EU Ecolabel criteria for cosmetic products and animal care products

User Manual

European Commission

EU Ecolabel criteria for cosmetic products and animal care products

Commission Decision 2021/1870/EU

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List of Contents

Using this manual

This manual guides you through the process of applying for an EU Ecolabel licence, in accordance with the applicable Criteria requirements. The following symbols are used throughout it:

Symbol	Description
	If necessary for the interpretation of the criterion, subtitles with explanations, examples of calculations, decisions from the Competent Body Forum, etc.
	Boxes with definitions or additional explanations of technical terms that could complement the definitions already included in the article 2 of the Commission Decision (EU) 2021/1870.
	Notable or important information.
	Documentation on how to fill in the application form and information about documents to be handed in with the application.
	Website links where further information can be found.

This User Manual is meant to be a guidance to facilitate the application to the EU Ecolabel. It is not a legal document and does not, in any way, replace the Commission Decision or any relevant legislation. In case of inconsistencies, the Commission Decision prevails. In case of doubt on specific points in the User Manual, please refer directly to the national Competent Body.

The manual is structured as follows:

- Part A: General Information – Provides information about the EU Ecolabel, details of the application process, and answers to frequently asked questions about applying.
- Part B: Product Assessment and Verification – Outlines the Criteria for a specific product group set out in the Commission Decision.

The manual contains the following elements as separate files:

- Application Form. This application form should be completed by the applicant. This is an excel file that can be provided electronicallyl to the competent body. The applicant should complete one excel file for each product formulation.
- Annex I. Declarations of the producer/supplier of the ingredients. This document consists of the declarations needed from suppliers concerning the excluded and restricted substances of the ingredients and the renewable content from palm oil, palm kernel oil or its derivates.

- Annex II. Declaration fo the producer/supplier of the packaging. This document consists of the information needed efrom suppliers of packaging to verify the criterion of packaging.
- Application Form Guide: A short guide on how to fill out the application form.

The applicant may gather all the declarations from his suppliers and provide them to the assessing Competent Body together with the application form. Alternatively, these declarations can also be provided directly from the supplier to the Competent Body.

Please read this manual all the way through before completing and submitting the verification form or any other documentation. EU Ecolabel Competent Bodies can help licence holders understand the EU Ecolabel Criteria and can provide guidance on how to assemble an application dossier.

In this document, tables for cosmetic products are yellow and tables for animale care products are orange.

Introduction

This User Manual[1] is for guidance only and is designed to help you to apply for the EU Ecolabel for Cosmetic Products or for the EU Ecolabel for Animal Care Products. It includes an outline of all data, tests and documentation that are required to demonstrate compliance with the criteria.

The basis for the manual is the Commission Decision (EU) 2021/1870 establishing the EU Ecolabel criteria for Cosmetic Products and Animal Care Products. Both product groups are covered by the same Commission Decision but criteria are separated in two annexes:

- Annex I: EU Ecolabel criteria for awarding the EU Ecolabel to cosmetic products, covering all products under Cosmetic Regulation.
- Annex II: EU Ecolabel criteria for awarding the EU Ecolabel to animal care products, covering rinse-off animal care products.

The official text of the criteria, together with the Correcting and Amending Decision, can be found at:

http://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html

This document is not aimed to duplicate the content of the criteria but is intended to support their interpretation, and only focused on helpful explanations and clarifications. Each criterion name appears as heading under Part B with a short summary of what documents are needed for the verification of the criterion. The exact criterion text does not appear in this user manual. Only additional information, clarifications and explanations are included.

Please read the Commission Decision (EU) 2021/1870 establishing the EU Ecolabel criteria for Cosmetic Products and Animal Care Products and this manual all the way through before completing and submitting the verification form or any other documentation.

For general questions about the EU Ecolabel and the application process please check out following pages:

http://ec.europa.eu/environment/ecolabel/faq.html
http://ec.europa.eu/environment/ecolabel/how-to-apply-for-eu-ecolabel.html

[1] This User Manual is for guidance only; it does not have any legal standing and does not, in any way, replace the Commission Decision or any relevant legislation. In case of doubt on specific points in the Manual, please refer directly to the national Competent Body.

Before you start

We recommend tha before you start you take the following steps:

- Read carefully the Commission Decision 2021/1870 and its Annexes. Available at: EUR-Lex - 32021D1870 - EN - EUR-Lex (europa.eu)
- Contact the Competent Body of your choice. More information of your Competent Body is available at: Competent Bodies - Ecolabel - EUROPA
- Make sure the candidate product fulfils all applicable legal requirements of the country or countries in which the product is intended to be placed on the market.
- Download the Application Form. Available at: https://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html
- Read the document "Instructions for completing the Application form for the EU Ecolabel for cosmetic products and animal care products". Available at: https://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html

Part A: General Information

Part A "General information" is a horizontal document for all EU Ecolabel products explaining the different steps of the application process in detail. It has been translated in each Member State language and can be found at:

https://ec.europa.eu/environment/ecolabel/documents.html

Part B: Product Assessment and Verification

Definitions

The following definitions shall apply to references throughout this User Manual, and in reference to the criteria document:

1. 'leave-on products' means products marketed as not intended to be removed with water after use in normal conditions;

2. 'rinse-off products' means products marketed as intended to be removed with water after use in normal conditions;

3. '**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;

4. '**mixture'** means a mixture or solution composed of two or more substances;

5. '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 and less than 10 ppm (0.0010 % w/w, 10.0 mg/kg) in the leave-on product;

Substances intentionally added to the ingredients in the raw material or in the final product are not considered to be impurities and they should be listed in the Application Form.

6. '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. Organic rubbing/abrasive agents are not included in the calculation of the active content;

7. '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;

8. '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;

9. '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;

10. '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;

11. '**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[2] (candidate list of substances of very high concern for authorisation), or according to Regulations (EU) No 528/2012[3] or (EC) No 1107/2009[4] of the European Parliament and of the Council. The National Authorities List I can be consulted[5], as it includes the substances that have undergone an evaluation of endocrine disrupting properties, as regulated in the EU in PPPR, BPR or REACH, and which are identified as endocrine disruptors;

12. **'children products'** means products marketed to be used up to the age of 12 years and products marketed as 'family product'.

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1). Hereafter "REACH Regulation'

[3] 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). Hereafter 'Biocidal Products Regulation', or 'BPR'

[4] 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). Hereafter 'Plant Protection Products Regulation', or 'PPPR'

[5] https://edlists.org/

Scope

The EU Ecolabel criteria for cosmetic products cover all products falling under the scope of Regulation (EC) 1223/2009 on cosmetic products[6]. The EU Ecolabel criteria for animal care products cover rinse-off products intended to be placed in contact with animal hair to clean them or to improve the condition of it. The scope of the product groups are defined in Article 1 and Article 2 of the Commission Decision 2021/1870.

Cosmetic products.

According to Article 1 of the Commission Decision, the product group 'cosmetic products' shall comprise any substance or mixture falling under the scope of Regulation (EC) No 1223/2009 intended to be placed in contact with the external parts of the human body, (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

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

Wet wipes are out of the scope of the Comision Decision 2021/1870.

'Cosmetic products' shall not cover products that are specifically marketed for disinfecting or anti-bacterial use, these products fall under the Biocidal products Regulation and are therefore out of the scope of Cosmetic Regulation. However, hand soaps with a primary cleaning function and a secondary function as antibacterial/sanitizing may be awarded the EU Ecolabel, if the product meets all the requirements and criteria established in Commission Decision (EU) 2021/1870.

Anti-dandruff shampoos are allowed as they are considered under the Cosmetics Regulation.

Cosmetic products that are sold in solid/powder form but that are intended to be used in liquid form, after dilution with water at home, are eligible for the EU Ecolabel if they fall under the Cosmetic Regulation.

[6] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223. Hereafter 'Cosmetics Regulation'

Soaps with antibacterial functions are allowed to be awarded the EU Ecolabel only if the product falls under the Cosmetic Regulation. However, no claims regarding antibacterial properties is allowed on the product.

Check in the following table whether your candidate product is in the scope and what type of product (rinse-off or leave-on) it is. Please note that the list of products in Table 1 is not exhaustive, and there may be products not specified in Table 1 that can be certified if they comply with Article 1 of the Commission Decision 2021/1870.

Table 1. Scope for cosmetic products.

Category	Type	Sub-categories
SHOWER, BATH and OTHER BODY CLEANSER PREPARATIONS	Rinse-off	Shampoo, shower preparations, liquid soaps Solid soaps and solid shampoos Hair conditioners Shaving foams, shaving gels and shaving creams Feminine hygiene cosmetic products
HAIR STYLING and TREATMENT	Rinse-off	Hair dyes
	Leave-on	Liquids, waxes, sprays, mousses, lacquers and dry shampoos
SKIN CARE PRODUCTS	Rinse-off	Exfoliants, cleansers
	Leave-on	Lotions, creams and oils (including massage products, after-sun and self-tanning creams) Solid hydration lotions Sun screen products Cleanser
MOUTHWASH	Rinse-off Leave-on	Mouthwashes and oral perfumes
TOOTHPASTE	Rinse-off	Dentifrice Dental cleanser Solid toothpastes
DEODORANTS and ANTIPERSPIRANTS	Leave-on	Personal deodorants and antiperspirants (solid and liquid)
DECORATIVE COSMETICS	Leave-on	Body colour cosmetics, eye colour cosmetics, face colour cosmetics, lip colour cosmetics, multiuse colour cosmetics, nail colour cosmetics
NAIL ENAMEL REMOVER	Leave-on	Nail enamel removers

The Cosmetics Regulation is supplemented by a guidance document on borderline products. The way borderline products are addressed in the Cosmetics Regulation is valid also for the EU Ecolabel for cosmetic products. .

Check in the following link whether your candidate product is in the borderline list: https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en

Multifunctional products shall be classified as the most restrictive product category. For example, in terms of biodegradability and toxicity, if a liquid product is intented to be used as a shampoo (CDV 11.000 l/g AC; aNBO and anNBO 20 mg/g AC) and a shower preparation (CDV 10.000 l/g AC; aNBO and anNBO 15 mg/g AC), it shall be classified as a shower preparation.

Animal care products.

According to Article 2 of the Commission Decision, the product group 'animal care products' shall comprise any substance or mixture intended to be placed in contact with animal hair to clean them or to improve the condition of it, such as shampoos and conditioners for animals.

Animal care products shall not cover products that are specifically marketed for disinfecting or anti-bacterial use.

