

ANNEX I

EU Ecolabel criteria for awarding the EU Ecolabel to cosmetic products

FRAMEWORK

Aims of the criteria

The EU Ecolabel criteria target the best cosmetic products on the market, in terms of environmental performance. The criteria focus on the main environmental impacts associated with the life cycle of these products and promote circular economy aspects.

In particular, the criteria aim to promote products that have limited impacts in terms of eco-toxicity and biodegradability, which may only contain a limited amount of hazardous substances and are marketed in a packaging easy to recycle.

To this end, the criteria:

- set requirements to limit the overall aquatic toxicity;
- set requirements to ensure that the ingredients are biodegradable and will not persist in water;
- recognise and reward the products with restricted use of hazardous substances;
- set requirements to allow the maximum usage of the product contained in a container and promotes the minimisation of use of packaging material and plastics recyclability;
- recognise and reward the products with renewable ingredients from sustainable origin,
- Set requirement that guarantees that the substrate (wipe) complies with EU ecolabel requirements and informs consumers on the correct disposal of the product;
- guarantees that the product meets certain quality requirements and user satisfaction.
- set a requirement to inform consumers on the environmental benefits associated with the product, in order to encourage the purchase of the product.

The criteria for awarding the EU Ecolabel to 'cosmetic products' are as follows:

1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)
2. Biodegradability
3. Hazardous substance restrictions
4. Packaging
5. Renewable ingredients
6. Specific requirements for wet wipes
7. Fitness for use
8. Information on EU Ecolabel

The next table shows which criteria apply to the different type of products.

Table 1. Criteria requirements for rinse-off and leave-on products

Criterion	Rinse-off products	Leave-on products
Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)	x	
Criterion 2. Biodegradability	x	x
Criterion 3. Excluded or limited substances and mixtures	x	x
Criterion 4. Packaging	x	x
Criterion 5. Renewable ingredients	x	x
Criterion 6. Specific requirements for wet wipes	-	-
Criterion 7. Fitness for use	x	x
Criterion 8. Information on EU Ecolabel	x	x

Assessment and verification:**a) Requirements**

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 and/or his/her supplier(s) and/or their supplier(s), etc. as appropriate.

Competent bodies shall preferentially recognise attestations which are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes and services.

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

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications or site inspections to check compliance with these criteria.

Changes in suppliers and production sites pertaining to products to which the EU Ecolabel has been granted shall be notified to Competent Bodies, together with supporting information to enable verification of continued compliance with the criteria.

As a prerequisite the product shall meet all applicable legal requirements of the country or countries in which the product is placed on the market. The applicant shall declare the product's compliance with this requirement.

A list of all ingoing substances in the final product shall be provided to the competent body, indicating the trade name (if existing), the chemical name, the CAS No, No and INCI

designations, DID No¹ (if existing), its function, form and concentration in mass percentage (including and excluding water), regardless of concentration in the final product formulation. All listed substances present in the form of nanomaterials shall be clearly indicated on the list with the word 'nano' written in brackets.

For each substance listed, the Safety Data Sheets (SDS) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council² shall be provided. Where an SDS is not available for a single substance because it is part of a mixture, the applicant shall provide the SDS of the mixture.

The Appendix makes reference to the 'Detergent Ingredient Database' list (DID list) which contains the most widely used ingredients in detergents and cosmetics formulations. It shall be used for deriving the data for the calculations of the Critical Dilution Volume (CDV) (criterion 1) and for the assessment of the biodegradability (criterion 2) of the ingoing substances. For substances not present on the DID list, guidance is given on how to calculate or extrapolate the relevant data. The latest version of the DID list is available from the EU Ecolabel website³ or via the websites of the individual competent bodies.

Note: Label and/or instructions information accompanying the product shall be used to categorize the product. Where a cosmetic product is marketed for different uses, the category for which stricter criteria applies shall be assigned to the product.

b) Measurement thresholds

Compliance with the ecological criteria is required for all substances as specified in Table 2.

¹ DID No is the number of the ingoing substance on the DID list

² 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 ([OJ L 396, 30.12.2006, p. 1](#))

³ http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf,
http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_en.pdf

Table 2

Threshold levels applicable to substances for cosmetic products (% weight by weight), shown by criterion

Criterion name		Preservatives	Colorants	Fragrances	Impurities	Ingoing substances (e.g. surfactants, enzymes)
Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)		no limit ^(*)	no limit ^(*)	no limit ^(*)	≥ 0,010	no limit ^(*)
Criterion 2. Biodegradability	Criterion 2 (a) (rinse-off and leave –on)	no limit ^(*)	no limit ^(*)	no limit ^(*)	≥ 0,010	no limit ^(**2)
	Criterion 2 (b) (i) (rinse-off)	no limit ^(*)	no limit ^(*)	no limit ^(*)	≥ 0,010	no limit ^(*)
	Criterion 2 (b) (ii) (leave-on)	no limit ^(*)	no limit ^(*)	no limit ^(*)	≥ 0,001	no limit ^(**3)
Criterion 3. Excluded or limited substances and mixtures	Criterion 3 (a) (i) (rinse-off)	≥ 0,010	≥ 0,010	≥ 0,010	≥ 0,010	≥ 0,010
	Criterion 3 (a) (i) (leave-on)	≥ 0,001	≥ 0,001	≥ 0,001	≥ 0,001	≥ 0,001
	Criterion 3 (a) (ii) (rinse-off)	no limit ^(*)				

