EN

ANNEX II

EU Ecolabel criteria for awarding the EU Ecolabel to animal care products

FRAMEWORK

Aims of the criteria

The EU Ecolabel criteria target the best 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, which are not animal tested and that use less packaging, which can be easily recycled. The use of recycled material and refillable packaging is promoted.

To this end, the criteria:

(1) set requirements to limit the overall aquatic toxicity;

(2) set requirements to ensure that the ingredients are biodegradable and will not persist in water;

(3) recognise and reward products with restricted use of hazardous substances;

(4) set requirements to allow the maximum usage of the product contained in a container and promotes the minimisation of use of packaging material and promote plastics recyclability;

(5) recognise and reward products with renewable ingredients from sustainable origin;

(6) guarantee that the product meets certain quality requirements;

(7) set a requirement to inform consumers on the environmental benefits associated with the product, in order to encourage its purchase;

(8) set a restriction on animal testing.

The criteria for awarding the EU Ecolabel to ‘animal care products' are the following:

(1) toxicity to aquatic organisms: Critical Dilution Volume (CDV);

(2) biodegradability;

(3) excluded and restricted substances;

(4) packaging;

(5) sustainable sourcing of palm oil, palm kernel oil and their derivatives;

(6) fitness for use;

(7) information on EU Ecolabel.

Assessment and verification:

a) Requirements

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.

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 included in 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.

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, International Nomenclature of Cosmetic Ingredients (INCI) designations, DID No[2] (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.

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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

For each substance listed, the Safety Data Sheets (SDS) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[3] 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.

A written confirmation from the applicant that all the criteria are fulfilled shall also be required for the assessment.

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

b) Measurement thresholds

Compliance with the ecological criteria is required for all substances as specified in Table 1.

[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)

Table 1

Threshold levels applicable to substances for animal care products (% weight by weight, % w/w), shown by criterion. Abbreviations: CLP: Classification, Labelling and Packaging; CMR: carcinogenic, mutagenic, toxic for reproduction; N/A: not applicable

Criterion name		Preservatives	Colorants	Fragrances	Impurities	Other substances (e.g. surfactants, enzymes)
Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0100	no limit (*1)
Criterion 2. Biodegradability		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0100	no limit (*1)
Criterion 3. Excluded and restricted substances	Criterion 3 (a) (i): Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council[4]	≥ 0,0100 (*2)	≥ 0,0100 (*2)	≥ 0,0100	≥ 0,0100	≥ 0,0100
	Criterion 3 (a) (ii) : Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 (carcinogenic, mutagenic, toxic for reproduction)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (a) (iii): product classification	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (b): Specified excluded	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)

[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).

	substances					
	Criterion 3 (c): Restrictions on Substances of Very High Concern	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 3 (d): Fragrances	N/A	N/A	no limit (*1)	≥ 0,0100	N/A
	Criterion 3 (e): Preservatives	no limit (*1)	N/A	N/A	≥ 0,0100	N/A
	Criterion 3 (f): Colorants	N/A	no limit (*1)	N/A	≥ 0,0100	N/A
Criterion 5. Sustainable sourcing of palm oil, palm kernel oil and their derivatives		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0100	no limit (*1)

(*1) "no limit" means: regardless of the concentration (analytical limit of detection) for all substances, with the exception of impurities, which can be present up to a concentration of 0,0100 % w/w in the final formulation.

(*2) for preservatives and colorants classified as H317 and H334 the threshold is 'no limit'.

