(a) The applicant shall provide valid, independently certified chain of custody certificates from the pulp supplier(s) demonstrating that pulp fibres have been grown according to Sustainable Forestry Management principles and/or are from legal sources.

FSC, PEFC and PEFC endorsed schemes shall be accepted as independent certification.

The pulp manufacturer shall demonstrate that due diligence processes have been followed as specified in Regulation (EC) 995/2010 in order to ensure that timber has been legally harvested. Valid FLEGT (Forest Law Enforcement, Governance and Trade) or CITES (Convention on International Trade in Endangered Species) licenses or third party certification shall be accepted as evidence of legal sourcing.

(b) The application shall provide evidence of compliance according to criterion 4.1 for cotton (sourcing and traceability).

3.2 Bleaching

The pulp used to manufacture fibres shall not be bleached with the use of chlorine gas. The resulting total amount of adsorbable organically bound halogens (AOX) and organically bound chlorine (OCl) shall not exceed:

- 0.17 kg/ADT, if measured in the wastewater from pulp manufacturing (AOX), or

- 150 ppm, if measured in the finished fibres (OCl).

Assessment and verification:

The applicant shall provide a declaration from the pulp supplier that chlorine gas is not used and a test report showing compliance with either the AOX or the OCl requirement, using the appropriate test method:

- *ISO 9562 or the equivalent EPA 9562 for AOX;*
- *ISO 11480 for OCl.*

3.3 Optical brighteners and colouring agents

Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the fibres.

Assessment and verification*:*

The applicant shall provide a declaration from the supplier that the requirements have been fulfilled.

3.4 Production of fibres

(a) More than 50% of pulp used to manufacture fibres shall be obtained from dissolving pulp mills that recover value from their spent process liquor either by i) generating on-site electricity and steam and/or ii) by manufacturing chemical co-products.

(b) The following limit values for the emission of sulphur compounds to air shall be respected in the viscose and in the modal fibres production process:

Fibre type	**Sulphur emissions to air - Limit value (g/kg)**
Staple fibre	30
Filament fibre	
- Batch washing	40
- Integrated washing	170
Note: Limit values expressed as annual average	

Assessment and verification:

(a) The applicant shall make the fibres manufacturers to provide a list of pulp suppliers used to produce the fibres and the proportion they supply. Supporting documentation and evidence shall be provided that the required proportion of suppliers has the appropriate energy generating equipment and/or co-product recovery and manufacturing systems installed at related production sites.

(b) The applicant shall provide detailed documentation and/or test reports showing compliance with this criterion, together with a declaration of compliance.

4. Cotton and other natural cellulosic seed fibres

4.1 Sourcing and traceability

(a) More than 10% of cotton and other natural cellulosic seed fibres (hereinafter referred to as cotton) shall be grown according to the requirements laid down in Regulation (EC) No 834/2007[4], the US National Organic Programme (NOP) or equivalent legal obligations set by trade partners of the EU. The organic cotton content may include organically grown cotton and transitional organic cotton.

(b) With the exception of organic cotton, all the cotton used shall be grown without the use of any of the following substances:

Alachlor, aldicarb, aldrin, campheclor (toxaphene), captafol, chlordane, 2,4,5-T, chlordimeform, chlorobenzilate, cypermethrin, DDT, dieldrin, dinoseb and its salts, endosulfan, endrin, glyphosulfate, heptachlor, hexachlorobenzene, hexachlorocyclohexane (total isomers), methamidophos, methyl-o-dematon, methylparathion, monocrotophos, neonicotinoids (chlothianidine, imidacloprid, thiametoxam), parathion, phosphamidon, pentachlorophenol, thiofanex, triafanex, triazophos

Cotton shall not contain more than 0.5 ppm in total of the substances listed above.

(c) All the cotton used shall come from non-genetically modified varieties and shall be fully traceable from the point of verification of the production standard.