The product group 'animal care products' shall include rinse-off products for both private and professional use.

Product Group Criteria

Criteria for awarding the EU Ecolabel to 'cosmetic products" and "to animal care products" are listed in Table 2.

Table 2. Criteria requirement for cosmetic products and animal care products

Criterion	Rinse-off cosmetic products	Leave-on cosmetic products	Animal care products
Toxicity to aquatic organisms: Critical Dilution Volume	x		x
Biodegradability	x		x
Aquatic toxicity and biodegradability of leave-on products		x	
Excluded and restricted substances	x	x	x
Packaging	x	x	x
Sustainable sourcing of palm oil, palm kernel oil and their derivatives	x	x	x
Fitness for use	x	x	x
Information on EU Ecolabel	x	x	x

Substances and measurement thresholds

Compliance with the ecological criteria is required for all substances that are present above the limits specified below in Table 3 (for cosmetic products) and in Table 4 (for animal care products).

The "Detergent Ingredient Database" list (DID list), available on the EU Ecolabel website, contains the most widely used substances in detergents and cosmetic formulations.

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

The DID list is regularly updated, and the applicant shall ensure that they use the most recent version of the DID list available on the EU Ecolabel website.

The applicant must provide the competent body a list of all substances present in the final product formulation in the concentrations above the limits specified in Table 3 for cosmetic products and Table 4 for animal care products, including the following information:

- the trade name (if existing),
- the chemical name (IUPAC or INCI),

- the CAS no.,
- the DID no.,
- the ingoing quantity,
- the function and the form present in the final product formulation

All ingoing substances present in the form of nanomaterials shall be clearly indicated with the word "nano" written in brackets, even if they are not listed on the label of the product.

For each substance listed, the latest available Safety Data Sheets (SDS) in accordance with Regulation (EC) No 1907/2006[2] 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 SDS used and provided by the applicant and its suppliers shall comply with the latest version of the Regulation (EC) No 1907/2006 (REACH Regulation).

https://ec.europa.eu/environment/chemicals/reach/legislation_en.htm

Table 3. Threshold levels applicable to substances for cosmetic products (% w/w), shown by criterion. CMR: carcinogenic, mutagenic, toxic for reproduction; N/A: not appliable

Criterion name		Preservatives	Colorants	Fragrances	Impurities	Other substances (e.g. surfactants, enzymes, UV filters)
Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV) of rinse-off cosmetic products		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0100	no limit (*1)
Criterion 2. Biodegradability of rinse-off cosmetic products		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0100	no limit (*1)
Criterion 3. Biodegradability and aquatic toxicity of leave-on cosmetic products		no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0010	no limit (*1)
Criterion 4. Excluded and restricted substances	Criterion 4 (a) (i): Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council[7] (rinse-off)	≥ 0,0100 (*2)	≥ 0,0100 (*2)	≥ 0,0100	≥ 0,0100	≥ 0,0100
	Criterion 4 (a) (i): Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 (leave-on)	≥ 0,0010 (*2)	≥ 0,0010 (*2)	≥ 0,0010	≥ 0,0010	≥ 0,0010
	Criterion 4 (a) (ii) : Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 (CMR) (rinse-off and leave-on)	no limit	no limit	no limit	no limit	no limit

[7] 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). Hereafter 'CLP Regulation'

	Criterion 4 (a) (iii): product classification (rinse-off and leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 4 (b): Specified excluded substances (rinse-off and leave-on)	no limit	no limit	no limit	no limit	no limit
	Criterion 4 (c): Restrictions on Substances of Very High Concern (rinse-off and leave-on)	no limit	no limit	no limit	no limit	no limit
	Criterion 4 (d): Fragrances (rinse-off)	N/A	N/A	no limit (*1)	≥ 0,0100	N/A
	Criterion 4 (d): Fragrances (leave-on)	N/A	N/A	no limit (*1)	≥ 0,0010	N/A
	Criterion 4 (e): Preservatives (rinse-off)	no limit (*1)	N/A	N/A	≥ 0,0100	N/A
	Criterion 4 (e): Preservatives (leave-on)	no limit (*1)	N/A	N/A	≥ 0,0010	N/A
	Criterion 4 (f): Colorants (rinse-off)	N/A	no limit (*1)	N/A	≥ 0,0100	N/A
	Criterion 4 (f): Colorants (leave-on)	N/A	no limit (*1)	N/A	≥ 0,0010	N/A
	Criterion 4 (g): UV filters (leave-on)	N/A	N/A	N/A	≥ 0,0010	no limit (*1) (*3)
Criterion 6. Sustainable sourcing of palm oil, palm kernel oil and their derivatives	Criterion 6: Sustainable sourcing of palm oil, palm kernel oil and their derivatives (rinse-off)	no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0100	no limit (*1)
	Criterion 6 (a): Sustainable sourcing of palm oil, palm kernel oil and their derivatives (leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	≥ 0,0010	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 in rinse-off products and up to 0,0010 %w/w in the final formulation in leave-on products.
(*2) for preservatives and colorants classified as H317 and H334 the threshold is 'no limit'

(*3) applicable only to UV filters

Table 4. Threshold levels applicable to substances for animal care products (% weight by weight), shown by criterion.

Criterion name		Preservatives	Colorants	Fragrances	Impurities	Other substances (e.g. surfactants, enzymes, UV filters)
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[7]	≥ 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 (CMR)	no limit	no limit	no limit	no limit	no limit
	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	no limit	no limit	no limit	no limit
	Criterion 3 (c): Restrictions on Substances of Very High Concern	no limit	no limit	no limit	no limit	no limit
	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 in rinse off products and up to 0,0010 %w/w in the final formulation in leave on products.
(*2) for preservatives and colorants classified as H317 and H334 the threshold is 'no limit'

Toxicity to aquatic organisms: Critical Dilution Volume

This criterion applies to:

- *Annex I: Rinse-off cosmetic products: Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV) of rinse-off cosmetic products.*
- *Annex II: Animal care products: Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV).*

- *CDV estimates the impact of a product on aquatic freshwater ecosystems through the calculation of the volume of natural water required to dilute a quantity of the product (or functional unit) down to a concentration without any foreseeable harmful impact on aquatic species.*
- *Degradation factor (DF) is an estimation of the degradation rate of a substance in the aquatic environment. It results from tests assessing aerobic biodegradability (Test methods 301 A to F or 310 in the OECD Guidelines for the Testing of Chemicals).*
- *Chronic toxicity factor (TF chronic) calculates the median value within each tropic level (fish, crustaceans or algae) using validated test results (NOEC or EC10) for chronic toxicity. It is the lowest median (NOEC or EC10) of the trophic levels divided by the safety factor (SF), which depends on how many trophic levels are tested and whether chronic test results are available or not.*

This criterion shall apply to: preservatives, colouring agents and fragrances regardless of their concentration, and any other ingoing except rubbing/abrasive agents.

The total CDV toxicity of the cosmetic product shall not exceed the limits in Table 5 below (or Table 2 of the Annex I of the Commission Decision 2021/1870). Please note that Table 5 lists the limits for CDV chronic.

Table 5. CDV (chronic) limits for cosmetic products

Product	CDV (l/g AC)
Solid forms of the following products: Shampoos, soaps, shower preparations Shaving soaps Toothpaste	2 200
Liquid soaps and shower preparations*	10 000
Shampoos (liquid form)	11 000
Feminine hygiene cosmetic products	12 000
Hair conditioners	12 000
Rinse-off hair styling and treatment products (hair dyes)	12 000
Rinse-off skin care products (exfoliants and cleansers)	12 000

Shaving foams, shaving gels and shaving creams	12 000
Toothpaste (dentifrice and dental cleanser) and mouthwash (and oral perfumes)	12 000
Other rinse-off products	12 000

* This category includes foam soaps

For concentrated products, the CDV should be calculated on the ready-to-use form (the diluted form), as this is the form that will enter the aquatic environment. Nevertheless, applicants are requested to provide the competent body (CB) with the formulation also for the concentrated form of the product.

Multi-function or 2-in-1 products should comply with the strictest limits among those of the product categories involved. For example, in the case of a product which is intended to be used as a shampoo (CDV 11.000 l/g AC) and a conditioner (CDV 12.000 l/g AC), the product should comply with the CDV limit of the shampoo category (11.000 l/g AC)

The total CDV toxicity of the animal care products shall not exceed the limits in Table 6 below (or Table 2 of the Annex II of the Comission Decision 2021/1870). Please note that Table 6 lists the limits for CDV chronic.

Table 6. CDV (chronic) limits for animal care products

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

The total CDV chronic of the product equals to the sum of the calculation of all the CDV of each substance of the product, according the following equation:

$$CDV_{chronic} = \sum CDV_{chronic}(i) = \sum weight\ (i)\ x\ DF\ (i)\ x\ \frac{1000}{TF\ chronic\ (i)}$$

Where (i) is the ingoing substance.

The values of DF and TF chronic can be found in the part A of the DID list.

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

If the ingoing substance is not present in the DID list-part A, the values can be calculated using the guidelines described in the DID list-part B.

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

The latest version of the DID list is available on the EU Ecolabel website or via the websites of the individual competent bodies.

The results of the calculation of the CDV shall be supported by relevant documentation explaining the data used. This can include test reports or literature references (if literature data is used), or results of reliable tests available in the ECHA database.

ECHA database:
https://echa.europa.eu/es/information-on-chemicals/registered-substances

To facilitate the CDV calculation, an Application Form can be found in the EU Ecolabel website, where the applicant can introduce the DID number and the weight of each substance, and the results of the CDV are generated automatically.

EU Ecolabel website:
http://ec.europa.eu/environment/ecolabel/products-groups-andcriteria.html

Required documentation for Assessment and verification:

Application Form

If the ingoing substance is not included in the DID list-part A, information from literature or other sources (ECHA database, information from suppliers, etc.), or appropriate test results, related to the calculation of the values of DF and TF chronic

Biodegradability

This criterion applies to:

- *Annex I: Rinse-off cosmetic products: Criterion 2. Biodegradability of rinse-off products.*
- *Annex II: Animal care products: Criterion 2. Biodegradability of animal care products*

This criterion covers the following sub-requirements:

a) Biodegradability of surfactants
b) Biodegradability of organic ingoing substances

(a) Biodegradability of surfactants

This sub-criterion applies to rinse-off cosmetic products and animal care products.

