

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 ecotoxicity 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;
- guarantee that the product meets certain quality requirements;
- 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 'animal care products' are as follows:

1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)
2. Biodegradability
3. [Restricted substances](#)
4. Packaging
5. Renewable ingredients
6. Fitness for use
7. Information on EU Ecolabel

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.

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 ([OJL396, 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

Note: Label and/or instructions information accompanying the product shall be used to categorize the product. Where a 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 1.

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Table 1

Threshold levels applicable to substances for animal care products (% weight by weight), shown by criterion. Abbreviations: CLP: Classification, Labelling and Packaging; N/A: not applicable; r.c.: regardless of the concentration

Criterion name		Preservatives	Colorants	Fragrances	Impurities	Ingoing substances (e.g. surfactants, enzymes)
Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)		≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010
Criterion 2. Biodegradability Criterion 2 (a)		≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010
Criterion 3. Restricted substances	Criterion 3 (a) (i): Restrictions on ingoing substances/mixtures classified under the CLP Regulation	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010
	Criterion 3 (a) (ii): : Restrictions on ingoing substances/mixtures classified under the CLP Regulation (CMR)	r.c. (*1)	r.c. (*1)	r.c. (*1)	r.c. (*1)	r.c. (*1)
	Criterion 3 (a) (iii): product classification	≥ 0.010 (*2)	≥ 0.010 (*2)	≥ 0.010 (*2)	≥ 0.010 (*2)	≥ 0.010 (*2)
	Criterion 3 (b): Specified excluded substances	r.c. (*1)	r.c. (*1)	r.c. (*1)	r.c. (*1)	r.c. (*1)

	Criterion 3 (c): Restrictions on Substances of Very High Concern	r.c. ^(*)	r.c. ^(*)	r.c. ^(*)	r.c. ^(*)	r.c. ^(*)
	Criterion 3 (d): Fragrances	N/A	N/A	≥ 0.010	N/A	N/A
	Criterion 3 (e): Preservatives	≥ 0.010	N/A	N/A	N/A	N/A
	Criterion 3 (f): Colorants	N/A	≥ 0.010	N/A	N/A	N/A
Criterion 5. Renewable ingredients	Criterion 5 (a): Sustainable sourcing of palm oil, palm kernel oil and their derivatives	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010
	Criterion 5 (b): Certification of plant based ingredients	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010

^(*) r.c. means regardless of the concentration: all substances, by-products and impurities from raw materials (analytical limit of detection).

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

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, including propellants contained in aerosol products. **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, arylamine, in situ-generated preservatives) are also regarded as ingoing substances. Impurities in the raw materials ≥ 1000 ppm (≥ 0.1000 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-%, 100 mg/kg) in the rinse off product.
- 4) '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;
- 5) '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;
- 6) '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;
- 7)

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 is calculated using the following equation:

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

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

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 3:

Table 3 aNBO and anNBO limits

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

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

(i) Unless derogated in Table 5, the product shall not contain substances or mixtures at or above the concentration of 0.010 % weight by weight, that are assigned any of the hazard classes, categories and associated hazard statement codes listed in Table 4, 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.

Table 4. Restricted hazard classes, categories and associated hazard statement codes

Acute toxicity

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)

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 (*)		
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		

(*) in the case of Respiratory and skin sensitization hazard class, the requirement applies at the substance level only.

Table 5. Derogations to restrictions on ongoing substances/mixtures classified under the CLP Regulation and applicable conditions

Substance /mixture type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Surfactants	Rinse-off products	H412: Harmful to aquatic life with long-lasting effects	total concentrations < 20 % in the final product

(ii) No substances or mixtures that meet the criteria for classification with the hazard statements listed in Table 6 shall 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) 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.

Surfactants regardless of their function classified with H412 are exempted from the requirement.

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

Substances and mixtures listed under Annex II to Regulation 1223/2008 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 and mixtures 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) Perfluorinated and polyfluorinated substances [2];
- (iii) Nitromusks and polycyclic musks;
- (iv) Butylated Hydroxytoluene (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.
- (vii) Microplastics and microbeads [3];
- (viii) Nanomaterials [4], unless an EU regulatory authority has evaluated and authorised the use of the nanomaterial [5];
- (ix) The fragrance tetramethyl acetyloctahydrophthalenes (OTNE);
- (x) Sodium hypochlorite, chloramine and sodium chlorite;
- (xi) ETPA (diethylenetriaminepentaacetic acid and its salts);
- (xii) Cocamide DEA;
- (xiii) Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate;
- (xiv) Substances identified to have endocrine disrupting properties [6].
- (xv) Phthalates;
- (xvi) Isothiazolines;
- (xvii) Ethylhexyl methoxycinnamate; Recorsinol; Benzophenones; Homosalate; Octocrylene; Butylphenyl methylpropional; Benzyl salicylate; Triphenyl phosphate.

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 present in the product, regardless of their concentration.

⁶ OJ L 396, 30.12.2006, p. 1

3(d) Fragrances

(i) Substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products' [7] and listed in the Annex cannot be present in EU Ecolabel products in concentrations higher than 0.01% in rinse-off products and 0.001% in leave-on products.

(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 $BCF < 500$ or $\log K_{ow} < 4$. If both BCF and $\log K_{ow}$ values are available, the highest measured BCF value shall be used.