Assessment and verification:

(a) Organic content should be certified by an independent control body to have been produced in conformity with the production and inspection requirements laid down in Regulation (EC) No 834/2007, the US National Organic Programme (NOP) or those set by other trade partners. Verification shall be provided on an annual basis for each country of origin.

(b) Cotton shall be tested for the listed substances. A test report shall be provided based on the following test methods, as appropriate:

- *US EPA 8081 B (organo-chlorine pesticides, with ultrasonic or Soxhlet extraction and apolar solvents (iso-octane or hexane)),*
- *US EPA 8151 A (chlorinated herbicides, using methanol),*
- *US EPA 8141 B (organophosphorus compounds),*
- *US EPA 8270 D (semi-volatile organic compounds).*

Tests shall be made on samples of raw cotton from each country of origin and before it passes through any wet treatment. For each country of origin testing shall be carried out on the following basis:

- *Where only one lot of cotton is used per year a sample shall be taken from a randomly selected bale,*
- *If more than two lots of cotton are used per year composite samples shall be taken from 5 % of the bales.*

4 Council Regulation (EC) No 834/2007of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ L 189, 20.7.2007, p. 1)

Cotton is not required to be tested where it has been certified as organic.

(c) Non-genetically modified varieties of cotton shall be verified in conformity with Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms.

The applicant shall also demonstrate compliance with the minimum cotton content requirement either for the annual volume of cotton purchased or for the blend of cotton used to manufacture the final product(s) and according to each product line:

- *On an annualised basis: Transaction records and/or invoices shall be provided that document the quantity of cotton purchased on an annual basis from farmers or producer groups, and/or the total weight of certified bales up until greige fabric production.*
- *On a final product basis: Documentation shall be provided from the non-woven fabric production stages. All documentation shall reference the Control Body or certifier of the different forms of cotton.*

4.2 Bleaching

Cotton shall not be bleached with the use of chlorine gas.

Assessment and verification:

The applicant should provide a declaration from the supplier that chlorine gas is not used.

4.3 Optical brighteners and colouring agents

Optical brighteners and colouring agents, including fluorescent whitening agents, shall not be intentionally added to the cotton.

Assessment and verification*:*

The applicant shall provide a declaration from the supplier that the requirements have been fulfilled

5. Plastic materials and super absorbent polymers

5.1 Sourcing and production of synthetic polymers used in plastic materials

(a) For the polymers used to produce plastic materials reported below, cradle-to-gate emissions of greenhouse gases and demand of energy resources shall be lower than the thresholds reported in the table (when applicable).

Synthetic polymer	GWP (kg CO2eq/kg)	Energy resources (MJ/kg, HHV)	
		Fuel energy	Feedstock
LDPE, resin	2.13	26.5	51.6
LLDPE, resin	1.89	24.1	48.6
HDPE, resin	1.96	22.5	54.3

PP, resin	2.00	20.8	52.6
PS, general purposes	2.25	36.48 (34.48 - 38.48)	46.3 (44.3 – 48.3)
PS, high impact	2.43	40.69 (38.69 - 42.69)	48.8 (48.3 - 49.3)

(b) The following measures shall be implemented in the plants producing plastic materials and synthetic polymers used in the product:

- Water-saving solutions (e.g. monitoring of water flow in a facility and circulating the water in closed systems);
- Integrated waste management plan to optimize prevention, reuse, recycling, recovery and final disposal of waste (e.g. separation of different waste fractions)
- Optimization of energy efficiency and energy management (e.g. reuse of the steam generated during the manufacture of SAPs)

Assessment and verification:

(a) Cradle-to-gate emissions of greenhouse gases and demand of non-renewable energy from the polymers used to manufacture the plastic materials listed in the table above shall be calculated according to ISO 14040/44, ISO 14025 and the guidelines provided by Plastic Europe in

- *http://www.plasticseurope.org/Documents/Document/20100312112214-PlasticsEuropeEPDProgrammeInstructions200709-20070620-006-EN-v1.pdf*
- *http://www.plasticseurope.org/documents/document/20110421141821-plasticseurope_eco-profile_methodology_version2-0_2011-04.pdf.*

Results will be third-party reviewed according to ISO 14040/44, ISO 14025 and ISO/DTS 14071 and summarised in a concise technical report for Competent Bodies.