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

1) ‘active content’ (AC) means the sum of organic ingoing 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. Inorganic rubbing/abrasive agents are not included in the calculation of the active content;

2) ‘ingoing substances’ means all substances in the product, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde from preservatives and arylamine from azodyes and azopigments) shall also be regarded as ingoing substances. Residuals, pollutants, contaminants, by-products, etc. from production, incl. production of raw materials, that remain in the raw materials ≥ 1000 ppm (≥ 0.1000 % w/w ≥ 1000 mg/kg) are always regarded as ingoing 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/w, 100 mg/kg) in the rinse-off product;

4) ‘microplastics’ means particles with a size of below 5 mm of insoluble macromolecular plastic, obtained through one of the following processes: a) a polymerisation process such as polyaddition or polycondensation or a similar process using monomers or other starting substances; b) chemical modification of natural or synthetic macromolecules; c) microbial fermentation;

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) ‘nanomaterial’ means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm, in accordance with Regulation (EC) No 1223/2009([5]);

7) ‘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;

8) ‘substances identified to have endocrine disrupting properties’ means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[6] (candidate list of substances of very high

[5] 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)

[6] 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).

concern for authorisation), or according to Regulations (EU) No 528/2012([7]) or (EC) No 1107/2009([8]) of the European Parliament and of the Council.

[7] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

EU ECOLABEL CRITERIA FOR ANIMAL CARE PRODUCTS

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

This criterion applies to final products.

The total CDV toxicity of the product shall not exceed the limits in Table 2:

Table 2 CDV limits

Product	**CDV (l/g AC)**
Animal care products	12 000

The CDV shall be calculated using the following equation:

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

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 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

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) or anaerobically non-biodegradable (anNBO) shall not exceed the limits in Table 3:

Table 3 aNBO and anNBO limits

Product	**aNBO (mg/g AC)**	**anNBO (mg/g AC)**
Animal care products	15	15

Assessment and verification: *the applicant shall provide documentation for the biodegradability 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 surfactants biodegradability values as well for aNBO and anNBO values for organic ingoing substances, reference shall be made 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, together with a toxicologist declaration 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 biodegradability if one of the following three conditions is fulfilled:

1. the substance is readily degradable and has low adsorption (A < 25 %);
2. the substance is readily degradable and has high desorption (D > 75 %);
3. the substance is readily degradable and non-bioaccumulating.

Testing for adsorption/desorption may be conducted in accordance with Guidelines 106 of the Organisation for Economic Co-operation and Development (OECD).

Criterion 3. Excluded and restricted substances

3(a) Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008

(i) Unless derogated in Table 5, the product shall not contain substances at or above the concentration of 0.0100 % weight by weight, that meet the criteria for classification with thehazard classes, categories and associated hazard statement codes listed in Table 4, in accordance with Regulation (EC) No 1272/2008.

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

Table 4. 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 on 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 (*[1])	
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 Harms public health and the environment by destroying ozone in the upper atmosphere	

(*[1]) Enzymes shall be exempt (including stabilisers and preservatives in the enzyme raw material) if they are in liquid form or as granulate capsules. In the case of colorants and preservatives with a H317 or H334 hazard class, the requirement shall apply regardless of the concentration.

Table 5. Derogations to restrictions on ingoing substances classified under Regulation (EC) No 1272/2008

Substance type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Surfactants	Animal care products	H412: Harmful to aquatic life with long-lasting effects	Total concentration < 20 % in the final product

(ii) Substances that meet the criteria for classification with the hazard statements listed in Table 6 shall not be contained 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) The final product shall not be classified and labelled as being acutely toxic, a specific target organ toxicant, a respiratory or skin sensitiser, carcinogenic, mutagenic or toxic for reproduction, or hazardous to the aquatic environment, as defined in Annex I to Regulation (EC) No 1272/2008 and in accordance with the list in Tables 4 and 6 of this Annex.

Criterion 3 (a) shall not apply to substances covered by Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006 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.