Criterion 3 (a) (ii) (leave-on)	no limit _(*)				
Criterion 3 (a) (iii) (rinse-off)	no limit _(*)	no limit _(*)	no limit _(*)	≥ 0,010	no limit _(*)
Criterion 3 (a) (iii) (leave-on)	no limit _(*)	no limit _(*)	no limit _(*)	≥ 0,001	no limit _(*)
Criterion 3 (b) (rinse-off)	no limit _(*)				
Criterion 3 (b) (leave-on)	no limit _(*)				
Criterion 3 (c) (rinse-off)	no limit _(*)				
Criterion 3 (c) (leave-on)	no limit _(*)				
Criterion 3 (d) (rinse-off)	N/A	N/A	no limit _(*)	N/A	N/A
Criterion 3 (d) (leave-on)	N/A	N/A	no limit _(*)	N/A	N/A
Criterion 3 (e) (rinse-off)	no limit _(*)	N/A	N/A	N/A	N/A

	Criterion 3 (e) (leave-on)	no limit ^(*)	N/A	N/A	N/A	N/A
	Criterion 3 (f) (rinse-off)	N/A	no limit ^(*)	N/A	N/A	N/A
	Criterion 3 (f) (leave-on)	N/A	no limit ^(*)	N/A	N/A	N/A
	Criterion 3 (g)	N/A	N/A	N/A	N/A	no limit ^(*)
Criterion 5. Renewable ingredients	Criterion 5 (a)	N/A	N/A	N/A	N/A	no limit ^(*)
	Criterion 5 (b) (rinse-off)	no limit ^(*)	no limit ^(*)	no limit ^(*)	≥ 0,010	no limit ^(*)
	Criterion 5 (b) (leave-on)	no limit ^(*)	no limit ^(*)	no limit ^(*)	≥ 0,001	no limit ^(*)

^(*) 'no limit' means: regardless of the concentration, all substances, by-products and impurities from raw materials (analytical limit of detection).

^(*) Surfactants with cleaning and/or foaming function in toothpastes are exempted

^(*) UV filters are exempted from this requirement

^(*) substances listed in Annexes IV and V to Regulation (EC) No 1907/2006 are exempted

The following definitions shall apply:

- 1) 'substance' means a chemical element and its compounds in the natural state or obtained by any production process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- 2) 'ingoin substances' means all substances in the cosmetic product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoin substances (e.g. formaldehyde, arylamine, in situ-generated preservatives) are also regarded as ingoin substances. Impurities in the raw materials ≥ 1000 ppm (≥ 0.1000 w-% ≥ 1000 mg/kg) are always regarded as ingoin substances, regardless of the concentration in the final product.
- 3) 'impurities' means residuals, pollutants, contaminants, by products, etc. from production, incl. production of raw materials that remain in the raw material/ingredient and/or in the in the final product in concentrations less than 100 ppm (0.0100 w-%, 100 mg/kg) in the rinse off product and less than 10 ppm (0.0010 w-%, 10.0 mg/kg) in the leave on product.
- 4) 'active content' (AC) means the sum of organic ingoin substances in the product excluding the water content of the ingredients (expressed in grams), calculated on the basis of the complete formulation of the final product, including propellants contained in aerosol products. Rubbing/abrasive agents are not included in the calculation of the active content;
- 5) 'primary packaging' means packaging in direct contact with the content conceived so as to constitute the smallest sales unit of distribution to the final user or consumer at the point of purchase;
- 6) 'secondary packaging' means packaging which can be removed from the product without affecting its characteristics and is conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold 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;
- 7) 'Infant, baby and/or children's products' are considered to be products that are marketed for or have words such as baby and/or children (<12) on the label.

EU ECOLABEL CRITERIA FOR COSMETIC PRODUCTS

Criterion 1- Toxicity to aquatic organisms: Critical Dilution Volume (CDV)

This criterion applies to final products. This criterion applies to rinse-off products only. The total CDV toxicity of the rinse-off product as specified in Table 3 shall not exceed the following limits:

Table 3 CDV limits

Product	CDV (l/g AC)
Shampoo, shower preparations and soaps (liquid form)	11 000
Feminine hygiene cosmetic products	12 000
Shampoos and soaps and shaving soaps (solid and dry form)	2 200
Hair conditioners	12 000
Toothpaste and mouthwash	12 000
Shaving foams, shaving gels, shaving creams	12 000
Rinse-off skin care products (exfoliants)	12 000
Rinse-off hair styling and treatment products (hair dyes)	12 000