(b) The applier shall make suppliers to provide a report describing how these requirements have been fulfilled in all the production plants. These may include layouts of the manufacturing plants with brief explanation and appropriate certification according to ISO 14001 (Environmental Management Systems) and ISO 50001 (Energy Management Systems).

5.2 Additives in plastic materials

(a) Contents of lead, cadmium, ~~mercury,~~ hexavalent chrome and related compounds ~~and attendant impurities as well as organostannic compounds~~ shall be lower than 0.01% (100 ppm) of the mass of each plastic material and synthetic polymer used in the product.

(b) Additives intentionally used in plastics in concentration above 0.1% by weight shall not be classified, according to 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 as:

- carcinogenic, mutagenic or toxic for reproduction, categories 1a, 1b and 2 (H340, H350, H350i, H360F, H360D, H360FD, H360Fd, H360Df);

- acutely toxic, categories 1 and 2 (H300, H310, H330, H304);
- toxic to specific target organs (STOT), category 1: (H370, H372);
- hazardous to the aquatic environment, categories 1 and 2 (H400, H410, H411).

Assessment and verification:

(a), (b) The applicant shall make suppliers to provide a declaration of non-use in conformity with ISO/IEC 17050, confirming that classified additives have not been intentionally used in the plastic material / synthetic polymer in concentrations above 0.01%. A list of added substances shall be also provided, including concentrations and related H statements/R phrases, supported by safety data sheets.

In order to facilitate follow-up and monitoring of the documentation provided, a random sample of suppliers may be examined. The supplier shall provide access to production facilities, warehouses and the like. Confidentiality applies to any documentation and information submitted and shared.

5.3 Super Absorbent Polymers

(a) Acryl amide (CAS number: 79-06-1) shall not be intentionally added to the product.

(b) Super Absorbent Polymers used in the product may contain a maximum of 1000 ppm residual monomers (total of unreacted acrylic acid and cross linkers) that are classified with the H-statements reported in criterion 7 on excluded or limited substances or mixtures. Sodium polyacrilate (CAS number: 9003-04-7) is exempted from this requirement.

(c) SAP used in the product may as a maximum contain 10% (weight/weight) of water-soluble extracts (i.e. monomers and oligomers of acrylic acid with lower molecular weight than SAP according to ISO 17190). Sodium polyacrilate (CAS number: 9003-04-7) is exempted from this requirement.

Assessment and verification:

(a) The applicant shall provide a declaration of non-use of the substance.

(b) The applicant shall provide a declaration from the supplier documenting the composition of the superabsorbent polymer(s) used in the product. This must be done by means of a product safety data sheets which specify the full name and CAS number and the residual monomers contained in the product classified in accordance with the above requirements and the quantities thereof. Recommended test methods are ISO 17190, WSP 210.2 (05), ERT 410.2 (02)/IST 210.2(02).. The methods used for the analyses shall be described and the names of the laboratories used for analysis shall be stated.

(c) The applicant shall provide a declaration from the supplier specifying the quantity of water-soluble extracts in the super-absorbent polymer(s). Recommended test methods are ISO 17190, WSP 270.2 (05), ERT 470.2 (02)/IST 270.2(02). The methods used for the analyses shall be described and the analysis laboratories shall be stated.

6. Other materials

6.1 Adhesive materials

Adhesive materials must not contain:

- Colophony resins (CAS numbers 8050-09-7, 8052-10-6, 73138-82-6),
- Diisobutyl phthalate (DIBP, CAS number 84-69-5)
- Diisononyl phthalate (DINP, CAS number 28553-12-0)
- Formaldehyde (CAS number 50-00-0).

The requirement does not apply if these substances:

1. Are not intentionally added to the material or to the final product, and
2. Are present in the adhesive materials in concentrations below 100 ppm (0.010% by weight).