3(b) Specified excluded substances

Substances listed under Annex II to Regulation (EC) No 1223/2009 shall not be present in the product, regardless of the concentration, neither as part of the formulation, as part of any mixture included in the formulation, nor as impurities. The following substances shall also not be included in the product, neither as part of the formulation, as part of any mixture included in the formulation, nor as impurities:

(i) Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives [1];

(ii) Butylated Hydroxytoluene (BHT) and Butylated hydroxyanisole (BHA);

(iii) Cocamide DEA;

(iv) Deltamethrin;

(v) Diethylenetriaminepentaacetic acid (DTPA) and its salts;

(vi) Ethylenediaminetetraacetic acid (EDTA) and its salts and non-readily biodegradable phosphonates;

(vii) Microplastics and microbaeds;

(viii) Nanomaterials, unless used according to the conditions laid down for specific nanomaterials in Annexes III, IV and VI to Regulation (EC) No 1223/2009 ;

(ix) Nitromusks and polycyclic musks;

(x) Perfluorinated and polyfluorinated substances;

(xi) Phthalates;

(xii) Resorcinol;

(xiii) Sodium hypochlorite, chloramine and sodium chlorite;

(xiv) Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate [2];

(xv) Substances identified to have endocrine disrupting properties;

(xvi) The following fragrances: benzyl salicylate, butylphenyl metylpropional, tetramethyl acetyloctahydranophthalenes (OTNE);

(xvii) The following isoflavones: daidzein, genistein;

(xviii) The following preservatives: benzalkonium chloride, formaldehyde releasers, isothiazolinones, kojic acid, parabens, triclocarban, triclosan;

(xix) Triphenyl phosphate

Notes:

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

[2] These substances may be allowed if present as impurities, but up to a total concentration of 500 ppm in the product formulation.

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

Substances meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 that have been identified according to the procedure described in Article 59 of that Regulation and included in the candidate list of substances of very high concern for authorisation shall not be present the product, regardless of their concentration.

3(d) Fragrances

(i) Substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products'[9] shall not be present in EU Ecolabel products in concentrations higher than 0,0100%.

(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.ifrafragrance.org/. The manufacturer shall follow the recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials.

3(e) Preservatives

(i) Preservatives classified as H317 or H334 shall be prohibited regardless of the concentration.

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

(iii) The product may contain preservatives provided that they are not bioaccumulating. A preservative is not considered bioaccumulating if BCF < 500 or log K_{ow} < 4. If both BCF and log K_{ow} values are available, the highest measured value shall be used.

3(f) Colorants

(i) Colorants classified as H317 or H334 shall be prohibited regardless of the concentration.

(ii) Colorants in the product shall not be bioaccumulating. A colorant is considered not bioaccumulating if BCF < 500 or log K_{ow} < 4. If both BCF and log K_{ow} values are available, the highest measured 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.

[9] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

Assessment and verification: *The applicant shall provide a signed declaration of compliance with all above sub-criteria, supported by declarations from suppliers for criteria 3 (a) (ii), 3 (e), and 3 (f); and the following supporting evidence:*

To demonstrate compliance with sub-criteria 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 sub-criteria 3(a), 3(b) and 3(c) are fulfilled.

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

For requirement sub-criterion3(c), reference to the latest list of substances of very high concern[10] shall be made on the date of application.

To demonstrate compliance with sub-criterion 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 sub-criterion 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 sub-criterion 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.

The above evidence may also be provided directly to competent bodies by any supplier in the applicant's product supply chain.

Criterion 4. Packaging

The minimum volume for an animal care product to be certified shall be 150ml.

(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, shall be allowed, with the exception of secondary packaging which groups the product and its refill and products that include several elements for their use. For the products for domestic use

[10] http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

sold with pump that can be opened without compromising the design, a refilling option shall be provided in the same or higher primary packaging capacity.

Note: Cardboard boxes used to transport the products to the retail stores shall not be considered as secondary packaging.

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) shall be less than 0,20 g of packaging per gram of product for each of the packaging in which the product is sold. Products packed in metal aerosol containers shall be exempted from this requirement. PIR shall be calculated (separately for each of the packaging) as follows:

$PIR = (W + (W_{refill} \times F) + N + (N_{refill} \times F))/(D + (D_{refill} \times F))$

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:

$F = V \times R/Vrefill$

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 shall 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.