- *Surfactant means any organic substance and/or mixture used in detergents, which has surface - active properties and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water, and of forming spreading or adsorption monolayers at the water-air interface, and of forming emulsions and/or microemulsions and/or micelles, and of adsorption at water-solid interfaces (Regulation (EC) No 648/2004).*
- *Biodegradability is the ease with which a material or product is broken down by microbes under the right conditions. In the process of biodegradation, carbon chains are used as a food source and are converted into water, biomass, carbon dioxide or methane (depending on whether the process takes place under aerobic or anaerobic conditions).*
    a. *Aerobic conditions: when the biodegradation process is carried out in the presence of oxygen.*
    b. *Anaerobic conditions: when the biodegradation process is carried out without oxygen.*

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

Surfactants with cleaning and/or foaming function in toothpastes are exempted from Criterion 2 (a).

(b) Biodegradability of organic ingoing substances

This sub-criterion applies to rinse-off cosmetic products and animal care products.

- *Organic compounds are any of a large class of chemical compounds in which one or more atoms of carbon are covalently linked to atoms of other elements, most commonly hydrogen, oxygen or nitrogen. The few carbon-containing compounds not classified as organic include carbides, carbonates and cyanides.*
- *Adsorption is the phenomenon of accumulation of a large number of molecular species at the surface of a liquid or solid phase in comparison to the bulk. The process of adsorption arises due to presence of unbalanced or residual forces at the surface of a liquid or solid phase. These unbalanced residual forces have a tendency to attract and retain the molecular species which come in contact with at the surface. Adsorption is essentially a surface phenomenon. Low adsorption means that the substance will not enter into or attach to the surface of a solid material.*
- *Desorption is the release of one substance from another, either from the surface or through the surface.Desorption can occur when an equilibrium situation is altered. High desorption means that a substance will readily remove itself from the surface of a solid material and enter into water.*
- *Bioaccumulation is the accumulation within living organisms of toxic substances occurring in the environment. Bioaccumulation occurs when an organism absorbs a - possibly toxic - substance at a rate faster than that at which the substance is lost by catabolism and excretion. Thus, the longer the biological half-life of a toxic substance the greater the risk of chronic poisoning, even if environmental levels of the toxin are not very high.*
- *Bioconcentration factor (BCF) is a measure of the extent of chemical sharing between an organism and the surrounding environment. In surface water, the BCF is the ratio of a chemical's concentration in an organism to the chemical's aqueous concentration. BCF is often expressed in units of litre per kilogram (ratio of mg of chemical per kg of organism to mg of chemical per litre of water).*
- *Octanol-water partition coefficient (K_{ow}) is the ratio between the molar concentration of an organic compound in octanol and the molar concentration of this organic compound in water when this twophase system is at equilibrium. Kow is generally reported as a unitless ratio. Within a series of compounds, greater partitioning into n-octanol corresponds to a greater accumulation in an organism.*
- *OECD guidelines are a tool for assessing the potential effects of chemicals on human health and the environment. Accepted internationally as standard methods for safety testing, the Guidelines are used by professionals in industry, academia and government involved in the testing and assessment of chemicals (industrial chemicals, pesticides, personal care products, etc.). These Guidelines are regularly updated with the assistance of thousands of national experts from OECD member countries. OECD Test Guidelines are covered by the Mutual Acceptance of Data, implying that data generated in the testing of chemicals in an OECD member country, or a partner country having adhered to the Decision, in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP), be accepted in other OECD countries and partner counties having adhered to the Decision, for the purposes of assessment and other uses relating to the protection of human health and the environment.*

This only applies to organic substances. Rubbing/abrasive agents (organic and inorganic) are not included in the calculation of the active content and should not be considered in the aNBO and anNBO calculation.

The content of organic ingoing substances in the cosmetic product that are aerobically non-biodegradable (aNBO) and anaerobically non-biodegradable (anNBO) shall not exceed the limits in Table 7 below (or Table 3 of the Annex I of the Commission Decision 2021/1870):

Table 7. aNBO and anNBO limits for cosmetic products

Product	aNBO (mg/g AC)	anNBO (mg/g AC)
Solid forms of the following products: Shampoos, soaps, shower preparations Toothpaste	5	5
Solid form of the shaving soaps	10	10
Feminine hygiene cosmetic products	15	15
Hair conditioners	15	15
Liquid soaps and shower preparations	15	15
Rinse-off hair styling and treatment products (hair dyes)	15	15
Rinse-off skin care products (exfoliants and cleansers)	15	15
Shampoo (liquid form)	20	20
Toothpastes (dentifrice and dental cleanser) and mouthwash (and oral perfumes)	15	15
Shaving foams, shaving gels, shaving creams	70	40
Other rinse-off products	15	15

Criterion 2 on biodegradability of rinse-off products also applies to fragrance ingredients. However, it is not necessary for a fragrance to be 100% biodegradable in order for the cosmetic product to be awarded the EU Ecolabel. The concentration/type of fragrance that is allowed in the product depends on the formulation of the product. It is the whole product that should comply with criterion 2.

For concentrated products, the aNBO and anNBO should be calculated on the ready-to-use form (the diluted form), as this is the form that will enter the aquatic environment. Nevertheless, applicants are requested to provide the competent body (CB) with the formulation also for the concentrated form of the product.

Multi-function or 2-in-1 products should comply with the strictest limits among those of the product categories involved. For example, in the case of a product which is intended to be used as a shampoo (aNBO and anNBO 20 mg/g AC) and a conditioner (aNBO and anNBO 15 mg/g

AC), the product should comply with the aNBO and anNBO limits of the shampoo category (15 mg/g AC)

The content of organic ingoing substances in the animal care product that are aerobically non-biodegradable (aNBO) and anaerobically non-biodegradable (anNBO) shall not exceed the limits in Table 8 below (or Table 3 of the Annex II of the Commission Decision 2021/1870):

Table 8. aNBO and anNBO limits for animal care products

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

The degradation values are available in the part A of the DID list: Degradation Factor, aerobic biodegradability and anaerobic biodegradability.

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

The latest version of the DID list is available on the EU Ecolabel website or via the websites of the individual competent bodies.

ⓘ How to calculate biodegradability of fragrances:

The DID list includes two exemptions on the ingredients database: perfumes and dyes. These ingredients are not strandardised but are used in most of the cosmetics products. For this reason, general values about toxicity and degradation of perfumes and dyes were included in the part A of the DID list. Nevertheless, if toxicity data is submitted by the licence applicant, the submitted data shall be used to calculate the TF and determine the biodegradadibility.

The biodegradability of the fragrances can be presented in different forms:

1. Providing specific data for the ingoing substances of the fragrance. Documentation explaining the data used should be attached, for example via test reports or literature references.
2. Test results of the fragrance. If test for aerobic and anaerobic biodegradability of the fragrance added are available, results can be added instead of the general values of the DID list. Fragrance must be tested according the test method OECD 301 A-F or 310 (readily biodegradable) or 302 A-C (inherently biodegradable).
3. If no data is available, the DID number 2549 shall be used.

If the ingoing substance is not listed in the part A of the DID list, the parameters should be calculated by using the guideline contained in the DID list-part B:

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

The substance must be tested according to test method OECD 301 A-F or 310 (readily biodegradable). In the absence of test results, relevant information from literature or other sources can be used showing the biodegradability of the substance.

The ECHA database includes information about the bioaccumulation and adsorption/desorption values for some substances. The *Brief Profile* of a substance summarizes the non-confidential data on substances as it is held in the databases of the European Chemicals Agency (ECHA), including data provided by third parties. This information can be used to justify the degradation values of a substance not included in the part A of the DID list.

ECHA database:
https://echa.europa.eu/es/information-on-chemicals/registered-substances

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:

- the substance is readily degradable and has low adsorption (A < 25 %);
- the substance is readily degradable and has high desorption (D > 75 %);
- the substance is readily degradable and non-bioaccumulating. A substance is not considered bioaccumulating if BCF < 500 or log Kow < 4.0.

Note that this exemption regarding documentation for anaerobic biodegradability does not apply to surfactants.

The Application Form is available in the EU Ecolabel website to complete the biodegradability calculation, where the applicant can introduce the DID number or the degradation values obtained from the literature and the weight of each substance, and the results of the biodegradabilities (aNBO and anNBO) are generated automatically.

EU Ecolabel website:
http://ec.europa.eu/environment/ecolabel/products-groups-andcriteria.html

Required documentation for Assessment and verification:

Application Form

If the ingoing substance is not included in the DID list-part A, information from literature or other sources (ECHA database, information from suppliers, etc.), or appropriate test results, showing that it is aerobically and anaerobically biodegradable

If an ingoing substance is exempted from the requirement for anaerobic biodegradability, testing for adsorption/desorption should be attached, in accordance with Guidelines 106 of the OECD

Aquatic toxicity and biodegradability of leave-on products

This criterion applies to:

- *Annex I: Cosmetic products: Criterion 3. Aquatic toxicity and biodegradability of leave-on products.*

- *EC_x means the effect concentration associated with x% response.*
- *No observed effect concentration (NOEC) means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect. The NOEC has no statistically significant adverse effect compared to the control.*
- *Median Lethal Concentration (LC_{50}) is the concentration of a test chemical that is estaimated to be lethal to 50% of the test organisms within the test duration.*

This criterion only applies to organic substances. Rubbing/abrasive agents (organic and inorganic) are not included in the calculation of the active content and should not be considered in the aNBO and anNBO calculation.

At least 95% of the total content of organic ingoing substances shall meet one of the following requirements:

- Readily biodegradable;
- Lowest aquatic toxicity NOEC/EC > 0,1 mg/l or EC/LC50 > 10,0 mg/l and not be bioaccumulable;
- Lowest aquatic toxicity NOEC/EC > 0,1 mg/l or EC/LC50 > 10,0 mg/l and be potentially biodegradable;
- Lowest aquatic toxicity NOEC/EC > 0,1 mg/l or EC/LC50 > 10,0 mg/l and not be bioavailable.

- Readily biodegradable.

The biodegradability of the substances can be extracted from the Part A of the DID-list: Aerobic degradation = R (Readily biodegradable according to OECD guidelines):

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

The latest version of the DID list is available on the EU Ecolabel website or via the websites of the individual competent bodies.

If an ingoing substance is not listed in Part A, the substance must be tested according to test method OECD 301 A-F or 310 (readily biodegradable). In the absence of test results, relevant information from literature or other sources can be used showing the biodegradability of the substance.

ECHA database:
https://echa.europa.eu/es/information-on-chemicals/registered-substances

- Lowest aquatic toxicity NOEC/EC > 0,1 mg/l or EC/LC50 > 10,0 mg/l and not be bioaccumulable.