The CDV is calculated using the following equation:

$$CDV = \sum CDV (\text{ingoing substance } i) (\text{l/gAC}) = \sum \text{weight } (i) \times DF (i) \times 1000/TF \text{ chronic } (i) (\text{mg/l})$$

Where:

weight (i) — is the weight of the ingoing substance (in grams) per 1 gram of AC (i.e. normalised weight contribution of the ingoing substance to the AC)

DF (i) — is the degradation factor of the ingoing added substance

TF chronic (i) — is the toxicity factor of the ingoing added substance (in milligrams/litre)

Assessment and verification: the applicant shall provide the calculation of the CDV of the product. A spreadsheet for calculation of the CDV value is available on the EU Ecolabel website. The values of DF and TF chronic shall be as given in the DID list-part A. If the ingoing substance is not included in the DID list-part A, the applicant shall determine the values using the guidelines described in the DID list-part B and attaching the associated documentation (for more information see the Appendix).

Criterion 2- Biodegradability

This criterion shall be fulfilled by each ingoing added substance.

a) Biodegradability of surfactants

All surfactants shall be readily biodegradable under aerobic conditions.

All surfactants classified as hazardous to the aquatic environment: Acute Category 1 (H400) or Chronic Category 3 (H412), in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council shall be in addition anaerobically biodegradable.

The following are exempt from the requirement on anaerobic biodegradability:

Surfactants with cleaning and/or foaming function in toothpastes

b) Biodegradability of organic ingoing substances

(i) Rinse-off products:

The content of all organic ingoing substances in the product that are aerobically non-biodegradable (not readily biodegradable) (aNBO) and anaerobically non-biodegradable (anNBO) shall not exceed the limits in Table 4:

Table 4 aNBO and anNBO limits

Product	aNBO (mg/g AC)	anNBO (mg/g AC)
Shampoo and liquid soaps	25	25
Shower preparations	20	20
Solid soaps/shampoos	10	10
Hair conditioners	20	20
Shaving foams, shaving gels, shaving creams	70	40
Shaving solid soaps	10	10
Feminine hygiene cosmetic products	15	15
Toothpastes, mouthwashes	15	15
Rinse-off skin care products (exfoliants)	15	15
Rinse-off hair styling and treatment products (hair dyes)	15	15

(ii) Leave-on products:

At least 95% by weight of the total content of organic ingoing substances must be:

- readily biodegradable (OECD 301 A-F), and/or
- lowest aquatic toxicity NOEC/EC_x > 0.1 mg/l or EC/LC₅₀ > 10.0 mg/l and not be bioaccumulable, and/or
- lowest aquatic toxicity NOEC/EC_x > 0.1 mg/l or EC/LC₅₀ > 10.0 mg/l and be potentially biodegradable (OECD 302 A-C) and/or
- lowest aquatic toxicity NOEC/EC_x > 0.1 mg/l or EC/LC₅₀ > 10.0 mg/l and not be bioavailable (molar weight > 700g/mol)

Exempt are:

- UV filters in sun products
- fibre material in wet wipes

Assessment and verification: *the applicant shall provide documentation for the degradability of surfactants, as well as the calculation of aNBO and anNBO for the product. A spreadsheet for calculating aNBO and anNBO values is available on the EU Ecolabel website.*

For both surfactants and aNBO and anNBO values, reference shall be done to the DID list. For ingoing substances which are not included in the DID list, the relevant information from literature or other sources, or appropriate test results, showing that they are aerobically and anaerobically biodegradable shall be provided as described in the Appendix.

In the absence of documentation in accordance with the above requirements, an ingoing 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 ($A < 25\%$);*
2. *Readily degradable and has high desorption ($D > 75\%$);*
3. *Readily degradable and non-bioaccumulating.*

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

Criterion 3. Hazardous substance restrictions

[Recommendations from the EU's Scientific Committee on Consumer Safety, SCCS Opinions, must be complied with where there is an unambiguous conclusion from SCCS. In cases where there is a direct conflict with other requirements in this criteria document, it is always the most restrictive requirement that applies.] **(text to be included in the User Manual)**

3(a) Restrictions on ingoing substances/mixtures classified under the Classification, Labelling and Packaging (CLP) Regulation

- (i) **Unless derogated in Table X**, the product shall not contain substances or mixtures at or above the concentration of 0.010 % weight by weight for rinse-off products and 0.001% weight by weight for leave-on cosmetics, that are assigned any of the following hazard classes, categories and associated hazard statement codes, in accordance with Regulation (EC) No 1272/2008⁴.

Where stricter, the generic or specific concentration limits determined in accordance with Article 10 of Regulation (EC) No 1272/2008 shall take precedence.