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

Note: [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 from the packaging manufacturer 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 demonstrate that the refills shall be available for purchase on the market. The applicant shall provide third party verification and traceability for postconsumer recycled content. Certificate of recyclers pursuant a certification scheme following standard EN15343 may be used to support verification. Certificates of product production for converters pursuant a certification scheme following a controlled blending model as described in the ISO 22095 may be used to support verification.*

(c) Information and design of primary packaging

(i) Information on primary packaging

Dosage and refills: Applicants shall indicate the correct dosage or the appropriate quantity to be used on the label of the primary packaging together with the following sentence:

"using the correct dosage of the product minimises impacts on the environment and saves money."

In cases where the correct dosage cannot be defined for a specific product because it depends on consumer aspects (e.g. length of the hair), the following sentence shall be used instead:

"*dose the product with care so as not to over-consume it unnecessarily*"

If the product is refillable, the applicant shall complete the information with a reference to use refills in order to minimise impacts on the environment and save money.

End of life information: Applicants shall include a sentence or a pictogram in relation to empty product disposal (e.g. *"when empty, the package/container should be disposed of in a dedicated container for recycling*")

Note: Products whose dimensions do not allow a proper display of information due to lack of space or text legibility reasons shall be exempted from this requirement.

(ii) Design of primary packaging

Applicants shall indicate the correct dosage or the appropriate quantity on the label of the primary packaging and a sentence which underlines the importance of using the correct dosage in order to minimise energy and water consumption, reduce water pollution and save money.

The primary packaging shall be designed:

a) to make correct dosage easy by using a pump [1] or ensuring that the opening at the top is not too wide. Refills are exempted from this requirement.

b) to ensure that at least 95% of the product can be easily removed from the container. The residual amount of the product in the container (R), which must be below 5%, 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)

Rinse-off products whose primary packaging can be manually opened and the residue product can be extracted with adding water shall be exempted from the requirement in b).

Notes:

[1] For liquid soap no pump or dispenser sold with the product may provide more than 2 g (or 3 ml) soap per full press.

Assessment and verification: *the applicant shall submit a description of the dosage device (e.g. schematic illustration, pictures…), the test report with results of measuring the residual quantity of the product in the packaging and a high resolution image of the product packaging that clearly shows the sentences indicated in sub-criterion 5 (c) (i) (if applicable). Applicant shall provide documented evidence of which case under sub-criterion 5 (c) (i) applies for their product(s). 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.

Pumps and aerosol containers are exempted from this requirement.

Table 7. Materials and components excluded from packaging elements

Packaging element	Excluded material or component*
Label or sleeve	- 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 - PETG label or sleeve in combination with a PET packaging. - PET label or sleeve (except LDPET (< 1 g/cm^3)) in combination with a PET packaging. - Any other plastic materials for sleeves/labels with a density > 1 g/cm3 used with a PET packaging - Any other plastic materials for sleeves/labels with a density < 1 g/cm3 used with a PP or HDPE packaging - Labels or sleeves that are metallised or are welded to a packaging body (in mould labelling). - PSL (pressure sensitive) label shall demonstrate that the adhesive is water releasable at washing conditions of the recycling process. - PET PSL label, unless the adhesive is water releasable at washing conditions of the recycling process and has no reactivation.
Closure	- 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/cm^3 in combination with a PET packaging - Closures (or part of) made of metal, glass, EVA - Closures (or part of) made of silicone. Exempted are silicone closures with a density < 1 g/cm^3 in combination with a PET packaging and silicone closures with a density > 1g/cm^3 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	- Polyamide, EVOH provided with tie layers made by a polymer different that the one used for the packaging body, functional polyolefins, metallised and light blocking barriers

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

Assessment and verification: *the applicant shall submit a signed declaration of compliance specifying the material composition, supported by manufacturer documentation, 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

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 non-governmental organisations (NGOs), industry, financial institutions and government and that addresses environmental impacts on soil, biodiversity, organic carbon stocks and conservation of natural resources.