The Part A of the DID list includes the values of LC50/EC50 for the acute toxicity and the NOEC for the chronic toxicity. These values can be used to justify the toxicity of the criterion.

If the ingoing substance is not listed in Part A, the substances must be tested for acute aquatic toxicity or chronic aquatic toxicity. The lowest available NOEC/ECx/EC/LC50 shall be used. If chronic values (NOEC) are available, they shall be used.

Acute aquatic toxicity	Fish 96 hour LC50 (OECD Test Guideline 203 or equivalent). Allowed only if the test was perfomed before March 2009.
	Crustacean species 48 hour EC50 (OECD Test Guideline 202 or equivalent)
	Algal species 72 or 96 hour EC50 (OECD Test Guideline 201 or equivalent)
Chronic aquatic toxicity	Fish Early Life Stage (OECD Test Guidelines 210). Allowed only if the test was perfomed before March 2009.
	Daphnia Reproduction (OECD Test Guidelines 202 Part 2 or 211)
	Test methods 2015 and 229 in the OECD Guideline for the Testing of chemicals, or equivalents. The results of toxicity testing using fish are allowed only if the test was perfomed before March 2009.
	OECD 201 may be used as chronic test: chronic endpoints must be chosen.

The results of acute or chronic toxicity testing using fish can not be used to document the toxicity of the substance.

A substance is not considered bioaccumulating if BCF < 500 or log K_{ow} < 4,0. The reference test for bioaccumulation shall be OECD 107 or 117 or equivalent.

- Lowest aquatic toxicity NOEC/EC > 0,1 mg/l or EC/LC50 > 10,0 mg/l and be potentially biodegradable.

The biodegradability of the substances can be extracted from the Part A of the DID-list: Aerobic degradation = I (Inherently biodegradable according to OECD guidelines):

If an ingoing substance is not listed in Part A, the substance must be tested according to test method OECD 302 A-C. In the absence of test results, relevant information from literature or other sources can be used showing the biodegradability of the substance.

- Lowest aquatic toxicity NOEC/EC > 0,1 mg/l or EC/LC50 > 10,0 mg/l and not be bioavailable.

The substance should have a molecular weight higher than 700 g/mol. As verification for the molecular weight an underlying report with the molecular formula and the calculation of the molecular mass shall be submited.

UV filters in leave-on products with sun protection function are excempted from the Criterion 3.

The Application Form is available in the EU Ecolabel website to complete the biodegradability calculation, where the applicant can relevant data and the weight of each substance, and the results of the biodegradability of leave-on cosmetic products are generated automatically.

EU Ecolabel website:
http://ec.europa.eu/environment/ecolabel/products-groups-andcriteria.html

Required documentation for Assessment and verification:

Application Form

If the ingoing substance is not included in the DID list-part A, information from literature or other sources (ECHA database, information from suppliers, etc.), or appropriate test results, showing the biodegradability and aquatic toxicity of the ingredient

Excluded and restricted substances

This criterion applies to:

- *Annex I: Cosmetic products: Criterion 4. Excluded and restricted substances.*
- *Annex II: Animal care products: Criterion 3. Excluded and restricted substances.*

This criterion covers the following sub-requirements for cosmetic and animal care products:

a) Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008
b) Specified excluded substances.
c) Restrictions on Substances of Very High Concern (SVHCs).
d) Fragrances
e) Preservatives
f) Colorants
g) UV filters (only for cosmetic products)

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

This sub-criterion applies to cosmetic products and animal care products.

This sub-criterion covers restricted and excluded substances under Regulation (EC) No 1272/2008.

(a)(i) RESTRICTED SUBSTANCES

Cosmetic products.

Cosmetic products shall not contain substances at or above the concentration of 0,0100 %w/w for rinse-off cosmetic, and 0,0010 %w/w for leave-on cosmetics that are assigned any of the hazard classes, categories and associated hazard statement codes listed in Table 9 below, in accordance with Regulation (EC) No 1272/2008 (*).

Table 10 lists derogated substances from Table 9 (for cosmetic products).

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

Substances intentionally added to the ingredients in the raw material or in the final product are not considered to be impurities and they should be listed in the Application Form. Only residuals, contaminants and carry-over substances are considered as impurities, and nevertheless only if present in a concentration in the final product < 0.0100% in rinse-off products and < 0.0010% in leave-on

productsTable 9. Restricted hazard classes, categories and associated hazard statement codes for substances included in cosmetic products and animal care products.

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 1A	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]) For cosmetic products the following substances are exempt: enzymes (including stabilisers and preservatives in the enzyme raw material) if they are in liquid form or as granulate capsules; α-tocopheryl acetate; amidoamin, which can be included with a maximum concentration of 0.3 %w/w as an impurity in Cocamidopropyl Betaine (CAPB). In the case of colorants and preservatives with a H317 or H334 hazard class, the requirement applies regardless of the concentration.

A fragrance can contain a substance classified as a skin sensitiser as long as the concentration of the skin-sensitising substance in the final product is below 0.0100% for rinse-off products and below 0.0010% for

leave-on products.(*1) For animal care products the following substances are also exempt: enzymes (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 applies regardless of the concentration.

Table 10. Derogations to restrictions on ingoing substances for cosmetic products classified under Regulation (EC) No 1272/2008 and applicable conditions.

Substance type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Surfactants	COSMETICS: Rinse-off and leave-on products	H412: Harmful to aquatic life with long-lasting effects	Total concentration <20%w/w in the final product
Sodium Fluoride	COSMETICS: Rinse-off oral care products	H301: Toxic if swallowed	Only in oral care products (mouthwash and toothpaste)

Zinc compounds are allowed in the product formulation, provided that they comply with the formula in criterion 4 (a) (iii)

For fragrances, the restrictions according to criterion 4.a apply to each one of the ingredients of a fragrance

Animal care products.

Animal care products shall not contain substances at or above the concentration of 0,0100 %w/w that are assigned any of the hazard classes, categories and associated hazard statement codes listed in Table 9 above, in accordance with Regulation (EC) No 1272/2008 (*).

Table 11 lists derogated substances from Table 9 (for animal care products).

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

Substances intentionally added to the ingredients in the raw material or in the final product are not considered to be impurities and they should be listed in the Application Form. Only residuals, contaminants and carry-over substances are considered as impurities, and nevertheless only if present in a concentration in the final product < 0.0100%

Table 11. Derogations to restrictions on ingoing substances for animal care products classified under Regulation (EC) No 1272/2008 and applicable conditions.

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 %w/w in the final product

(a)(ii) EXCLUDED SUBSTANCES

Cosmetic products.

Substances that meet the criteria for classification with the hazard statements listed in Table 12 below shall not be contained in the final product nor in its ingredients, regardless of their concentration.

Table 13 lists derogated substances from Table 12 (for cosmetic products).

Table 12. Excluded hazard classes, categories and associated hazard statement codes for substances included in cosmetic products and animal care products.

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	

Table 13. Derogations to restrictions on ingoing substances for cosmetic products classified as CMR under Regulation (EC) No 1272/2008 and applicable conditions.

Substance type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Titanium dioxide (nano-form)	UV filters in cosmetic leave-on products with sun protection function	H351: Suspected of causing cancer	Must comply with SCCS/1516/13, SCCS/1580/16, and SCCS/1583/17. It cannot be used in powder or spray form

Animal care products.

Substances that meet the criteria for classification with the hazard statements listed in Table 12 shall not be contained in the final product nor in its ingredients, regardless of their concentration.

(a)(iii) FINAL PRODUCT

Cosmetic products.

For cosmetic products, ingoing substances classified as hazardous to the aquatic environment (Table 9) according to Regulation EC 1272/2008 may be included in the product up to a maximum concentration of 2,5%, calculated according to the formula below:

$$100 \cdot c\,[H410] + 10 \cdot c\,[H411] + c\,[H412] \leq 2{,}5\%$$

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

The following exemptions apply:

- Compounds of zinc (classified H410) may however be included in zinc ointment/cream marketed to heal irritated skin to a maximum of 25 % and may, in these cases, be exempted from the calculation.
- Surfactants classified as H412 shall be exempted from the requirement.

Criterion 4.a.iii applies next to criterion 4.a.i. This means that substances classified as H410, H411 and H412 can be present in the formulation only in concentrations < 0,0100% w/w for rinse-off products, and in concentrations < 0,0010% for leave-on products (with the exceptions mentioned above).

Surfactants may be added to a cosmetic product because of different functions: as detergents, wetting agents, emulsifiers, foaming agents, or dispersants. All of these functions are exempted from the requirement (a) (iii).

For fragrances, it is possible to specify all ingoing substances either one by one or grouped together according to their hazardous to the aquatic environment (H410, H411, H412 and not classified (NC)).

ⓘ Example: How to calculate the maximum of substances classified as environmentally hazardous.

Ingoing substance	Function	Hazardous classification according to Reg. (EC) 1272/2008	Formula A	Formula B	Notes
Aqua	Solvent	Not classified	80,67%	80,67%	
Sodium Laureth Sulfate	Surfactant	H315, H318, H412	8,00%	8,00%	Shall not be included in the formula (exception for surfactants)
Coco-glucoside	Mild surfactant	H315, H318	5%	5%	
Cocamidopropyl Betaine	Mild surfactant	H319	4%	4%	
Sodium Chloride	Thickener	Not classified	0,30%	0,30%	
Phenoxyethanol	Preservative	H302, H319	0,90%	0,90%	
Ethylhexylglicerin	Preservative	H318, H412	0,01%	0,01%	Shall be included in the formula
Substances perfume NC	Perfume	Not classified	0,35%	0,60%	
Substances perfume H412	Perfume	H412	0,50%	0,33%	Shall be included in the formula (aggregated like here or individually)
Substances perfume H411	Perfume	H411	0,13%	0,06%	Shall be included in the formula (aggregated like here or individually)
Substances perfume H410 no.1	Perfume	H410	0,01%	0,003%	Shall be included in the formula (individually like here or aggregated)
Substances perfume H410 no.2	Perfume	H410	0,005%	0,003%	Shall be included in the formula (individually like here or aggregated)
Substances perfume H410 no.3	Perfume	H410	0,005%	0,004%	Shall be included in the formula (individually like here or aggregated)
Citric Acid	pH adjuster	H319	0,02%	0,02%	
Colorant	Colorant	Not classified	0,01%	0,01%	

According to formula 100·c [H410] +10·c [H411] +c [H412]:

Formula A: $100 \cdot (0{,}01 + 0{,}005 + 0{,}005) + 10 \cdot 0{,}13 + 1 \cdot (0{,}01 + 0{,}5) = 2 + 1{,}3 + 0{,}51 = 3{,}81\%$ (>2,5%) The combination of ethylhexylglycerin and parfum may not be included at these percentages.