⁴ 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)

Table 5 Restricted hazard classes, categories and associated hazard statement codes

Acute toxicity	
Categories 1 and 2	Category 3
H300 Fatal if swallowed	H301 Toxic if swallowed
H310 Fatal in contact with skin	H311 Toxic in contact with skin
H330 Fatal if inhaled	H331 Toxic if inhaled
H304 May be fatal if swallowed and enters airways	EUH070 Toxic by eye contact
Specific target organ toxicity	
Category 1	Category 2
H370 Causes damage to organs	H371 May cause damage to organs
H372 Causes damage to organs through prolonged or repeated exposure	H373 May cause damage to organs through prolonged or repeated exposure
Respiratory and skin sensitisation	
Category 1^a	Category 1B
H317 May cause allergic skin reaction	H317 May cause allergic skin reaction
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
Hazardous to the aquatic environment	
Categories 1 and 2	Category 3 and 4
H400 Very toxic to aquatic life	H412 Harmful to aquatic life with long-lasting effects
H410 Very toxic to aquatic life with long-lasting effects	H413 May cause long-lasting effects to aquatic life
H411 Toxic to aquatic life with long-lasting effects	
Hazardous to the ozone layer	
H420 Hazardous to the ozone layer	

Table X. Derogations to restrictions on ongoing substances/mixtures classified under the CLP Regulation and applicable conditions (No substantiated derogation request using template in annex I received)

Substance /mixture type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Industry must submit derogations during 2020			

in order to be evaluated			
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- (ii) No substances or mixtures that meet the criteria for classification with the hazard statements listed in Table 6 shall be added in the final product or its ingredients, regardless of their concentration.

Table 6 Excluded hazard classes, categories and associated hazard statement codes

Carcinogenic, mutagenic or toxic for reproduction	
Categories 1A and 1B	Category 2
H340 May cause genetic defects	H341 Suspected of causing genetic defects
H350 May cause cancer	H351 Suspected of causing cancer
H350i May cause cancer by inhalation	
H360F May damage fertility	H361f Suspected of damaging fertility
H360D May damage the unborn child	H361d Suspected of damaging the unborn child
H360FD May damage fertility. May damage the unborn child	H361fd Suspected of damaging fertility. Suspected of damaging the unborn child
H360Fd May damage fertility. Suspected of damaging the unborn child	H362 May cause harm to breast fed children
H360Df May damage the unborn child. Suspected of damaging fertility	

- (iii) Ingoing substances or mixtures classified as environmentally hazardous according to Regulation EC 1272/2008 may be included in the product to a maximum:

$$100 \cdot c [H410] + 10 \cdot c [H411] + c [H412] \leq 2.5\%$$

where c is the fraction of the product, measured in percentage by weight, made up of the classified substance.

This criterion does not apply to substances covered by Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006⁵ which sets out criteria for exempting substances within Annexes IV and V to that Regulation from the registration, downstream user and evaluation requirements. In order to determine whether that exclusion applies, the applicant shall screen any substance and mixture in the final product.

⁵ 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 (OJ L 396, 30.12.2006, p. 1)

3(b) Specified excluded substances

The substances listed below shall not be added in the final product:

- (i) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1];
- (ii) Perfluorinated and polyfluorinated substances;
- (iii) Nitromusks and polycyclic musks;
- (iv) Butylated Hydroxy Toluene (BHT) and Butylated hydroxyanisole (BHA);
- (v) Ethylenediaminetetraacetate (EDTA) and its salts and non-readily biodegradable phosphonates;
- (vi) The following preservatives: triclosan, parabens, formaldehyde releasers, benzalkonium chloride, phenoxyethanol [2];
- (vii) Microplastics [3];
- (viii) Nanomaterials, unless an EU regulatory authority has evaluated the use of the nanomaterial and found that it is safe from health and environmental perspective;
- (ix) The fragrance tetramethyl acetyloctahydranophthalenes (OTNE);
- (x) Sodium hypochlorite, chloramine and sodium chlorite;
- (xi) ETPA (diethylenetriaminepentaacetic acid and its salts);
- (xii) Cocamide DEA;
- (xiii) Sodium Lauryl Sulphate (SLS) on toothpaste products;
- (xiv) Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate;
- (xv) Substances and mixtures identified to have endocrine disrupting properties [4];
- (xvi) Aluminium and its salts [5];
- (xvii) Phthalates;
- (xviii) Isothiazolines.

3(c) Restrictions on Substances of Very High Concern (SVHCs)

Ingoing substances and mixtures meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006⁶ that have been identified according to the procedure described in Article 59 of the mentioned Regulation and included in the candidate list of substances of very high concern for authorisation shall not be added to the product, regardless of their concentration.

3(d) Fragrances

- (i) Products marketed as designed and intended for children shall be fragrance-free.

⁶ OJ L 396, 30.12.2006, p. 1

(ii) Any substance or mixture 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 the 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.

3(e) Preservatives

(i) Preservatives in the product shall not release or degrade to substances that are classified in accordance with the requirements of criterion 3(a).

(ii) The product may contain preservatives provided that they are not bioaccumulating. A preservative is not considered bioaccumulating if $BCF < 100$ or $\log K_{ow} < 3$. If both BCF and $\log K_{ow}$ values are available, the highest measured BCF value shall be used.