For formaldehyde, the maximum limit for the content of formaldehyde generated during adhesive production is 250 ppm, measured in newly produced polymer dispersion. Content of free formaldehyde in hardened adhesive (glue) must not exceed 10 ppm. Hotmelt adhesives are exempted from this requirement.

Assessment and verification:

The applicant shall provide a declaration from the supplier that the requirements have been fulfilled. Safety data sheets may be used as proof. Test results for formaldehyde shall be provided, with the exception of hotmelt adhesives.

Formatted: Not Highlight

6.2 Inks and dyes

The product and any homogeneous part of it must not be dyed. This prescription does not apply to tampon strings, packaging materials and tapes.

Titanium dioxide in polymers and viscose is exempted from this requirement.

Materials that are not directly in contact with the skin may however be dyed if the dye has the specific function of reducing visibility of the product through white or light coloured clothing.

Inks and dyes shall also comply with Criterion 7 on Excluded or limited substances or mixtures.

Assessment and verification:

The applicant shall provide and shall make suppliers to provide a declaration that the requirements have been fulfilled. In case dyes are used, their presence will be justified by indicating the specific function provided.

6.3 Fragrances

(a) Products intended for infants, babies and children under the age of twelve years shall 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 under the age of twelve years or have any of these words on the label/packaging.

(b) 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. The used fragrances shall also comply with Criterion 7 on Excluded or limited substances or mixtures.

(c) In case of their presence, the manufacturer shall indicate on the packaging the fragrances used in the product.

***Assessment and verification**:*

(a), (b), (c) The applicant shall provide a declaration that the requirements have been fulfilled. A sample of product with packaging shall be also provided.

6.4 Lotions

In case of their presence, the manufacturer shall indicate on the packaging the lotions used on the product. The used lotions shall comply with Criterion 7 on Excluded or limited substances or mixtures.

***Assessment and verification**:*

The applicant shall provide a declaration that the requirements have been fulfilled. A sample of product with packaging shall be also provided.

6.5 Silicone

a) Where components of the product are treated with silicone, the manufacturer shall ensure that employees are protected from the solvents.

b) Neither octamethyl cyclotetrasiloxane D4 (CAS 556-67-2) nor decamethyl cyclopentasiloxane D5 (CAS 541-02-6) shall be present in chemical products used in the silicone treatment of components. The requirement does not apply if D4 and D5:

1. are not intentionally added to the material or to the final product, and
2. are present in the silicone in concentrations below 100 ppm (0.01% by weight)

Assessment and verification:

a) The applicant shall provide information on the method used for the treatment of silicone and documentation attesting that employees are protected.

b) The applicant shall provide a declaration from the supplier that the requirement has been fulfilled.

6.6 Nanosilver particles

Nanosilver particles shall not be intentionally added to the product or to any homogeneous part or material of it.

Assessment and verification

The applicant shall provide a declaration and shall make suppliers to provide a declaration that the requirement has been fulfilled.

7. Excluded or limited substances or mixtures

7.1 Hazardous substances and mixtures

The EU Ecolabel may not be awarded if the product or any article of it, as defined in Article 3(3) of Regulation (EC) No 1907/2006, or any homogenous part of it contain substances or mixtures meeting the criteria for classification with the hazard statements or risk phrases specified in the table below, in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council or Council Directive 67/548/EC, nor they contain substances or mixtures referred to in Article 57 of Regulation (EC) No 1907/2006, unless they have been specifically derogated.

The most recent classification rules adopted by the European Union shall take precedence over the listed hazard classifications and risk phrases. Applicants shall therefore ensure that any classifications are based on the most recent classification rules.

The hazard statements and the risk phrases in the table below generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures apply.

The use of substances or mixtures which change their properties upon processing (e.g. become no longer bioavailable or undergo chemical modification) so that the identified hazards no longer apply are exempted from the above requirements. This shall include for instance modified polymers and monomers or additives which become covalently bonded within plastic coatings.