Formula B: $100 \cdot (0{,}003 + 0{,}003 + 0{,}004) + 10 \cdot 0{,}06 + 1 \cdot (0{,}01 + 0{,}33) = 1 + 0{,}6 + 0{,}34 = 1{,}94\%$ (≤2,5%) The combination of ethylhexylglycerin and parfum may be included at these percentages.

Criterion 4(a) for cosmetic products 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.

Required documentation for Assessment and verification:

- Application Form
- Compiled declarations from suppliers
- SDS supporting hazard classification or non-classification.

- The Application Form shall suffice to comply for substances listed in Annexes IV and V to Regulation (EC) No 1907/2006.
- Declarations in application form can also be provided directly to competent bodies by any supplier in the applicant's supply chain.
- In the fragrance declaration template, all substances contained in the fragrance must be stated in Table 1 of the fragrance, including the impurities that are known to end up in the fragrance. If the fragrance contains substances mentioned in criterion 4.a.i, it is sufficient to mention only the substance with the highest concentration. If the fragrance contains substances listed in Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products'[8], it is sufficient to mention only the substance with the highest concentration
- For Table 2 in the fragrance declaration template, it is not mandatory to use the default value for fragrances indicated in the DID-list Part A. Applicants can provide fragrance-specific data in Table 2, by using the columns "if DID list not available".

Animal care products.

For animal care products, 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 Table 9 and Table 12 above.

Criterion 3(a) for animal care products 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.

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

Required documentation for Assessment and verification:

- Application form
- Compiled declarations from suppliers
- SDS supporting hazard classification or non-classification

- The Application Form shall suffice to comply for substances listed in Annexes IV and V to Regulation (EC) No 1907/2006.
- Declarations in the Application Form can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

(b) Specified excluded substances

This sub-criterion applies to cosmetic products and animal care products.

Cosmetic products.

The following substances and mixtures shall also not be included in the cosmetic product, regardless of the concentration, neither as part of the formulation, as part of any mixture included in the formulation:

1. Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives (substance name: "Alkyl phenol", under: https://echa.europa.eu/es/advanced-search-for-chemicals);
2. Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA) (BHT may still be used in perfumes provided that total BHT content in the perfume is below 100 ppm and total BHT concentration in the final product is below 0,0010%w/w);
3. Cocamide DEA;
4. Deltamethrin;
5. Diethylenetriaminepentaacetic acid (DTPA) and its salts;
6. Ethylenediaminetetraacetic acid (EDTA) and its salts and non-readily biodegradable phosphonates (non-readily biodegradable phosphonate may still be used in solid rinse-off products up to a total concentration of 0,0600%w/w);
7. Microplastics and microbeads;

8. Mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in lip care products, where the recommendations by Cosmetic Europe for mineral oils are not complied[9];
9. Nanomaterials, unless used according to the conditions laid down for specific nanomaterials in Annexes III, IV and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council;
10. Nitromusks and polycyclic musks;
11. Perfluorinated and polyfluorinated substances (also named per- and polyfluoroalkyl substances (PFASs));
12. Phthalates;
13. Resorcinol;
14. Sodium hypochlorite, chloramine and sodium chlorite;
15. Sodium Lauryl Sulphate (SLS) in toothpaste products;
16. Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate (these substances may be allowed if present as impurities, but up to a total concentration of 500 ppm in the product formulation);
17. Substances identified to have endocrine disrupting properties;
18. The following fragrances: benzyl salicylate, butylphenyl metylpropional, tetramethyl acetyloctahydranophthalenes (OTNE);
19. The following isoflavones: daidzein, genistein;
20. The following preservatives: benzalkonium chloride, formaldehyde releasers, isothiazolinones, kojic acid, parabens, triclocarban, triclosan;
21. The following UV filters: benzopehenone, benzopehenone-1, benzopehenone-2, benzopehenone-3, benzopehenone-4, benzopehenone-5, ethylhexyl methoxycinnamate, homosalate, octocrylene;
22. Triphenyl phosphate.

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[10] (candidate list of substances of very high concern for authorisation) or according to Regulations (EU)

[9] https://www.cosmeticseurope.eu/files/3715/3907/8160/Recommendation_14_Mineral_Hydro_Carbons.pdf

[10] 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).

No 528/2012 or (EC) No 1107/2009 of the European Parliament and of the Council. The National Authorities List I can be consulted, as it includes the substances that have undergone an evaluation of endocrine disrupting properties, as regulated in the EU in PPPR, BPR or REACH, and which are identified as endocrine disruptors.

The only nanomaterials that are allowed in EU Ecolabel products are those mentioned in Annexes III, IV and VI to the Cosmetic Products Regulation, up to the concentration limits specified in those Annexes. The applicant shall follow the guidelines in Annexes III, IV and VI to the Cosmetic Products Regulation for all substances where, in those Annexes, [nano] is written. If a nano substance is not listed in the Annexes, it cannot be used in EU Ecolabel products

It is recommended to check the national authority list to have an overview of all identified endocrine disrupting subtances evaluated in the context of different EU Regulations (list I).

It is advised to avoid as far as possible the substances in the list II (substances under evaluation for endocrine disruption under an EU legislation), as these are likely to be banned in future EU Ecolabel criteria revisions and/or EU Regulations.

https://edlists.org/

Required documentation for Assessment and verification:

- Application Form
- Compiled declarations from suppliers

- The applicant shall compile declarations from suppliers and provide them. All these declarations are included in the Application Form.
- For mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in sub-criterion 4 (b) of cosmetic products, compliance with the recommendations by Cosmetic Europe for mineral oils shall be demonstrated.

https://www.cosmeticseurope.eu/files/3715/3907/8160/Recommendation_14_Mineral_Hydro_Carbons.pdf

- Declarations in application form can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

Animal care products.

The following substances shall not be included in the animal care product, regardless of the concentration, neither as part of the formulation, as part of any mixture included in the formulation:

1. Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives (substance name: "Alkyl phenol", under: https://echa.europa.eu/es/advanced-search-for-chemicals);
2. Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA) (BHT may still be used in perfumes provided that total BHT content in the perfume is below 100 ppm and total BHT concentration in the final product is below 0,0010%w/w);
3. Cocamide DEA;
4. Deltamethrin;
5. Diethylenetriaminepentaacetic acid (DTPA) and its salts;
6. Ethylenediaminetetraacetic acid (EDTA) and its salts and non-readily biodegradable phosphonates (non-readily biodegradable phosphonate may still be used in solid rinse-off products up to a total concentration of 0,0600%w/w);
7. Microplastics and microbeads;
8. Nanomaterials, unless used according to the conditions laid down for specific nanomaterials in Annexes III, IV and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council;
9. Nitromusks and polycyclic musks;
10. Perfluorinated and polyfluorinated substances (also named per- and polyfluoroalkyl substances (PFASs));
11. Phthalates;
12. Resorcinol;
13. Sodium hypochlorite, chloramine and sodium chlorite;
14. Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate (these substances may be allowed if present as impurities, but up to a total concentration of 500 ppm in the product formulation;
15. Substances identified to have endocrine disrupting properties;
16. The following fragrances: benzyl salicylate, butylphenyl metylpropional, tetramethyl acetyloctahydranophthalenes (OTNE);
17. The following isoflavones: daidzein, genistein;
18. The following preservatives: benzalkonium chloride, formaldehyde releasers, isothiazolinones, kojic acid, parabens, triclocarban, triclosan;
19. Triphenyl phosphate.

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

Required documentation for Assessment and verification:

- Application Form
- Compiled declarations from suppliers.

- The applicant shall compile declarations from suppliers and provide them. All these declarations are included in the application form.
- Declarations in the application form can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

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

This sub-criterion applies to cosmetic products and animal care products.

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 (SVHCs) for authorisation shall not be present the product, regardless of their concentration.

There are no derogations to this requirement.

- The applicant shall compile declarations from suppliers (annex I) on the non-presence of SVHCs, regardless of their concentration.

Declarations shall be with reference to the latest version of the Candidate List published by ECHA.

Candidate List: https://www.echa.europa.eu/candidate-list-table

Required documentation for assessment and verification:

- Application Form
- Compiled declarations from suppliers

➲ Declarations in the Application Form can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

(d) Fragrances

⚠ *This sub-criterion applies to cosmetic products and animal care products.*

Cosmetic products.

Substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products' shall not be present in EU Ecolabel products in concentrations higher than 0,0100% (w/w) in rinse-off cosmetic products and 0,0010% (w/w) in leave-on cosmetic products.

Find the SCCS opinion at the following link:
https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

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

IFRA website:
https://ifrafragrance.org/safe-use/library

⚠ *Baby (0-3 years), children (3-12 years) and family products shall be fragrance-free.*

⚠ *Products marketed as "mild/sensitive" shall be fragrance-free.*

Mild/sensitive products include products which claim that the product is mild or gentle, but also products which claim for sensitive skin.

⚠ *Toothpastes marketed for children can contain fragrances.*

Required documentation for assessment and verification:

Application form

Compiled declarations from suppliers.

- The applicant shall compile declarations from their fragrance suppliers (applicant form) to calculate and demonstrate that the product do not contain fragrance allergens above the specified theresholds, and the fragrance complies with the code of practice of the IFRA.
- Declarations in application form can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

Animal care products.

Substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products' shall not be present in EU Ecolabel animal care products in concentrations higher than 0.010%.

Find the SCCS opinion at the following link:

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

As in cosmetic products, 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. The manufacturer shall follow the recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials.

IFRA website:
https://ifrafragrance.org/safe-use/library

Required documentation for assessment and verification:

- Application Form
- Compiled declarations from suppliers

- The applicant shall compile declarations from their fragrance suppliers (applicant form) to calculate and demonstrate that the product do not contain fragrance allergens above the specified theresholds, and the fragrance complies with the code of practice of the IFRA.
- Declarations in application form can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

(e) Preservatives

This sub-criterion applies to cosmetic products and animal care products.

Cosmetic products.