(iii) Preservatives used in toothpaste must be approved as food additives, according to Regulation (EC) No 1333/2008 on food additives.

3(f) Colorants

(i) Colorants in the product must not be bioaccumulating. A colorant is considered not bioaccumulating if $BCF < 100$ or $\log K_{ow} < 3$. If both BCF and $\log K_{ow}$ values are available, the highest measured BCF value shall be used. In the case of colouring agents approved for use in food, it is not necessary to submit documentation of bioaccumulation potential.

(ii) Colorants used in toothpaste must be approved as food additives according to Regulation (EC) No 1333/2008 on food additives.

(iii) The use of barium, lead, mercury, cadmium, six inhalant chromium, nickel and bismuth in colourants for decorative cosmetics and hair dyes is restricted to concentrations below 10 ppm.

3(g) UV filters

UV filters may only be added to leave-on products and only to protect the user – not the product.

All organic UV filters contained in the product:

- must not be bioaccumulating ($BCF < 100$ / $\log K_{ow} < 3$) or must have a lowest measured toxicity of $NOEC/ECx > 0.1$ mg/l or $EC/LC50 > 10.0$ mg/l

-if including nano TiO_2 , must fulfil the conditions expressed in Annex VI of Regulation EC No 1223/2009 and its amendments.

-if including nano TiO_2 coated with either silica and cetyl phosphate (up to 16% and 6% respectively); alumina and manganese dioxide (up to 7% and 0.7% respectively); or alumina and triethoxycaprylylsilane (up to 3% and 9% respectively), the product must not be in the form of powders or sprayable products.

Assessment and verification: *The applicant shall provide a signed declaration of compliance with all above sub-requirements, supported by declarations from suppliers, if appropriate; and the following supporting evidence:*

To demonstrate compliance with 3(a) the applicant shall provide the SDS of the final product.

To demonstrate compliance with 3(a), 3(b) and 3(c) the applicant shall provide:

- (i) SDS of any substance/mixture and their concentration in the final product.*
- (ii) A written confirmation that 3(a), 3(b) and 3(c) is fulfilled.*

For substances exempted from requirement 3(a) (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration to this effect by the applicant shall suffice to comply.

For requirement 3(c) reference to the latest list of substances of very high concern⁷ shall be made on the date of application.

To demonstrate compliance with 3(d) the applicant shall provide a signed declaration of compliance, supported by a declaration of the fragrance manufacturer, as appropriate.

To demonstrate compliance with 3(e) the applicant shall provide: copies of the SDS of any preservative added, and information on its BCF and/or log K_{ow} values.

To demonstrate compliance with 3(f) the applicant shall provide: copies of the SDS of any colorant added together with information on its BCF and/or log K_{ow} value, or documentation to ensure that the colouring agent is approved for use in food.

To demonstrate compliance with 3(g) the applicant shall provide: copies of the SDS of any UV filter added together with information on its BCF and/or log K_{ow} value, or lowest available NOEC/EC₅₀/LC50 value. In addition, a declaration that, if used, nano TiO₂ fulfils the conditions expressed in Annex VI of Regulation EC 1223/2009 and its latest amendments must be provided.

The above evidence can also be provided directly to Competent Bodies by any supplier in the applicant's product supply chain.

Notes:

[1] Substance name = "Alkyl phenol", under: <https://echa.europa.eu/es/advanced-search-for-chemicals>

[2] The restriction for phenoxyethanol only applies to leave-on products for children under 12 years old.

⁷ http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

[3] The definition of 'microplastic' can be found in "Annex XV report" for its registry of restriction intention: <https://echa.europa.eu/es/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73>

[4] "Substances identified to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) in the Candidate List of SVHC, in Regulation 528/2012 or in Regulation 1107/2009.

[5] The restriction for aluminium and its salts only apply to leave-on products if the concentration in the final product is higher to 0.6% (w/w).

Criterion 4. Packaging

a) Primary packaging

Primary packaging shall be in direct contact with the contents.

No additional packaging for the product as it is sold, e.g. cardboard over a bottle, is allowed, with the exception of secondary packaging which groups the product and its refill. For the products sold with pump, a refilling option should be provided in the same or higher packaging capacity.

Assessment and verification: *the applicant shall provide a signed declaration and relevant evidence (e.g. pictures of the products as marketed).*

(b) Packaging Impact Ratio (PIR)

The Packaging Impact Ratio (PIR) must be less than 0.24 g of packaging per gram of product for each of the packaging in which the product is sold. Products packed in metal aerosol containers are exempted from this requirement. PIR shall be calculated (separately for each of the packaging) as follows:

$$\text{PIR} = (\text{W} + (\text{W}_{\text{refill}} \times \text{F}) + \text{N} + (\text{N}_{\text{refill}} \times \text{F})) / (\text{D} + (\text{D}_{\text{refill}} \times \text{F}))$$

Where:

W —weight of packaging (primary + proportion of secondary (1), including labels)(g)

W_{refill} —weight of refill packaging (primary + proportion of secondary (1), including labels) (g)

N —weight of non-renewable + non-recycled packaging (primary + proportion of secondary (1), including labels) (g)

N_{refill} —weight of non-renewable and non-recycled refill packaging (primary + proportion of secondary (1), including labels) (g)

D —weight of product contained in the 'parent' pack (g) D_{refill} —weight of product delivered by the refill (g)

F —number of refills required to meet the total refillable quantity, calculated as follows:

$$F = V \times R / V_{\text{refill}}$$

Where;

V —volume capacity of the parent pack (ml)

V_{refill} —volume capacity of the refill pack (ml)

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.