Assessment and verification: *To demonstrate compliance, evidence through third-party chain of custody certificating that the raw materials used in the product or in its 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 shall be accepted:*

- until 1st January 2025: identity preserved, segregated, and mass balance;

- after 1st January 2025: identity preserved and segregated.

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 shall be accepted: identity preserved, segregated, and mass balance.

For palm oil, palm kernel oil and their derivatives, a mass balance calculation and/or invoices/delivery notes from the raw material producer shall be provided, showing that the proportion of certified raw material corresponds to the amount of certified palm oil, palm kernel oil and/or their derivatives. Alternatively, a declaration from the producer of raw materials shall be provided, showing that all purchased palm oil, palm kernel oil and/or their derivatives are certified. Competent bodies shall annually check the validity of the certificates for each certified product/ingredient [1].

Notes: [1] The verification can be done via RSPO website, where the status of the Certificate is showed in real time: https://www.rspo.org/certification/search-for-supply-chain-certificate-holders

Criterion 6: Fitness for use

The animal care product's capacity to fulfil its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e.g. colour protection, moisturizing) shall be supported by adequate and verifiable studies, data and information of ingredients.

Carrying out of animal testing of final formulations, ingredients or combinations of ingredients shall be strictly prohibited.

Assessment and verification: *The applicant shall present studies, data and information of ingredients or final formulation to 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 for animal care products

The optional label with box shall contain the following information:

- 'Fulfills strict requirements on harmful substances';

- 'Tested performance (not animal tested)';

- 'Less 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.*

Appendix

Detergents Ingredients Database (DID) list

The DID list (Part A) is a list containing information on 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 the 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:

https://ec.europa.eu/environment/ecolabel/documents/DID%20List%20PART%20A%202016%20FINAL.pdf

https://ec.europa.eu/environment/ecolabel/documents/DID_List_PART_B_2016_FINAL.pdf

For substances with no data regarding aquatic toxicity and biodegradability, 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 added substance	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 is 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 Council Directive 67/548/EEC [11], 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-day 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 biodegradability shall be EN ISO 11734, ECETOC No 28 (June 1988), OECD 311 or an equivalent test method, with the requirement of 60 % ultimate biodegradability under anaerobic conditions. Test methods simulating the conditions in a relevant anaerobic environment may also be used to document that 60 % ultimate biodegradability has been attained under anaerobic conditions.

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 biodegradability 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

[11] 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).

been shown not to be anaerobically degradable, it can be assumed that a similar type of surfactant is also not anaerobically biodegradable.

(2) Perform screening test for anaerobic biodegradability. 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 biodegradability 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 < 500 or log Kow is < 4,0.

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 < 500 or log Kow is < 4,0

Documentation on aquatic toxicity:

The lowest available NOEC/ECx/EC/LC50 value shall be used. If chronic values are available, they shall be used instead of acute ones.

For acute aquatic toxicity test methods nos. 201, 202 and 203* in the OECD Guideline for the Testing of Chemicals or equivalent test methods shall be used.

For chronic aquatic toxicity test methods nos. 210*, 211, 215*and 229* in the OECD Guideline for the Testing of Chemicals or equivalent test methods shall be used. OECD 201 may be used as chronic test if chronic endpoints are chosen.

*The Commission prohibited animal testing of ingredients for cosmetic products from March 2009 onwards. To determine aquatic toxicity, however, the prohibition only concerns testing with fish (does not include invertebrates). As such, OECD test guideline no. 203 (acute toxicity – fish), 210, 215 and 229 (chronic toxicity – fish) shall not be used to document

acute/chronic toxicity. The results of acute/chronic toxicity testing using fish produced before March 2009 may still be used, however.