



Sevilla, 10th September 2020

EU Ecolabel criteria for cosmetic products

JRC discussion paper ahead of the sub-group meeting

Introduction

The main objective of this expert sub-group meeting is to discuss the need of granting derogation to specific substances that do not comply with EU Ecolabel sub-criterion 3 (a) (i) Restrictions on ingoing substances/mixtures classified under the Classification, Labelling and Packaging Regulation¹.

The legal text of sub-criterion 3 (a) (i) as detailed in the second version of the Technical Report is reported below.

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

- (i) Unless derogated in Table X, the product shall not contain substances or mixtures at or above the concentration of 0.010 % weight by weight for rinse-off products and 0.001% weight by weight for leave-on cosmetics, that are assigned any of the following hazard classes, categories and associated hazard statement codes, in accordance with Regulation (EC) No 1272/2008 (*).

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

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

Acute toxicity	
Categories 1 and 2	Category 3
H300 Fatal if swallowed	H301 Toxic if swallowed
H310 Fatal in contact with skin	H311 Toxic in contact with skin
H330 Fatal if inhaled	H331 Toxic if inhaled
H304 May be fatal if swallowed and enters airways	EUH070 Toxic by eye contact
Specific target organ toxicity	
Category 1	Category 2
H370 Causes damage to organs	H371 May cause damage to organs
H372 Causes damage to organs through prolonged or repeated exposure	H373 May cause damage to organs through prolonged or repeated exposure
Respiratory and skin sensitisation	
Category 1^a	Category 1B
H317 May cause allergic skin reaction	H317 May cause allergic skin reaction

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
Hazardous to the aquatic environment	
Categories 1 and 2	Category 3 and 4
H400 Very toxic to aquatic life	H412 Harmful to aquatic life with long-lasting effects
H410 Very toxic to aquatic life with long-lasting effects	H413 May cause long-lasting effects to aquatic life
H411 Toxic to aquatic life with long-lasting effects	
Hazardous to the ozone layer	
H420 Hazardous to the ozone layer	

Granting derogation is permitted according to the EU Ecolabel Regulation², on the premise that certain conditions must be met before a substance can be placed on the derogation list. Namely:

- when it is not technically feasible to substitute these substances as such, or via the use of alternative materials or designs,
- or in the case of products which have a significantly higher overall environmental performance compared with other goods of the same category.

The existing EU Ecolabel criteria for rinse-off cosmetics³ grant two derogations from sub-criterion 3 (a), namely to surfactants classified as H412 and/or H413 (in total concentrations < 20 % in the final product), and to Zinc pyrithione (ZPT) used in anti-dandruff shampoos.

During the first revision of the Technical Report⁴ it was proposed to remove the derogations granted so far, and request industries to submit official derogation requests, if need be.

During the stakeholder consultation period following the 2nd Ad-Hoc Working Group (AHWG) meeting, six derogation requests were submitted to the JRC by five industries. The substances for which a derogation request was submitted are:

- Sodium Laureth Sulfate
- Cocamidopropyl betaine
- Ethyl N2-dodecanoyl-L-argininate hydrochloride (LAE)
- Surfactants classified as H400 or H412
- Sodium fluoride
- Titanium dioxide

These derogation requests are proposed to be discussed by the expert subgroup in terms of the hazard of the substance, the relevance of the substance in cosmetic products, and the technical and economic availability of substitutes.

² Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel

³ Commission Decision of 9 December 2014 establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products

⁴ <https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/444/documents>

The expert sub-group is composed of industries and consumer organisations with expertise in the field. This document aims at guiding on the specific discussion points to be addressed by the sub-group members.

Sodium Laureth Sulfate (SLES)

Sodium Laureth Sulfate, or sodium lauryl ether sulfate (SLES), is an anionic surfactant used in many personal care products. Its properties include cleaning, foaming and emulsifying. It is derived from palm kernel oil or coconut oil, and is very inexpensive.

According to the classification provided by companies to ECHA in REACH registrations this substance causes serious eye damage (H318), is harmful to aquatic life with long lasting effects (H412) and causes skin irritation (H315)⁵. According to the Safer Choice of the U.S. Environmental Protection Agency (EPA), the chemical has been verified to be of low concern (determined to be safer than traditional chemical ingredients).

SLES can be present in the shampoo/soap formulation in concentrations up to 11%. This substance is manufactured and/or imported in the European Economic Area in 100 000 – 1 000 000 tonnes per year.

Industries report that no alternatives to SLES have been proposed by suppliers yet.

Cocamidopropyl betaine

Cocamidopropyl betaine (CAPB) is a mixture of closely related organic compounds derived from coconut oil and dimethylaminopropylamine, and is used as a zwitterionic surfactant (containing both positive and negative charges on its head group) in personal care products. Its properties include cleaning, foaming, thickening, conditioning and viscosity controlling.