In case no refill is offered PIR shall be calculated as follows:

$$\text{PIR} = (W + N) / D$$

The manufacturer shall provide the number of foreseen refillings, or use the default values of R = 5 for plastics and R = 2 for cardboard.

Primary packaging made of more than 80% of recycled materials is exempted from this requirement.

(1) Proportional weight of the grouping packaging (e.g. 50 % of the total grouping packaging weight, if two products are sold together).

Assessment and verification: *the applicant shall provide the calculation of the PIR of the product. A spreadsheet for this calculation is available on the EU Ecolabel website. If the product is sold in different packaging (i.e. with different volumes), the calculation shall be submitted for each packaging size for which the EU Ecolabel shall be awarded. The applicant shall provide a signed declaration for the content of post-consumer recycled material or material from renewable origin in the packaging and a description of the refill system offered, if applicable (kinds of refills, volume). For approval of refill packaging, the applicant or retailer shall document that the refills shall be available for purchase on the market.*

c) Design of primary packaging

The primary packaging shall be designed to make correct dosage easy* (e.g. by ensuring that the opening at the top is not too wide) and to ensure that at least 92% of the product can be easily removed from the container. The residual amount of the product in the container (R), which must be below 8%, shall be calculated as follows:

$$R = ((m_2 - m_3) / (m_1 - m_3)) \times 100 (\%)$$

Where:

m₁ —Primary packaging and product (g)

m₂ —Primary packaging and product residue in normal conditions of use (g)

m₃ —Primary packaging emptied and cleaned (g)

*For liquid hand soap no pump or dispenser sold with the product may provide more than 2 g soap per full press.

Assessment and verification: *the applicant shall submit a description of the dosage device (e.g. schematic illustration, pictures...) and test report with results of measuring the residual quantity of a rinse-off cosmetic product in the packaging. The test procedure for measuring the residual quantity is described in the user manual available on the EU Ecolabel website.*

(d) Design for recycling of plastic packaging

Plastic packaging shall be designed to facilitate effective recycling by avoiding potential contaminants and incompatible materials that are known to impede separation or reprocessing or to reduce the quality of recyclate. The label or sleeve, closure and, where applicable, barrier coatings shall not comprise, either singularly or in combination the materials and components listed in Table 7.

Table 7. Materials and components excluded from packaging elements

Packaging element	Excluded material or component*
Label or sleeve	<ul style="list-style-type: none"> - Full sleeves [1] are not permitted. - PS label or sleeve in combination with a PET, PP or HDPE packaging - PVC label or sleeve in combination with a PET, PP or HDPE packaging - Any PET label or sleeve in combination with a PET packaging - Sleeves made of different polymer than the packaging - Labels or sleeves that are metallised or are welded to a packaging body (in mould labelling)
Closure	<ul style="list-style-type: none"> - PS closure in combination a with a PET, PP or HDPE packaging - PVC closure in combination with a PET, PP or HDPE packaging - PETG closures and/or closure material with density of above 1 g/cm³ in combination with a PET packaging - Closures made of metal, glass, EVA - Closures made of silicone. Exempted are silicone closures with a density < 1 g/cm³ in combination with a PET packaging and silicone closures with a density > 1g/cm³ in combination with PP or HDPE packaging - Metallic foils or seals which remain fixed to the bottle or its closure after the product has been opened
Barrier coatings	<ul style="list-style-type: none"> - Polyamide, EVOH (maximum content of 3% by weight), functional polyolefins, metallised and light blocking barriers

(*) EVA — Ethylene Vinyl Acetate, EVOH — Ethylene vinyl alcohol, HDPE — High-density polyethylene, PET — Polyethylene terephthalate, PETC – crystalline polyethylene terephthalate, PETG — Polyethylene terephthalate glycol-modified, PP — Polypropylene, PS — Polystyrene, PVC — Polyvinylchloride

[1] full sleeves are labels that cover the entire bottle/package

Toothpaste tubes, pumps and aerosol containers are exempted from this requirement.

Assessment and verification: *the applicant shall submit a signed declaration of compliance specifying the material composition of the packaging including the container, label or sleeve, adhesives, closure and barrier coating, together with a sample of primary packaging.*

(e) Take-back system

For products to be used by accommodation services in a packaging lower than 75ml of capacity, the applicant shall offer a take back service in order to collect empty products consumed in the accommodation.