Hazard Statement [1]	**Risk Phrase** [2]
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
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 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	R39/23/24/25/26/27/28
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
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
H317 (Sub-category 1A): May cause allergic skin reaction (trigger concentration ≥0.1% w/w)[3]	R43
H317 (Sub-category 1B): May cause allergic skin reaction (trigger concentration ≥1.0% w/w)[3]	
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42

Notes

1 According to 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 According to Directive 67/548/EEC and the REACH Directive 2006/121/EC and Directive 1999/45/EC as amended.

3 According to 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.

Assessment and verification:

The applicant shall provide the bill of materials of the product, including a list with all articles and homogeneous part of it.

The applicant shall screen the presence of substances and mistures that may be classified with the hazard statements or risk phrases reported above in the criterion. The applicant shall provide a declaration of compliance with requirement 10(a) for the product, any article of it or any homogenous part of it.

Applicants shall select the appropriate forms of verification. The main forms of verification are foreseen as follows:

- Articles manufactured according to a specific chemical formulation: Safety Data Sheets shall be provided for the final article or for the substances and mixtures composing the final article above a cut-off limit of 0.10% w/w.

- Homogenous parts and any associated treatments or impurities (e.g. plastic parts): Safety Data Sheets shall be provided for the materials composing that part of product and for substances and mixtures used in the formulation and treatment of the materials remaining in the final part above a cut-off limit of 0.10% w/w.

- Chemical recipes used to impart a specific function to the product or to components of the product (e.g. glues and adhesives, dyes): Safety Data Sheets shall be provided for substances and mixtures used in the assembly of the final product or substances and mixtures applied to components of the product during production, dyeing, printing and finishing processes and remaining in the components of the product.

The declaration shall include related documentation, such as declarations of compliance signed by the suppliers, on the non-classification of the substances, mixtures or materials with any of the hazard classes associated to the hazard statements or risk phrases referred in the list above in accordance with Regulation (EC) No 1272/2008, as far as this can be determined, as a minimum, from the information meeting the requirements listed in Annex VII to Regulation (EC) No 1907/2006.

The information provided shall relate to the forms or physical states of the substances or mixtures as used in the final product.

The following technical information shall be provided to support the declaration of classification or non-classification for each substance and mixture:

- *(i) For substances that have not been registered under Regulation (EC) No 1907/2006 and/or which do not yet have a harmonised CLP classification: information meeting the requirements listed in Annex VII to that Regulation;*
- *(ii) For substances that have been registered under Regulation (EC) No 1907/2006 and which do not meet the requirements for CLP classification: information based on the REACH registration dossier confirming the non-classified status of the substance;*
- *(iii)For substances that have a harmonised classification or are self-classified: safety data sheets where available. If these are not available or the substance is self-classified then*

information shall be provided relevant to the substances hazard classification according to Annex II to Regulation (EC) No 1907/2006;

- *(iv) In the case of mixtures: safety data sheets where available. If these are not available then calculation of the mixture classification shall be provided according to the rules under Regulation (EC) No 1272/2008 together with information relevant to the mixtures hazard classification according to Annex II to Regulation (EC) No 1907/2006.*

Safety Data Sheets (SDS) shall be completed in accordance with the guidance in Section 10, 11 and 12 of Annex II of Regulation (EC) 1907/2006 (Requirements for the Compilation of Safety Data Sheets). Incomplete SDS will require supplementing with information from declarations by chemical suppliers.

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 to Regulation (EC) No 1907/2006. The sharing of relevant data across the supply chain is strongly encouraged.

Where substances used are derogated according to their hazard classification then the declaration shall specifically identify those derogated substances and provide supporting evidence showing how the derogation conditions are met.

7.2 Substances listed in accordance with Article 59(1) of Regulation (EC) No 1907/2006

No derogation from the exclusion in Article 6(6) of Regulation (EC) No 66/2010 shall be given concerning substances identified as substances of very high concern and included in the list provided for in Article 59(1) of Regulation (EC) No 1907/2006, present in mixtures, in an article or in any homogeneous part of the product in concentrations > 0.10% by weight.

