COMMISSION DECISION

of 9 December 2014

establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products

(notified under document C(2014) 9302)

(Text with EEA relevance)

(2014/893/EU)

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 Ecolabelling 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) Since environmental impacts mainly in terms of eco-toxicity and resource consumption are associated to the chemicals used in rinse-off cosmetic products and to their packaging, it is appropriate to establish the EU Ecolabel criteria for this product group. The criteria should in particular promote products that have reduced impact on aquatic ecosystems, contain limited amount of hazardous substances and minimise waste production by reducing the amount of packaging.

(4) Commission Decision 2007/506/EC ([2]) has established the ecological criteria and related assessment and verification requirement for soaps, shampoos and hair-conditioners. Those criteria have been reviewed in the light of technological developments. It results from the review that it is necessary to modify the name and the definition of the product group so as to include a new sub-product group and to establish new criteria.

(5) Decision 2007/506/EC should be replaced for reasons of clarity.

(6) A transitional period should be allowed for producers whose products have been awarded the Ecolabel for soaps, shampoos and hair conditioners on the basis of the criteria set out in Decision 2007/506/EC, so that they have sufficient time to adapt their products to comply with the revised criteria and requirements. Producers should also be allowed to submit applications based on the criteria set out in Decision 2007/506/EC or on the criteria set out in this Decision until the lapse of vailidity of that Decision.

(7) 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,

HAS ADOPTED THIS DECISION:

Article 1

The product group 'Rinse-off cosmetic products' shall comprise any rinse-off substance or mixture falling under the scope of Regulation (EC) No 1223/2009 of the European Parliament and of the Council ([3]) intended to be placed in contact with the epidermis and/or the hair system with a view exclusively or mainly to cleaning them (toilet soaps, shower preparations, shampoos), to improve the condition of the hair (hair conditioning products) or to protect the epidermis and lubricate the hair before shaving (shaving products).

([1]) OJ L 27, 30.1.2010, p. 1.
([2]) Commission Decision 2007/506/EC of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners (OJ L 186, 18.7.2007, p. 36).
([3]) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

The product group 'Rinse-off cosmetic products' shall include products for both private and professional use.

The product group shall not cover products that are specifically marketed for disinfecting or anti-bacterial use. Anti-dandruff shampoos are allowed.

Article 2

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

(1) 'ingoing substances' means preservatives, fragrances and colorants, regardless of the concentration, and other substances intentionally added, by-products and impurities from raw materials, the concentration of which equals or exceeds 0.010 % by weight of final formulation;

(2) 'active content' (AC) means the sum of organic ingoing substances in the product (expressed in grams), calculated on the basis of the complete formulation of the product, including propellants contained in aerosol products. Rubbing/abrasive agents are not included in the calculation of the active content;

(3) '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;

(4) '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.

Article 3

The criteria for awarding the EU Ecolabel under Regulation (EC) No 66/2010 for a product falling within the product group 'rinse-off cosmetic products' defined in Article 1 of this Decision as well as the related assessment and verification requirements are set out in the Annex.

Article 4

The criteria and the related assessment and verification requirements set out in the Annex shall be valid for four years from the date of adoption of this Decision.

Article 5

For administrative purposes, the code number assigned to the product group 'rinse-off cosmetic products' shall be '30'.

Article 6

Decision 2007/506/EC is repealed.

Article 7

1. By derogation from Article 6, applications for the EU Ecolabel for products falling within the product group 'soaps, shampoos and hair conditioners' submitted before the date of adoption of this Decision shall be evaluated in accordance with the conditions laid down in Decision 2007/506/EC.

2. Applications for the EU Ecolabel for products falling within the product group 'soaps, shampoos and hair conditioners' submitted within two months from the adoption of this Decision may be based either on the criteria set out in Decision 2007/506/EC or on the criteria set out in this Decision.

Those applications shall be evaluated in accordance with the criteria on which they are based.

3. EU Ecolabel licences awarded in accordance with the criteria set out in Decision 2007/506/EC may be used for 12 months from the date of adoption of this Decision.

Article 8

This Decision is addressed to the Member States.

Done at Brussels, 9 December 2014.