1. Preservatives classified as H317 or H334 are prohibited regardless of the concentration.
2. Preservatives in the product shall not release or degrade to substances that are classified in accordance with the requirements of criterion 4(a) for cosmetic products, e.g. formaldehyde releasers such as imidazolidinyl urea, diazolidinyl urea, DMDM hydantoin.
3. The product may contain preservatives provided that they are not bioaccumulating. A preservative is not considered bioaccumulating if BCF < 500 or log Kow < 4.0.

If both BCF and log Kow values are available, the highest measured value shall be used.

ⓘ Example:

PRESERVATIVE A: BCF 400, log Kow 3 → Not bioaccumulating, it may be included in the product.

PRESERVATIVE B: BCF 600, log Kow 3 → Bioaccumulating, it shall not be included in the product.

PRESERVATIVE C: BCF 400, log Kow 5 → Bioaccumulating, it shall not be included in the product.

4. Preservatives used in cosmetic products that enter in contact with the mouth (e.g. toothpaste, mouthwash, lip care products, nail polish) shall have been approved as food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

Commission Regulation (EU) No 1129/2011 of 11 November 2011 amended Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives Text with EEA relevance. Part B point 3 of Regulation (EU) No 1229/2011 lists the additives other than colours and sweeteners that have been approved as food additives.

Find the list of additives other than colours and sweeteners (among them, preservatives) approved as food additives at the following link:

https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32011R1129

Required documentation for assessment and verification:

- Application Form
- Compiled declarations from suppliers.
- SDS supporting hazard classification or non-classification.

➲ The applicant shall compile declarations from the suppliers (annex I) to demonstrate compliance with the sub-criterion: the preservative is not classified as H317 or H334, it does not degrade to classified substances, it is not bioaccumulating (information on its BCF and/or log Kow values), or it is approved as food additive.

➲ Declarations in application form can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

Animal care products.

1. Preservatives classified as H317 or H334 shall be prohibited regardless of the concentration.
2. Preservatives in the product shall not release or degrade to substances that are classified in accordance with the requirements of criterion 3(a) for animal care products, e.g. example formaldehyde releasers such as imidazolidinyl urea, diazolidinyl urea, DMDM hydantoin.
3. The product may contain preservatives provided that they are not bioaccumulating. A preservative is not considered bioaccumulating if BCF < 500 or log Kow < 4.0.

If both BCF and log Kow values are available, the highest measured value shall be used (see the case for cosmetic products as an example).

Required documentation for assessment and verification:

- Application Form
- Compiled declarations from suppliers
- SDS supporting hazard classification or non-classification

➲ Declarations in application form can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

(f) Colorants

This sub-criterion applies to cosmetic products and animal care products.

Cosmetic products.

1. Colorants classified as H317 or H334 shall be prohibited regardless of the concentration.
2. Colorants in the product shall not be bioaccumulating. A colorant is considered not bioaccumulating if BCF < 500 or log Kow < 4.0.

If both BCF and log Kow values are available, the highest measured BCF or log Kow value shall be used (see the case for preservatives as an example).

In the case of colouring agents approved for use in food, it is not necessary to submit documentation of bioaccumulation potential.

3. Colorants used in cosmetic products in contact with the mouth (e.g. toothpaste, mouthwash, lip care products, nail polish) shall have been approved as food additives in accordance with Regulation (EC) No 1333/2008.

Commission Regulation (EU) No 1129/2011 of 11 November 2011 amended Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives Text with EEA relevance. Part B point 1 of Regulation (EU) No 1229/2011 lists the food colours that have been approved as food additives.

Find the list of food colours approved in the following link:
https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32011R1129

4. The content of barium, bismuth, cadmium, cobalt, hexavalent chromium (Chromium VI), lead and nickel occurring as impurity in decorative cosmetics and hair dyes shall be restricted to concentrations below 10 ppm. The content of mercury occurring as impurity in decorative cosmetics and hair dyes shall be restricted to concentrations below 1 ppm.

Required documentation for assessment and verification:

- Application Form
- Compiled declarations from suppliers.
- SDS supporting hazard classification or non-classification

Declarations in application form can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

Animal care products.

1. Colorants classified as H317 or H334 shall be prohibited regardless of the concentration.
2. Colorants in the product shall not be bioaccumulating. A colorant is considered not bioaccumulating if BCF < 500 or log Kow < 4.0.

If both BCF and log Kow values are available, the highest measured BCF or log Kow value shall be used (see the case for preservatives as an example).

In the case of colouring agents approved for use in food, it is not necessary to submit documentation of bioaccumulation potential.

Required documentation for assessment and verification:

- Application Form
- Compiled declarations from suppliers.
- SDS supporting hazard classification or non-classification.

Declarations in application form can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

(g) UV filters

This sub-criterion applies only to cosmetic products.

UV filters may only be added to leave-on products that target the solar protection of the user, e.g. sunscreens and multi-purpose products with a sunscreen function. UV filters shall only protect the user – not the product (e.g. UV filters are not allowed to protect the colour of the cosmetic product).

The most ecotoxic UV filters are not allowed. All organic UV filters contained in the product:

- Must not be bioaccumulating (BCF<500 or log K_{ow}<4.0, the highest available value)

or

- Must have a lowest toxicity (NOEC or ECx > 0,1 mg/l, or EC or LC50 > 10,0 mg/l, the lowest available value).

State one of the following: the highest available BCF value or log Kow value, or the lowest available NOEC/ECx/EC/LC50 value.

Relevant data from safety data sheets, ECHA database or standardized test results are accepted to demonstrate UV filter bioaccumulation or toxicity values.

Required documentation for assessment and verification:

Application Form

Compiled declarations from suppliers

Declarations in Application Form can also be provided directly to competent bodies by any supplier in the applicant's supply chain.

The following list of UV filters are allowed in EU Ecolabel cosmetic products:

- *PHENYLBENZIMIDAZOLE SULFONIC ACID*
- *TEREPHTHALYLIDENE DICAMPHOR SULFONIC ACID*
- *BUTYL METHOXYDIBENZOYLMETHANE*
- *BENZYLIDENE CAMPHOR SULFONIC ACID*
- *PEG-25 PABA*
- *DISODIUM PHENYL DIBENZIMIDAZOLE TETRASULFONATE*
- *TITANIUM DIOXIDE*
- *TITANIUM DIOXIDE (NANO)*

Please note that the list above is not exhaustive. Other UV filters can be used if bioaccumulation and toxicity data from suppliers demostrante compliance with EU Ecolabel criteria.

If nano TiO_2 is used, applicant shall declare in the application form that it fulfils the conditions laid down in Annex VI to Regulation (EC) No 1223/2009.

Packaging

This criterion applies to:

- *Annex I: Cosmetic products: Criterion 5. Packaging.*
- *Annex II: Animal care products: Criterion 4. Packaging.*

This criterion covers the following sub-requirements:

a) Primary packaging
b) Packaging Impact Ratio (PIR)
c) Inofrmation and design of primary packaging
d) Design for recycling of plastic packaging

The minimum volume for a liquid rinse-off cosmetic products and animal care products shall be 150ml. Thootpastes and solid products are exempt from this requirement.

Concentrated products should comply with the packaging limits in the form in which it is sold (concentrated form, either solid or liquid). Concentrated products sold in solid form are exempted from the 150 ml requirement.

(a) Primary packaging

This sub-criterion applies to cosmetic products and animal care products.

- *Primary packaging means packaging in direct contact with the content conceived so as to constitute the smallest sales unit of distribution ot the final user or consumer at the point of purchase. The main role of primary packaging is to protect the product from damage during storage and transportation. Products sold to refill an empty packaging are not considered primary packaging.*
- *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 sales.*
- *When a refill is offered, parent packaging is the packaging refillable.*

No additional packaging shall be allowed, with the following exemptions:

- Secondary packaging which groups the product and its refill.
- Secondary packaging for products that include several elements for their use.

A refilling option is mandatoy for rinse-off products for domestic use sold with pump (if it can be opened without compromising the design).

Secondary packaging is allowed for concentrated products if it serves the purpose of grouping together the items necessary for its use. No other secondary packaging is allowed.

Required documentation for Assessment and verification:

Application Form

Pictures or description of the products as marketed, or other relevant evidence

(b) Packaging impact ratio (PIR)

This sub-criterion applies to cosmetic products and animal care products.

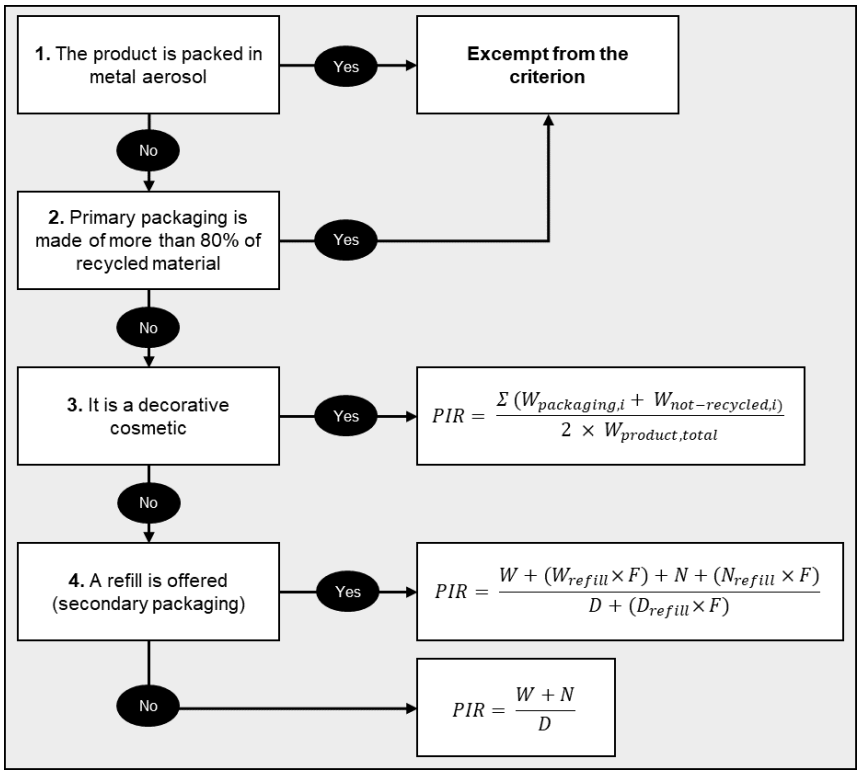
- *Decorative cosmetics are cosmetic products used to change the appearance of the human body. Included in this group of products are: body colour cosmetics, eye colour cosmetics, face colour cosmetics, lip colour cosmetics, multiuse colour cosmetics, nail colour cosmetics.*
- *The proportion of secondary packaging includes the proportional weight of the grouping packaging:*
    a. *50% of the total grouping packaging weight, if two products are sold together*
    b. *33% of the total grouping packaging weight, if three products are sold together*
    c. *25% of the total grouping packaging weight, if four products are sold together*
    d. *...*

The Packaging Impact Ratio (PIR) shall be calculated for the primary packaging. When the product is sold in more of one packaging, PIR shall be calculated for each of the packagings.