Assessment and verification

Reference to the latest list of substances of very high concern shall be made on the date of application. The applicant shall provide a declaration of compliance with requirement 10(b), together with related documentation, including declarations of compliance signed by the material suppliers and copies of relevant Safety Data Sheets for substances or mixtures in accordance with Annex II to Regulation (EC) No 1907/2006 for substances or mixtures. Concentration limits shall be specified in the safety data sheets in accordance with Article 31 of Regulation (EC) No 1907/2006 for substances and mixtures.

8. Material efficiency in the manufacturing

The quantity of waste generated during the manufacture and packaging of the products, at the net of the fraction that is reused or converted into useful materials and/or energy, shall not exceed:

- 10% by weight of the end products for tampons
- 5% by weight of the end products for all the other products

Assessment and verification

The applicant shall provide evidence of the quantity of waste that has not been reused within the manufacturing process or that is not converted into materials and/or energy.

Calculations shall be shown in accordance with ISO 14025 and shall specify:

- *the weight of product and packaging,*
- *all the waste streams generated during the manufacture and*
- *the respective treatment processing (e.g. recycling, incineration), including the fraction of recovered waste and that disposed of.*

The net waste shall be calculated as waste produced – waste recovered.

9. Guidance on the product disposal

The producers shall write or indicate through visual symbols on the packaging

- That the product must not be flushed into toilets
- How to dispose the product correctly.

Assessment and verification:

The applicant shall provide a sample of the packaging.

10. Fitness for use and quality of the product

The efficiency/quality of the product shall be satisfactory and at the least equivalent of products already on the market. Fitness-for-use shall be tested with respect to the characteristics and parameters reported in the table below. Performance thresholds shall be matched, where these have been identified.

Characteristic		**Testing practice required (performance threshold)**			
		Baby diapers	**Feminine care pads**	**Tampons**	**Breast pads**
Quality and Safety		Compliance with the WHO´s Good Manufacturing Practices (GMP)			
In-use tests	U1. Absorption and leakage protection	Consumer panel test (Leakage occurs in less than 5% of the product uses)			
	U2. Skin dryness	Consumer panel test (80% of the consumers testing the product shall rate the performance as "good" (rating 7-8) or "very good" (rating 9-10) in a rating scale from 1 to 10)		Not applicable	As for baby diapers
	U3. Fit and comfort	Consumer panel test (80% of the consumers testing the product shall rate the performance as "good" (rating 7-8) or "very good" (rating 9-10) in a rating scale from 1 to 10)			
	U4. Overall performance	Consumer panel test (80% of the consumers testing the product shall rate the performance as "good" (rating 7-8) or "very good" (rating 9-10) in a rating scale from 1 to 10)			
Technical	T1. Absorption and	Absorption rate and		Syngina	No method

tests	leakage protection	absorption before leakage	method	recommended
	T2. Skin dryness	TEWL, rewet method or corneometric testing	Not applicable	No method recommended

Assessment and verification:

The applicant shall provide a declaration the of compliance with the WHO´s Good Manufacturing Practices (GMP).

A test report shall be provided for in-use and technical tests including a description of test methods, test results and data used. Tests shall be carried out by laboratories certified to implement quality management systems, no matter if internal or external. Test results shall be assessed by an impartial and competent organization.

Sampling, test design, panel recruitment and the analysis of test results shall comply with ASTM E1958-07e1. Tests shall be conducted for all the products applying for the EU Ecolabel. Special care shall be taken regarding sampling, transport and storage of the products to guarantee reproducible results. It is recommended not to blind products or repack them in neutral packaging due to the risk of altering the performance of products and/or packaging.

Information on testing shall be made available to Competent Bodies and to all interested parties, for instance through the company website. Test results shall be clearly explained and presented in language, units and symbols that are understandable to consumers. The following elements shall be specified: place and data of the tests; criteria used to select the products tested and their representativeness; selected testing characteristics and, if applicable, the reasons why some were not included; test methods used and their limitations if any. External factors such as branding, market shares and advertising that may have an impact on the perceived performance of the products shall be communicated. Clear guidelines on the use of test results shall be provided.