For the Commission

Karmenu VELLA

Member of the Commission

ANNEX

EU ECOLABEL CRITERIA AND ASSESSMENT AND VERIFICATION REQUIREMENTS

FRAMEWORK

CRITERIA

Criteria for awarding the EU Ecolabel to 'rinse-off cosmetic products':

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

2. Biodegradability

3. Excluded or limited substances and mixtures

4. Packaging

5. Sustainable sourcing of palm oil, palm kernel oil and their derivatives

6. Fitness for use

7. Information appearing on the EU Ecolabel

ASSESSMENT AND VERIFICATION

a) Requirements

The specific assessment and verification requirements are indicated for 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(s) or both.

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

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications.

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) and for the assessment of the biodegradability 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 website ([1]) or via the websites of the individual competent bodies.

The following information shall be provided to the competent body:

(i) The full formulation of the product indicating trade name, chemical name, CAS No and INCI designations, DID No ([2]), the ingoing quantity including and excluding water, the function and the form of all ingredients regardless of concentration;

(ii) safety data sheets for each ingoing substance or mixture in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([3]).

([1]) 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

([2]) DID No is the number of the ingoing substance on the DID list.

([3]) 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).

b) Measurement thresholds

Compliance with the ecological criteria is required for all ingoing substances as defined above, with the exception of criterion 3(b) and 3(c), where preservatives, colorants and fragrances are requested to comply when their concentration equals or exceeds 0,010 % by weight in the final formulation.

EU ECOLABEL CRITERIA

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

The total CDV toxicity of the product shall not exceed the limits in Table 1:

Table 1

CDV limits

Product	CDV (l/g AC)
Shampoo, shower preparations and liquid soaps	18 000
Solid soaps	3 300
Hair conditioners	25 000
Shaving foams, shaving gels, shaving creams	20 000
Shaving solid soaps	3 300

The CDV is calculated using the following equation:

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

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 substance

TF chronic (i) — is the toxicity factor of the ingoing 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

(a) Biodegradability of surfactants

All surfactants shall be readily biodegradable under aerobic conditions and biodegradable under anaerobic conditions.

(b) Biodegradability of organic ingoing substances

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 2:

Table 2

aNBO and anNBO limits

Product	aNBO (mg/g AC)	anNBO (mg/g AC)
Shampoo, shower products and liquid soaps	25	25
Solid soaps	10	10
Hair conditioners	45	45
Shaving foams, shaving gels, shaving creams	70	40
Shaving solid soaps	10	10

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 — Excluded or limited substances and mixtures

(a) Specified excluded ingoing substances and mixtures

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

(i) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives;

(ii) Nitrilo-tri-acetate (NTA);

(iii) Boric acid, borates and perborates;

(iv) Nitromusks and polycyclic musks;

(v) Octamethylcyclotetrasiloxane (D4);

(vi) Butylated Hydroxi Toluene (BHT);

(vii) Ethylenediaminetetraacetate (EDTA) and its salts and non-readily biodegradable phosphonates;

(viii) The following preservatives: triclosan, parabens, formaldehyde and formaldehyde releasers.

(ix) The following fragrances and ingredients of the fragrance mixtures: Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), Atranol and Chloroatranol;

(x) Micro-plastics;

(xi) Nanosilver.

Assessment and verification: the applicant shall provide a signed declaration of compliance supported by declarations from manufacturers of mixtures, as appropriate, confirming that the listed substances and/or mixtures have not been included in the product.

(b) Hazardous substances and mixtures

According to Article 6(6) of Regulation (EC) No 66/2010, the EU Ecolabel may not be awarded to any product that contains substances meeting criteria for classification with the hazard statements or risk phrases specified in Table 3 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([1]) or Council Directive 67/548/EC ([2]) or substances referred to in Article 57 of Regulation (EC) No 1907/2006. In case the threshold for classification of a substance or mixture with a hazard statement differs from the one of a risk phrase than the former prevails. The risk phrases in Table 3 generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures apply.

Substances or mixtures which change their properties through processing and thus become no longer bioavailable, or undergo chemical modification in a way that removes the previously identified hazard are exempted from criterion 3(b).

Table 3

Hazard statements and Risk Phrases

Hazard Statement	Risk Phrase
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

([1]) 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).