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

The PIR shall be less than 0,20 g of packaging per gram of product.

For decorative cosmetics, the PIR shall be less than 0,80 g of packaging per gram of product.



Where:

- W: weight of packaging (primary + proportion of secondary) (g)
- Wrefill: weight of refill packaging (primary + proportion of secondary) (g)
- N: weight of non-renewable + non-recycled packaging (primary + proportion of secondary) (g)
- Nrefill: weight of non-renewable and non-recycled refill packaging (primary + proportion of secondary) (g)
- D: weight of product contained in the packaging (or in the 'parent' pack if a refill is offered) (g)
- Drefill: weight of product delivered by the refill (g)
- F: number of refills required to meet the total refillable quantity, calculated as follows:

$$F = \frac{V \times R}{V_{refill}}$$

Where:

- V: volume capacity of the parent pack (ml)
- Vrefill: volume capacity of the refill pack (ml)
- r: the refillable quantity. This is the number of times that the parent pack can be refilled. Where F is not a whole number, it shall be rounded up to the next whole number.

The calculation shall include the weight of all the components of the packaging, including labels.

The PIR calculation should include the refill option even if the refill is not sold together with the parent packaging; it is enough that the refill is available on the market

To be considered refillable, it is not mandatory for the parent packaging to have a screw cap, but it should be possible to open it and refill it easily. For rinse-off products whose packaging is equipped with a pump that can be opened without compromising the design, a refilling option shall be provided in the same or higher primary packaging capacity.

Starter kits for concentrated products (i.e. when multiple items are sold together) can be awarded the EU Ecolabel if complying with the PIR limit.

Required documentation for Assessment and verification:

Application Form

If the packaging is made of post-consumer recycled material or material from renewable origin

- Compiled declarations from packaging manufacturers
- Third party verification and traceability for postconsumer recycled content.

(c) Information and design of primary packaging

This sub-criterion applies to cosmetic products and animal care products.

- *Residual amount (R) is the amount of product remaining in the container after the consumer has emptied the container. The rate is expressed as a weight percentatge and defined as follows: R = mass of the product residue (m2 – m3) divided by mass of product in the container (m1 – m3).*

(c)(i) INFORMATION ON PRIMARY PACKAGING

The following information shall be included on the primary packaging:

- For products for which a correct dosage can be identified: the correct dosage or the appropriate quantity to be used, together with the following sentence:

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

- For products for which a correct dosage cannot be defined (for example, because it depends on consumer aspects): the following sentence: "*dose the product with care so as not to over-consume it unnecessarily*".

  A sentence or a pictogram in relation to the disposal of the empty packaging, such as: "*when empty, the package/container should be disposed of in a dedicated container for recycling*"

  Pictograms can be used according to specific national regulation on waste:

The text included in the packaging should be readable.

The packaging is exempted from containing the information on the dosage of the product and end-of-life of the packaging when the packaging is of small dimensions, and the available space is already filled with information that should be displayed according to an EU or national law. Filling the packaging with market-related information does not exempt the packaging from displaying the information on the dosage and the end-of-life as mandated in criterion 4.c.ii. If several languages are displayed, a QR code can be used to make the information available to consumers

(c)(ii) DESIGN OF PRIMARY PACKAGING

- For rinse-off products (including cosmetic products and animal care products):

The correct dosage of the product should be easy to obtain by designing the packaging appropriately, for example using a pump dosing system or ensuring that the opening at the top is not too wide. The maximum amount of product dispensed with a pump shall be 2 g (or 3 ml) per full press.

The residual amount of the product in the container (R), calculated according to the formula below, must be below 5%.

$$R = \frac{m2 - m3}{m1 - m3} \; x \; 100(\%)$$

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)

If the primary packaging can be manually opened and the residue product can be extracted with adding water, the rinse-of product is exempt from this requirement.

- For leave-on products (cosmetic products)

This requirement only applies to leave-on conditioner bottles and cream bottles.

The residual amount of the product in the container (R), calculated according to the formula above for rinse-off products, must be below 10%.

The residual amount of product shall be verified in accordance with the normal use of each product.

Normal conditions of use for some examples of packaging:

- Tube: applying for three muntes successive pressure on the body of the primary packaging in direct contact, with the cap in downward position. The test is considered complete when no amount of liquid will flow after five successive pressures on the body of the primary packaging in direct contact. Neither the cap is dismantled, nor water is introduced inside the packaging.
- Spray: applying successive pressures on the tip of the spray by pressing the spring down entirely. Wait until the spring has returned to its initial position prior to applying a new pressure. Repeat until no amount of product flows from the spray after five successive pressures. Neither the cap is dismantled, nor water is introduced inside the packaging.
- Pot: the product is removed using the index and middle fingers by rubbing the edges and the bottom of the pot carefully but relentlessly. Neither the cap is dismantled, nor water is introduced inside the packaging.
- Vial/flask: returns the vial upside down, with the cap in downward position. After the trickle is not continuous, the bottle is left in the same position for another two minutes. Neither the cap is dismantled, nor water is introduced inside the packaging.

For concentrated products, the R requirement (criterion 5.c.ii) is the only packaging requirement that applies on the ready-to-use form, and only applicable if the applicant supplies the final product container to the consumer.

Required documentation for Assessment and verification:

- Application Form
- Compiled declarations from packaging manufacturers
- Image of the product packaging

(d) Design for recycling of plastic packaging

This sub-criterion applies to cosmetic products and animal care products with packaging made of plastic.

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

For concentrated products, criterion 5.d applies to all packaging sold

The plastic packaging shall be designed not to contain label or sleeve, closure and, where applicable, barrier coatings that comprise, either singularly or in combination, the materials and components listed in Table 14 below.

Table 14 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/cm3)) 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 (except for PP labels and polyolefins (PO) sleeves used in combination with a PP packaging or PE labels and PE sleeves used in combination with a HDPE packaging) - Labels or sleeves that are metallised or are welded to a packaging body (in mould labelling). - PSL (pressure sensitive) label unless 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/cm3 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/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	- 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, PO — Polyolefins, PP — Polypropylene, PS — Polystyrene, PSL – pressure sensitive label, PVC — Polyvinylchloride

Barrier coatings include layers coated or anchored outside the monomaterial body as well as barrier layers buried internally in the structure of the package.

Despite the different production processes and internal structure of the packaging, both options mentioned interfere with the recycling of plastics. Coatings and barriers cannot be separated and would end up being recycled with the main polymer, compromising the recycled polymer's quality and end-use applications.

PP and HDPE packaging

PP labels and PO sleeves used in a PP packaging are allowed.

PE labels and PE sleeves used in a HDPE packaging are allowed.

Polyolefins (PO) are a type of polymer usually derived from a small set of simple olefins.
They include, dominantly, polyethylene (PE) and polypropylene (PP), but also polybutene

Pressure sensitive labels (PSL)

PSL are like stickers, using pressure to form a bond between the adhesive and the product.

PSL are made up of three layers: a face stock, an adhesive and a release liner (also called the "label sandwich"). When the label is manufactured, these three components are sandwiched together to create a label material that can be printed on, laminated, die-cut, and finally peeled off and applied to the product (see Figure 1 below).

The face stock could be paper, film, or metallic foil, and is the layer where the ink is applied on press. For specific applications, a topcoat or laminate may be applied to protect the label artwork or enhance certain areas of the design.

PSL are provided with a permanent adhesive which contaminate the recycled material

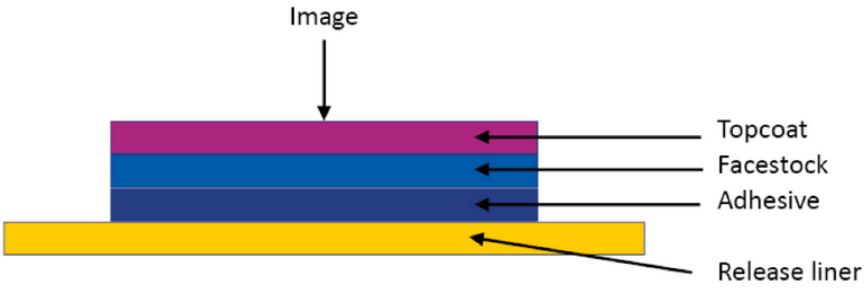


Figure 1 Schematic representation of Pressure Sensitive Labels

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Pressure sensitive labels (PSL) can only be used if the adhesive is water releasable at washing conditions of the recycling process, i.e. if the labels detach from the packaging body during washing steps in the recycling plant.

If PSL are used in an EU Ecolabel product, the Applicant should submit additional documentation demonstrate that the adhesive is water releasable at washing conditions of the recycling process. Example of accepted tests are presented below. The mentioned tests are for guidance only, and are not the sole means of demonstrating compliance with the criterion.

Testing procedures are standardized and valid throughout Europe and take into account the state of the art of sorting and recycling facilities. Differences between lines and between Member States are normally minimal.

See here the link to the Recyclass protocol for polyolefins (HDPE and PP): https://recyclass.eu/wp-content/uploads/2022/04/RecyClass-Washing-QT-Procedure-for-Film-Labels-applied-on-HDPE-and-PP-Containers-v1.1.pdf

See here the link to the Recyclass protocol for polystyrene (PET): https://www.epbp.org/download/329/qt-508-pressure-sensitive-labels-new

Required documentation for Assessment and verification:

Application Form

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

This criterion applies to:

- *Annex I: Cosmetic products: Criterion 6. Sustainable sourcing of palm oil, palm kernel oil and their derivates.*
- *Annex II: Animal care products: Criterion 5. Sustainable sourcing of palm oil, palm kernel oil and their derivates.*

- *Palm oil is oil obtained by pressing from the flesh of the fruits of the oil palm tree.*
- *Palm kernel oil is oil produced from the kernel (or stone) of the fruit of the oil palm tree.*
- *Derivatives are chemical products obtained by further processing of the palm oil and palm kernel oil. A range of derivates and fractions can produce (more information below).*
- *Third-party chain of custody certification (CoC) is a tool/system that verifies that certified material is identified or kept segregated from non-certified or non-controlled material throughout the chain of custody. The CoC system must be in place from the forest unit of origin to the final point of sale, which provides a link between the sustainable-certified material in the product or product line and certified forest/plantation unit. Mixing of sustainable-certified and non-certified products must be done under controlled procedures that meet the CoC requirements.*
- *The Roundtable of Sustainable Palm Oil (RSPO) is a not for profit, international membership organisation that unites stakeholders from the different sectors of the palm oil industry: oil palm producers, processors and traders, consumer goods manufacturers, retailers, banks/investors, and environmental and social non-governmental organisations (NGOs), to develop and implement global standards for sustainable palm oil production.*

If renewable ingredinets 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 requirement for sustainable production of a certification scheme. Evidence through third-party chain of custody shall be provided.