3(f) Colorants

(i) Colorants in the product must 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 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 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.

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] also named per- and polyfluoroalkyl substances (PFASs)

[3] The definition of 'microplastic' and 'microbaeds' 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> The derogations set in paragraphs 3 and 5 of this document also apply.

[4] As defined in article 2 of the Cosmetic Regulation

[5] Opinions will be accepted if coming from SCCS (for the assessment of the human health of the nanomaterial) or from RAC or SCHEER (for the assessment of the environmental impacts of the nanomaterial). The list of cosmetic products containing nanomaterials can be found at the online Cosmetic Products Notification Portal: <https://ec.europa.eu/growth/sectors/cosmetics/cpnp/> The list of nanomaterials placed on the EU market can be found at the EU Observatory for Nanomaterials database: <https://euon.echa.europa.eu/search-for-nanomaterials>

[6] "Substances identified to have endocrine disrupting properties" are the ones which have been identified to have endocrine disrupting properties (human health and/or environment) according to article 57(f) of REACH Regulation (Candidate List of SVHCs), in Regulation 528/2012 or in Regulation 1107/2009. **[to be included in the User Manual: No list exists for ED substances in the Biocidal Products Regulation. ECHA's endocrine disruptor (ED) assessment list (<https://echa.europa.eu/ed-assessment>) can be consulted, as it includes the substances with ongoing or concluded ED assessment under REACH or the Biocidal Products Regulation that have been brought for discussion to ECHA's ED Expert Group]**

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

Criterion 4. Packaging

The minimum volume for a rinse off product to be certified should 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, 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.

Note: Cardboard boxes used to transport the products to the retail stores should 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) must 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 are exempted from this requirement. PIR shall be calculated (separately for each of the packaging) as follows:

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

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:

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

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 [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 document that the refills shall be available for purchase on the market.*

**The declaration must fulfil the conditions of the future (January 2022) implementing act of Directive 2019/904 laying down the rules for the calculation and verification of the targets on recycled content.*

c) 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:

i) to make correct dosage easy by using a pump* or ensuring that the opening at the top is not too wide (diameter opening at the top below XX mm). Refills are exempted from this requirement.

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

ii) to ensure that at least 94% of the product can be easily removed from the container. The residual amount of the product in the container (R), which must be below 6%, 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)

Products which primary packaging can be manually opened and the residue product can be extracted with adding water are exempted.

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 product in the packaging and a high resolution image of the product packaging that clearly shows the indicated dosage. 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	- Full sleeves [1] are not permitted.

	<ul style="list-style-type: none"> - 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 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). - Virgin PET and rPET from already food contact approved material shall not be allowed to use. - SAL (self adhesive) or PSL (pressure sensitive) label shall demonstrate the adhesive is water releasable at washing conditions of the recycling process. And in case of PET they also have to demonstrate no reactivation.
Closure	<ul style="list-style-type: none"> - PS closure in combination 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 5% 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/packaging

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) SVHCs in cosmetic packaging

The packaging shall not contain any 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 the mentioned Regulation and included in the candidate list of substances of very high concern for authorisation, at or above the concentration of 0.10% weight by weight.

Assessment and verification: *the applicant shall submit a signed declaration of compliance together with a description of how they control this through the supply chain. Declarations from the suppliers could also be provided.*

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, financial institutions 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 case raw materials/ingredients to which Regulation 2018/848 (*) applies are used, a minimum threshold of 20% w/w of these ingredients shall be produced according to organic production and certified organic. Raw materials outside the scope of certification to Regulation 2018/848 do not contribute to the minimum threshold. Water is also excluded from the calculation.

Assessment and verification: *To demonstrate compliance with sub-criterion (a) evidence through third-party chain of custody certifying that the raw materials used in the product or in its manufacturing originate from sustainably managed plantations shall be provided. 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, and mass balance.*

Competent Bodies should annually check the validity of the certificates for each certified product/ingredient [1].

To demonstrate compliance with sub-criterion (b), the applicant shall provide third-party certificates for each raw materials/ingredients certified to the EU Organic Regulation. Raw materials outside the scope of certification to the EU Organic Regulation (Regulation 2018/848), or other Regulations recognised as equivalent by the EU, are not considered organic for the purposes of the EU Ecolabel. Certificates accepted shall include those awarded by Competent Bodies duly recognised and appointed through the EU Regulation on organic production 2018/848 or equivalent.

In the case of palm oil and palm kernel oil, certifications of compliance with RSPO supply chain systems (identity preserved, segregated, mass balance, and independent smallholders credits) and with the EU Organic Regulation can be used interchangeably (i.e. holding one of the two certifications will be sufficient to comply with criterion 6).

[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>

References:

(Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007]*

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 is 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:

- Restricted hazardous substances;

- Tested performance (not animal tested);

- Limited 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 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.

(2) After 1 December 2015:

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

Regulation (EC) No 1907/2006 foresees in Annex XI that the standard testing regime can be adapted by the use of non-tested methods such as qualitative or quantitative structure-activity relationship (Q(SAR) models). **Q(SAR) models should only be accepted if actual test data is missing.**

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 < 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 must be used. If chronic values are available, they must 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 can 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) cannot be used to document acute/chronic toxicity in the future. The results of acute/chronic toxicity testing using fish produced before March 2009 may still be used, however.