([2]) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

Hazard Statement	Risk Phrase
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 through prolonged or repeated exposure	R48/25/24/23
H373 May cause damage to organs through prolonged or repeated exposure	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 harmful effects to aquatic life	R53
EUH059 Hazardous to the ozone layer	R59
EUH029 Contact with water liberates toxic gas	R29
EUH031 Contact with acids liberates toxic gas	R31
EUH032 Contact with acids liberates very toxic gas	R32
EUH070 Toxic by eye contact	R39-41
Sensitising substances	
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
H317: May cause allergic skin reaction	R43

For rinse-off cosmetic products, the substances in Table 4 are exempted from the obligation in Article 6(6) of Regulation (EC) No 66/2010 following application of Article 6(7) of the same Regulation.

Table 4

Derogated substances

Substances	Hazard statements	Risk phrases
Surfactants (in total concentrations < 20 % in the final product)	H412: Harmful to aquatic life with long-lasting effects H413: May cause long-term adverse effects to aquatic life	R52-53 R53
Fragrances (*)	H412: Harmful to aquatic life with long-lasting effects H413: May cause long-term adverse effects to aquatic life	R52-53 R53
Preservatives (**)	H411: Toxic to aquatic life with long-lasting effects H412: Harmful to aquatic life with long-lasting effects H413: May cause long-term adverse effects to aquatic life	R51-53 R52-53 R53
Zinc pyrithione (ZPT) used in anti-dandruff shampoos	H400 Very toxic to aquatic life	R50

(*) Derogation is only for criterion 3(b). Fragrances shall comply with criterion 3(d).
(**) Derogation is only for criterion 3(b). Preservatives shall comply with criterion 3(e).

Assessment and verification: the applicant shall demonstrate compliance with criterion 3(b) for any ingoing substance or mixture present at concentrations greater than 0,010 % in the product.

A declaration of compliance shall be provided by the applicant supported, where appropriate, by the declarations from producer(s) of the raw materials that none of these ingoing substances and/or mixtures meet the criteria for classification with one or more of hazard statements or risk phrases listed in Table 3 in the form(s) and physical state(s) they are present in the product.

The following technical information related to the form(s) and physical state(s) of the ingoing substances and/or mixtures as present in the product shall be provided to support the declaration of non-classification:

(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.

For substances listed in Annexes IV and V to Regulation (EC) No 1907/2006, which are exempted from registration obligations under point (a) and (b) of Article 2(7) of that Regulation, a declaration to this effect by the applicant shall suffice to comply with criterion 3(b).

A declaration on the presence of ingoing substances that fulfil the derogation conditions shall be provided by the applicant, supported, where appropriate, by declarations from the producer(s) of the raw materials. Where required for the derogation, the applicant shall confirm the concentrations of these ingoing substances in the final product.

(c) Ingoing 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 ingoing 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 ([1]), present in the product in concentrations higher than 0,010 % (weight by weight).

Assessment and verification: reference to the list of substances identified as substances of very high concern shall be made on the date of application. The applicant shall provide the full formulation of the product to the competent body. The applicant shall also provide a declaration of compliance with criterion 3(c), together with related documentation, such as declarations of compliance signed by the material suppliers and copies of relevant safety data sheets for substances or mixtures.

(d) Fragrances

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

(ii) Any ingoing 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.

Assessment and verification: the applicant shall provide a signed declaration of compliance, supported by a declaration of the fragrance manufacturer, as appropriate.

(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(b).

(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} < 3,0. If both BCF and log K_{ow} values are available, the highest measured BCF value shall be used.

Assessment and verification: the applicant shall provide a signed declaration of compliance, together with copies of the safety data sheets of any preservative added, and information on its BCF and/or log K_{ow} values.

(f) Colorants

Colorants in the product must not be bioaccumulating. A colorant is considered not bioaccumulating if BCF < 100 or log K_{ow} < 3,0. 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.

Assessment and verification: the applicant shall provide copies of the safety data sheets 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.

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. carton over a bottle, is allowed, with the exception of secondary packaging which groups two or more products together (e.g. the product and refill).

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

([1]) http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

(b) Packaging Impact Ratio (PIR)

The Packaging Impact Ratio (PIR) must be less than 0,28 g of packaging per gram of product for each of the packaging in which the product is sold. Pre-shaving products packed in metal aerosol containers are exempted from this requirement.