Palm Oil amb Palm kernel Oils are those that contain a majoritiy of C8-C18 C-Chains. Products with other dominant C-Chains >C18 will not be derived from palm oil and palm kernel oil.

Refined palm oil (“refined, bleached and deodorised palm oil” - RBDPO) falls under the palm oil category. Olein fractions are palm oil derivatives.

Fatty Acid, Methyl esters, Fatty Alcohols

- If the C-Chain distribution is > 65 % in the range C8 – C14, the derivative shall be considered to be produced from palm kernel oil.
- If the C-Chain distribution is > 95 % in the range C16 – C18, the derivative shall be considered to be produced from palm oil.

- Other C-Chain length distributions shall be considered as derived from a blend of palm and palm kernel oil, their raw material reference shall be palm oil.

Fatty Amines

- Tertiary Amines shall be considered to be derived from palm kernel oil, reflecting their primary production from Fatty Alcohol C12 - C14. Primary Amines shall be considered in line with Fatty Acids and Methyl esters.

Required documentation for Assessment and verification:

- Application Form
- Declaration from the raw material supplier
- Third-party certifications that the palm oil and palm kernel oil used in the manufacturing of the product originates from sustainably managed plantations (RSPO of any equivalent or stricter sustainable production scheme)

ⓘ The RSPO Supply Chain Standard guarantees that the palm oil or palm kernel oil used is covered through this system. It supports the following supply chain models for the uptake of the certified palm oil and palm kernel oil products:

- The Identity Preserved (IP) supply chain model assures that the RSPO certified oil palm product delivered to the end user is uniquely identifiable to a single RSPO certified mill and its certified supply base.
- The Segregated (SG) supply chain model assures that RSPO certified oil palm products delivered to the end user come only from RSPO certified sources (a mixture of IP products).
- Mass Balance system (MB) is a supply chain model that allows certified claims to be transferred from one oil palm product to another either through physical blending or administratively as described in Module C of the RSPO Supply Chain Certification Standard.

The traceability of certified palm oil is ensured throughout the supply chain until the last refinery through the RSPO supply chain database thanks to identification numbers put on invoices and certificates. From the final refinery until the end product, the traceability is made by invoices and supply chain certification of companies.

To ensure the equivalence of the certification scheme chosen, with a proper traceability system, any of the mentioned traceability systems are accepted for this criterion: IP, SG or MB.

More infromation about the RSPO supply chain certification systems:
https://rspo.org/library/lib_files/preview/1044

Certified companies whose operations have been certified against the RSPO Supply Chain Certification Standard can be fount in the next link:
https://www.rspo.org/certification/search-for-supply-chain-certificate-holders

Fitness for use

This criterion applies to:

- *Annex I: Cosmetic products: Criterion 7. Fitness for use.*
- *Annex II: Animal care products: Criterion 6. Fitness for use.*

Cosmetic products.

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

Consumer and laboratory tests shall be conducted following the "Guidelines for the Evaluation of the Efficacy of Cosmetic Products" available for download here:

https://cosmeticseurope.eu/files/4214/6407/6830/Guidelines_for_the_Evaluation_of_the_Efficacy_of_Cosmetic_Products_-_2008.pdf

The tests shall be conducted on the dosage indicated by the applicant on primary packaging, criterion 5 (c) (i), if a correct dosage can be identified. In the case a correct dosage could not be specified in criterion 5 (c) (i), the applicant shall indicate the dosage used for carrying out the test, substantiating the choice.

Concentrated products should be tested on the ready-to-use form, using as a reference dosage the one stated in criterion 5.c.i.

The following information shall be reported, as a minimum:

- Study objective.
- Product to be tested and reference product (if used).
- Type of product (e.g. skin cream) and quantity of product applied if applicable.
- When (timetable) and where (study location) was the test performed?
- Who performed the test?
- Who ordered the test?
- How were the testers chosen? Inclusion/exclusion criteria, number of subjects.
- Methodology: Summary of protocol, what parameters/properties were tested? why were they chosen? It is important to describe why each testing parameter/property has been included

in the test. Some parameters/properties may have benn included in the test for reasons other than performance (e.g. the scent of the product or similar).

- Test results.
- Conclusions of the test.
- Signatures of the persons responsible for testing.

LABORATORY TESTS:

In case recognised standardised laboratory test are available for a specific product to demonstrate a specific function, these tests must be followed. In this case, consumer tests will not be accepted.

An official list of recognised standardised tests for the efficacy of cosmetic products, or for secondary claims is not available at the moment.

Recognised standardised laboratory tests available are:

- Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (link)
- National guidelines on fluorine content in toothpaste (depending on the Member State)

Laboratory tests performed in compliance with Regulation (EC) No 1223/2009 and Commission Regulation (EU) No 655/2013 may be used to demonstrate that the product fulfils its primary function and any secondary claimed function. If such tests were already performed in the context of the Cosmetics Regulation, and these tests comply with criterion 7 of the EU Ecolabel criterion, it is not necessary to perform new specific tests.

The criteria presented in Commission Regulation (EU) No 655/2013 on claims on cosmetic products are binding and mandatory for all cosmetic products – therefore these should always be respected.

Laboratory tests shall include at least the following parameters:

- How/why the test method was chosen and how it can be used to document the product's performance/quality
- The parameters and/or properties that were tested and why they were chosen

Claims saying that the product is mild, gentle, sensitive, hypoallergenic and similar can be documented by testing methods to document mildness, e.g. HET-CAM or a test for red blood cells (RBC test) (Brantom PG et al, 1997, Ronald E. Hester et al., 2006) or patch test or by expert assessment that gives a corresponding result. The requirement for patch tests is that the number of

test persons must be at least 25, leave-on products must be tested undiluted and for rinse-off products we accept dilution of 5%.

The following results may be approved:

- In RBC tests non-irritant and slightly irritant
- In HET-CAM non-irritating and slightly irritating
- In Patch test "no reaction"

Claims of "gentle/mild/sensitive" and similar can also be demonstrated if the product meets the following three points:

- Not containing fragrances or fragrances in plant extract
- Containing < 10% surfactants classified with H318
- pH between 4 and 8 (9 for toothpaste).

Note that animal testing is not permitted and the analysis laboratory shall fulfil the general requirements of standard EN ISO 17025 or have official GLP status.

The applicant's own analysis laboratory/test procedure may be approved for analysis and testing if:

- The authorities monitor the sampling and analysis process, or if
- The manufacturer has a quality management system encompassing sampling and analysis and has been certified to ISO 9001 or ISO 9001, or if
- The manufacturer can demonstrate agreement between a first-time test conducted at the manufacturer's own laboratory and testing carried out in parallel at an independent test institute, and that the manufacturer takes samples according to a set sampling plan.

CONSUMER TESTS:

Consumer tests may be used in case recognized standard laboratory tests are not available.

For consumer tests, the consumers shall be asked about the product's efficiency/performance compared to an equivalent market-leading product. The questions to the consumers shall cover at least the following aspects:

- How well does the product perform in comparison with a market-leading product using the same dosage?

- How easy is it to apply and rinse off (for rinse-off products) the product to/from the hair and/or skin in comparison with a market-leading product?

Consumer tests shall include a minimum of 20 consumers.

At least 80% of them shall be at least as satisfied with the product as with an equivalent market-leading product.This applies for each individual parameter tested.

The market-leading product shall be one present in the region, where the applicant's product is to be marketed and making the similar claims about efficacy properties as the applicant's product. The market-leading product must be approved by the competent body in charge of the aplication prior to the testing, and the trade name must be referenced in the test report and technical sheets and the label shall be provided to the competent body.

Old efficiency test reports on rinse-off cosmetics can be accepted if the product has not changed its composition (from the old application/criteria to the new)

If the applicant submits tests to demonstrate a specific function in accordance with Regulation (EC) No 1223/2009, there are three possibilities:

- the test performed in accordance with Regulation (EC) No 1223/2009 is a laboratory test → it can be accepted for the EU Ecolabel;
- the test performed in accordance with Regulation (EC) No 1223/2009 is a consumer test and a standardised laboratory test does not exist to demonstrate that function → the consumer test can be accepted;
- the test performed in accordance with Regulation (EC) No 1223/2009 is a consumer test and a standardised laboratory test does exist to demonstrate that function → the consumer test cannot be accepted, and a laboratory test should be carried out instead.

An official list of all standardised efficacy tests for cosmetic products, or for secondary claims is not available. The only two cases of standardised efficacy laboratory tests at this moment are:

- Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto, OJ L 265, 26.9.2006, p. 39–43, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006H0
- National guidelines on fluorine content in toothpaste (depending on the Member States)

Required documentation for Assessment and verification:

Application Form

Report of laboratory or consumer test results to demonstrate efficacy of cosmetic products

Animal care products.

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.

Bibliographic data from published studies, and information or technical data from suppliers (recommended use levels, efficacy tests of ingredients, etc.) will be accepted as function demonstration.

Required documentation for Assessment and verification:

Application Form

Bibliographic data to demostrate efficacy of animal care products

Information on EU Ecolabel

This criterion applies to:

- *Annex I: Cosmetic products: Criterion 8. Information appearing on the EU Ecolabel for cosmetic products.*
- *Annex II: Animal care products: Criterion 7. Information appearing on the EU Ecolabel for animal care products.*

The optional label with box shall contain the following information:

Cosmetic products.

- Fulfills strict requirements on harmful substances.
- Tested performance.
- Less packaging waste.

Animal care products.

- Fulfills strict requirements on harmful substances.
- Tested performance (not animal tested).
- Less packaging waste.

The guidelines for the use of the optional label with text box can be found in the "Guidelines for use of the Ecolabel logo" on the website:

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

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.

Required documentation for assessment and verification:

Application Form