Assessment and verification: *the applicant shall submit a description of the service conditions and a declaration of compliance.*

Criterion 5: Renewable ingredients

(a) Sustainable sourcing of palm oil, palm kernel oil and their derivatives

In the specific case of renewable ingredients from palm oil or palm kernel oil, or derived from palm oil or palm kernel oil, 100% w/w of the renewable ingredients used shall meet the requirements for sustainable production of a certification scheme that is a multi-stakeholder organisation with a broad membership, including NGOs, industry and government and that addresses environmental impacts on soil, biodiversity, organic carbon stocks and conservation of natural resources.

(b) Certification of plant based ingredients

In the specific case of ingredients covered by the scope of the EU organic Regulation (EC 834/2007), 20% w/w of the ingredients used shall be produced according to organic production and certified by a third-party.

Assessment and verification: *To demonstrate compliance with sub-criterion (a) evidence through third-party chain of custody certifying that the input materials used in the manufacturing originate from sustainably managed plantations shall be provided. For palm oil and palm kernel oil, Roundtable for Sustainable Palm Oil (RSPO) certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models: identity preserved, segregated, mass balance, and independent smallholders credits shall be accepted. For palm oil and palm kernel oil*

derivatives, RSPO certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models: identity preserved, segregated, mass balance, book and claim, and independent smallholders credits shall be accepted. Additionally, to demonstrate compliance in the case of the Book and Claim supply chain model, the amounts of RSPO credits purchased and claimed in the RSPO PalmTrace system model corresponding to that specific derivatives during the most recent annual trading period shall be provided. Competent Bodies should make annual audits in order to verify the validity of RSPO certificates.

To demonstrate compliance with sub-criterion (b), the applicant shall provide third-party certifications for the ingredients covered by the scope of the EU Organic Regulation. Certifications accepted shall include those awarded by Competent Bodies appointed through the EU Regulation on organic production 834/2007, as well as IFOAM family of standards, COSMOS, or any equivalent scheme.

Criterion 6: Specific requirements for wet wipes

This criterion only applies to wet wipes

(a) Raw materials

(i) Paper materials

The paper substrate shall bear the EU Ecolabel for "Graphic paper, tissue paper and tissue products" in accordance with Commission Decision (EU) 2019/70, Annex II.

(ii) Fibres materials

The fibre substrate shall bear the EU Ecolabel for "Absorbent Hygiene Products" in accordance with Commission Decision (EU) 2014/763.

(b) User information

The packaging shall include information on the correct disposal of the wipes.

Assessment and verification: *The applicant shall provide a copy of a valid EU Ecolabel certificate for the substrate used in a final product and a signed declaration of compliance along with a sample of the product packaging design.*

Criterion 7: Fitness for use

The product's capacity to fulfil its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e.g. anti-dandruff, colour protection) shall be demonstrated either through laboratory test(s) or a consumer test. The tests shall be conducted following the

‘Guidelines for the Evaluation of the Efficacy of Cosmetic Products’⁸ and the instructions given in the user manual available on the EU Ecolabel website.

For consumer tests, 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 a market-leading product using the same dosage?
- 2) How easy is it to apply the dosage of the product in comparison with a market-leading product?
- 3) How easy is it to apply and rinse-off (for rinse-off products) the product to/from the hair and/or skin in comparison with a market-leading product?

A minimum of 20 consumers are requested and at least 80% must be at least as satisfied with the product as with a market-leading product.

Assessment and verification: *The applicant shall document the test protocol (laboratory test(s) or consumer test) that has been followed in order to test the product's efficacy. Applicants shall present results from this protocol that demonstrate that the product fulfils the primary and secondary functions claimed on the product label or packaging.*

Laboratory test performed to comply with Cosmetics Regulation and Regulation 655/2013 can be suitable to demonstrate that the product fulfils its primary function and any secondary claimed function. It is not necessary to perform new specific tests to demonstrate a function previously demonstrated.

Criterion 8: Information appearing on the EU Ecolabel for cosmetic products

The optional label with box shall contain the following information:

- Limited impact on aquatic environment
- Fulfils strict biodegradability requirements
- Limits packaging waste

The applicant shall follow the instructions on how to properly use the EU Ecolabel logo provided in the EU Ecolabel Logo Guidelines:

http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

Assessment and verification: *The applicant shall provide a declaration of compliance with this criterion, supported by a high resolution image of the product packaging that clearly shows the label, the registration/licence number and, where relevant, the statements that can be displayed together with the label.*

⁸ Available at: <https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=23> and the EU Ecolabel website.

Appendix

Detergents Ingredients Database (DID) list

The DID list (Part A) is a list containing information of the aquatic toxicity and biodegradability of ingredients typically used in detergent formulations. The list includes information on the toxicity and biodegradability of a range of substances used in washing and cleaning products. The list is not comprehensive, but guidance is given in Part B of the DID list concerning the determination of the relevant calculation parameters for substances not present on the DID list (e.g. the Toxicity Factor (TF) and degradation factor (DF), which are used for calculation of the critical dilution volume). The list is a generic source of information and substances present on the DID list are not automatically approved for use in EU Ecolabel products.