PIR shall be calculated (separately for each of the packaging) as follows:

$$PIR = (W + (Wrefill \times F) + N + (Nrefill \times F))/(D + (Drefill \times F))$$

Where:

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

Wrefill — 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)

Nrefill — 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)

Drefill — weight of product delivered by the refill (g)

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

$$F = V \times R/Vrefill$$

Where;

V — volume capacity of the parent pack (ml)

Vrefill — 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:

$$PIR = (W + N)/D$$

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

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.

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

(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 90 % of the product can be removed easily from the container. The residual amount of the product in the container (R), which must be below 10 %, shall be calculated as follows:

$$R = ((m2 - m3)/(m1 - m3)) \times 100 \ (\%)$$

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)

Assessment and verification: the applicant shall submit a description of the dosage device 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 5.

Table 5

Materials and components excluded from packaging elements

Packaging element	Excluded materials and components [1]
Label or sleeve	— PS label or sleeve in combination with a PET, PP or HDPE bottle — PVC label or sleeve in combination with a PET, PP or HDPE bottle — PETG label or sleeve in combination with a PET bottle — Sleeves made of different polymer than the bottle — Labels or sleeves that are metallised or are welded to a packaging body (in mould labelling)
Closure	— PS closure in combination a with a PET, PP or HDPE bottle — PVC closure in combination with a PET, PP or HDPE bottle — PETG closures and/or closure material with density of above 1 g/cm³ in combination with a PET bottle — 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 bottle and silicone closures with a density > 1g/cm³ in combination with PP or HDPE bottle — Metallic foils or seals which remain fixed to the bottle or its closure after the product has been opened
Barrier coatings	— Polyamide, EVOH, functional polyolefins, metallised and light blocking barriers

[1] EVA — Ethylene Vinyl Acetate, EVOH — Ethylene vinyl alcohol, HDPE — High-density polyethylene, PET — Polyethylene terephtalate, PETG — Polyethylene terephthalate glycol-modified, PP — Polypropylene, PS — Polystyrene, PVC — Polyvinylchloride,

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.

Criterion 5 — Sustainable sourcing of palm oil, palm kernel oil and their derivatives

Palm oil and palm kernel oil and their derivatives used in the product must be sourced from plantations that meet criteria for sustainable management that have been developed by multi-stakeholder organisations that have a broad-based membership including NGOs, industry and government.

Assessment and verification: the applicant shall provide third-party certifications that the palm oil and palm kernel oil used in the manufacturing of the product originates from sustainably managed plantations. Certifications accepted shall include RSPO (by identity preserved, segregated or mass balance) or any equivalent scheme based on multi-stakeholder sustainable management criteria. For chemical derivatives of palm oil and palm kernel oil ([1]), it is acceptable to demonstrate sustainability through book and claim systems such as GreenPalm or equivalent.

Criterion 6 — 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' ([2]) and the instructions given in the user manual available on the EU Ecolabel website.

Assessment and verification: the applicant shall document the test protocol 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.

Criterion 7 — Information appearing on the EU Ecolabel

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

— Reduced impact on aquatic ecosystems,

— Fulfils strict biodegradability requirements,

— Limits packaging waste.

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

Assessment and verification: the applicant shall provide a sample of the product label or an artwork of the packaging where the EU Ecolabel is placed, together with a signed declaration of compliance.

([1]) As defined by the RSPO in the 'RSPO Rules for Home and Personal Care Derivatives', available at: http://www.greenpalm.org/upload/files/45/RSPO_Guiding_Rules_for_HPC_derivativesV9.pdf.

([2]) 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 Ecolabelled 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:

	Acute toxicity			Chronic toxicity			Degradation		
Ingoing substance	LC50/EC50	$SF_{(acute)}$	$TF_{(acute)}$	NOEC (*)	$SF_{(chronic)}$ (*)	$TF_{(chronic)}$	DF	Aerobic	Anaerobic
'Name'	1 mg/l	10,000	0,0001			0,0001	1	P	N

(*) 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

(2) After 1 December 2015:

The test methods provided for in Regulation (EC) No 1272/2008

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)).

(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 ^{14}C measurements or chemical analyses. Testing at low dosages may be performed by use of OECD 308 (August 2000) or an equivalent method.