Additional requirements for user tests:

- *Consumer surveys shall be conducted and analysed according to standard statistical practices, e.g. ASTM E1958-07e1*
- *Each product shall be assessed on the basis of a questionnaire. The test is to last at least 72 hours, a full week when possible.*
- *For skin dryness, fit and comfort and overall performance, testers shall be asked to indicate how much they are satisfied from a scale 1 to 10, where 1-2 indicate a very bad performance, 3-4 indicate a bad performance, 5-6 indicate an average performance, 7-8 indicate a good performance, 9-10 indicate a very good performance.*
- *For absorption and leakage protection, testers shall be asked to indicate if leakage has occurred or not.*
- *The recommended number of testers shall be at least 30. All the individuals participating to the survey shall be current users of the specific type/size of product tested.*
- *When the product is not designed specifically for a single gender, the ratio of male to female individuals shall be 1:1*
- *A mixture of individuals representing proportionally different groups of consumers available on the market shall take part to the survey. Age, countries and genders shall be clearly stated.*
- *The product shall be used in the same way and conditions of the product normally used.*

- *Sick individuals and those with a chronic skin condition should not participate in the test. In cases where individuals become ill during the course of the user trial, this is to be indicated on the questionnaire and the answers shall not be taken into consideration for the assessment.*
- *For skin dryness, fit and comfort and overall performance, 80% of the consumers testing the product shall rate the performance as "good" (rating 7-8) or "very good" (rating 9-10) in a rating scale from 1 to 10*
- *For absorption and leakage protection, leakage shall occur in less than 5% of the products tested*
- *The results are to be statistically evaluated after the user trial has been completed.*

Additional requirements for technical tests:

- *Test methods shall be based as much as possible on product-relevant, reproducible and rigorous methods.*
- *A minimum of 5 samples shall be tested. Average results shall be reported together with indication of the standard deviation*

Weight, dimensions and design features of the product shall be described and provided.

11. Information appearing on the EU Ecolabel

The use of the EU Ecolabel logo is protected in primary EU law. The logo should be visible and legible. The EU Ecolabel registration/license number must appear on the product, it must be legible and clearly visible.

The optional label with text box shall contain the following text:

1. The product is designed in order to reduce the impact from the consumption of resources
2. The use of substances of concern for human health and the environment is restricted;
3. The product satisfies performance and quality tests.

The guidelines for the use of the optional label with text box can be found in the "Guidelines for use of the Ecolabel logo" on the website: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

The following text should moreover appear on the packaging:

"For more information on why this product has been awarded the EU Ecolabel, please visit http://ec.europa.eu/environment/ecolabel/".

Assessment and verification

The applicant shall provide a sample of the product label, together with a declaration of compliance with this criterion

12. Social aspects

Applicants shall ensure that the fundamental principles and rights at work as described in the International Labour Organisation's (ILO) Core Labour Standards, the UN Global Compact and the OECD Guidelines for Multi-National Enterprises shall be observed by all production sites used to manufacture the licensed product(s).

For the purpose of verification the following ILO Core Labour Standards shall be referred to:

029 Forced Labour

087 Freedom of Association and Protection of the Right to Organise

098 Right to Organise and Collective Bargaining

100 Equal remuneration

105 Abolition of Forced Labour

111 Discrimination (Employment and Occupation)

138 Minimum Age Convention

155 Occupational safety and health

182 Elimination of the Worst Forms of Child Labour

These standards shall be communicated to production sites along the supply chain used to manufacture the final product. Exemptions from specific ILO Core Labour Standards shall apply where there are applicable national laws.

Assessment and verification

The applicant shall provide and shall make supplier to provide documentary evidence of compliance with the requirement. This shall be based on third party verification, including site visits by auditors, for all production sites in the supply chain for the licensed products.

The criterion shall be fulfilled since the date of application and subsequently during the license period if new production sites are introduced.