Part A and Part B of the DID list can be found on the EU Ecolabel website at:

http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_a_en.pdf

http://ec.europa.eu/environment/ecolabel/documents/did_list/didlist_part_b_en.pdf

For substances with no data regarding aquatic toxicity and degradability, structure analogies with similar substances may be used to assess the TF and DF. Such structure analogies shall be approved by the competent body granting the EU Ecolabel license. Alternatively, a worst case approach shall be applied, using the parameters below:

Worst case approach:

Ingoing added substance	Acute toxicity			Chronic toxicity			Degradation		
	LC50/EC50	SF (acute)	TF (acute)	NOEC (1)	SF (chronic) (1)	TF (chronic)	DF	Aerobic	Anaerobic
'Name'	1mg/l	10,000	0,0001			0,0001	1	P	N

(1) If no acceptable chronic toxicity data are found, these columns are empty. In this case, TF (chronic) is defined as equal to TF (acute).

Documentation of ready biodegradability

The following test methods for ready biodegradability shall be used:

(1) Until 1 December 2015:

The test methods for ready biodegradability provided for in Directive 67/548/EEC, in particular the methods detailed in Annex V.C4 to that Directive, or their equivalent OECD 301 A-F test methods, or their equivalent ISO tests.

The 10 days window principle shall not apply for surfactants. The pass levels shall be 70 % for the tests referred to in Annex V.C4-A and C4-B to Directive 67/548/EEC (and their

equivalent OECD 301 A and E tests and ISO equivalents), and shall be 60 % for tests C4-C, D, E and F (and their equivalent OECD 301 B, C, D and F tests and ISO equivalents).

or

The test methods provided for in Regulation (EC) No 1272/2008 or Regulation (EC) No 1907/2006 foresees in Annex XI that the standard testing regime can be adapted by de use of non-tested methods such as qualitative or quantitative structure-activity relationship (Q(SAR) models).

(2) After 1 December 2015:

The test methods provided for in Regulation (EC) No 1272/2008 or Regulation (EC) No 1907/2006 foresees in Annex XI that the standard testing regime can be adapted by de use of non-tested methods such as qualitative or quantitative structure-activity relationship (Q(SAR) models).

Documentation of anaerobic biodegradability

The reference test for anaerobic degradability shall be EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent test method, with the requirement of 60 % ultimate degradability under anaerobic conditions. Test methods simulating the conditions in a relevant anaerobic environment may also be used to document that 60 % ultimate degradability has been attained under anaerobic conditions.

Extrapolation for substances not listed in the DID-list

Where the ingoing substances are not listed in the DID-list, the following approach may be used to provide the necessary documentation of anaerobic biodegradability:

(1) Apply reasonable extrapolation. Use test results obtained with one raw material to extrapolate the ultimate anaerobic degradability of structurally related surfactants. Where anaerobic biodegradability has been confirmed for a surfactant (or a group of homologues) according to the DID-list, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g., C12-15 A 1-3 EO sulphate [DID No 8] is anaerobically biodegradable, and a similar anaerobic biodegradability may also be assumed for C12-15 A 6 EO sulphate). Where anaerobic biodegradability has been confirmed for a surfactant by use of an appropriate test method, it can be assumed that a similar type of surfactant is also anaerobically biodegradable (e.g., literature data confirming the anaerobic biodegradability of surfactants belonging to the group alkyl ester ammonium salts may be used as documentation for a similar anaerobic biodegradability of other quaternary ammonium salts containing ester-linkages in the alkyl chain(s)). Nevertheless, vice-versa if a structurally similar surfactant has been shown not to be anaerobically degradable, it can be assumed that a similar type of surfactant is also anaerobically biodegradable.

(2) Perform screening test for anaerobic degradability. If new testing is necessary, perform a screening test by use of EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent method.

(3) Perform low-dosage degradability test. If new testing is necessary, and in the case of experimental problems in the screening test (e.g. inhibition due to toxicity of test substance), repeat testing by using a low dosage of surfactant and monitor degradation by 14C measurements or chemical analyses. Testing at low dosages may be performed by use of OECD 308 (August 2000) or an equivalent method.

Documentation of bioaccumulation

The following test methods for bioaccumulation shall be used:

(1) Until 1 March 2009:

The reference test for bioaccumulation shall be OECD 107 or 117 or equivalent. The pass levels shall be < 100 or $\log K_{ow}$ is $< 3,0$.

The OECD 305 test on fish. For a $BCF < 500$ the substance is considered not bioaccumulative. If there is a measured BCF value, it is always the highest measured BCF that is used in assessing a substance's bioaccumulative potential.

(2) After 1 March 2009:

The reference test for bioaccumulation shall be OECD 107 or 117 or equivalent with the requirement of < 100 or $\log K_{ow}$ is $< 3,0$.