According to the classification provided by companies to ECHA in CLP notifications this substance is very toxic to aquatic life (H400), causes serious eye damage (H319) and causes skin irritation (H315)⁶. According to the Safer Choice of the U.S. Environmental Protection Agency (EPA), the chemical has been verified to be of low concern (determined to be safer than traditional chemical ingredients).

CAPB has to a significant degree replaced cocamide DEA, which has a notified classification and labelling as H315 and H318 and is banned in EU Ecolabel cosmetics according to criterion 3 (b). CAPB is also used to reduce irritation that purely ionic surfactants would cause. However, some studies indicate it is an allergen.⁷

⁵ <https://echa.europa.eu/brief-profile/-/briefprofile/100.105.723>

⁶ <https://echa.europa.eu/brief-profile/-/briefprofile/100.057.308>

⁷ Mowad, C. (2001). "Cocamidopropyl betaine allergy". *American Journal of Contact Dermatitis*. 12 (4): 223–224. doi:10.1053/ajcd.2001.29549

CAPB can be present in the shampoo/soap formulation in concentrations up to 3%. This substance is manufactured and/or imported in the European Economic Area in 10 - 100 tonnes per year.

Industries report that no alternatives to CAPB have been proposed by suppliers yet.

Ethyl N2-dodecanoyl-L-argininate hydrochloride (LAE)

Ethyl N2-dodecanoyl-L-argininate hydrochloride (LAE) is a substance used in personal care products for its properties as a preservative and conditioner.

According to the harmonised classification and labelling (ATP01) approved by the European Union, this substance is very toxic to aquatic life (H400) and causes serious eye damage (H318). Additionally, the classification provided by companies to ECHA in REACH registrations identifies that this substance is harmful to aquatic life with long lasting effects (H412)⁸. LAE is approved as a food additive (E 243). According to the Safer Choice of the U.S. Environmental Protection Agency (EPA), the chemical has been verified to be of low concern (determined to be safer than traditional chemical ingredients).

LAE can be present in concentrations up to 0.4% as a preservative in ready to use preparations (Not to be used in lip products, oral products and spray products). Alternatively, it can be present in concentrations up to 0.8% as a hair/skin Conditioner in soaps, anti-dandruff shampoos and deodorants (not in form of spray). This substance is manufactured and/or imported in the European Economic Area in 10 - 100 tonnes per year.

Alternatives to LAE are: Zinc Pyrithione in anti-dandruff shampoos; Phenoxyethanol as a preservative; Triclosan as a preservative in mouthwash; Polyquaterniums as a conditioner.

Surfactants classified as H400 or H412

Surfactants are essential compounds in personal care products for their cleaning properties. Surfactants act by lowering the surface tension between two liquids, between a gas and a liquid, or between a liquid and a solid. Surfactants have important properties such as cleaning, wetting, dispersing, emulsifying, foaming and anti-foaming agents.

The derogation of surfactants classified as H412 and/or H413 was permitted in the existing EU Ecolabel criteria, on the condition that such surfactants are present in total concentrations < 20 % in the final product. Prolonged exposure to surfactants can irritate and damage the skin because surfactants disrupt the lipid membrane that protects skin and other cells. Skin irritancy generally increases in the series non-ionic, amphoteric, anionic, cationic surfactants.

Typical concentration of surfactants is between Typical concentration of surfactants H 412 is between 1% and 20 %, till 25% (as active content), depending of the product.

According to the industry, substances classified H 400 - H 412 are readily biodegradable. After the introduction of the 2nd ATP to CLP Regulation, usually a tighter labelling was assigned to the same

⁸ <https://echa.europa.eu/brief-profile/-/briefprofile/100.103.285>

surfactants without any changes of surfactants properties. According to the industry, most of alternative surfactants are dangerous for environment. A few non-classified surfactants exist but with a lower associated efficiency. It is envisaged that if a derogation is not granted, products will be not so effective to satisfy Criterion 7. Moreover, the price of non-classified surfactants is reported to be at least three times higher, which is not a negligible aspect considering that their presence can be in a concentration up to 25% of the product formulation. Moreover, the market availability of non-classified surfactants is said to be poor.

Sodium fluoride (NaF)

Sodium fluoride (NaF) is an inorganic compound often used in trace amounts as a source of fluoride in the production of pharmaceuticals and in toothpaste to prevent dental cavities.

According to the harmonised classification and labelling (CLP00) approved by the European Union, this substance is toxic if swallowed (H301), causes serious eye irritation (H319) and causes skin irritation (H315)⁹. Due to its classification as H301, NaF was proposed to be banned in EU Ecolabel toothpaste according to criterion 3 (b).

According to the Annex III of the Cosmetic Product Regulation, NaF is permitted up to “0.15 % calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.15 %. The product must be accompanied by the labelling *Contains Sodium Fluoride*. For any toothpaste with compounds containing fluorine in a concentration of 0.1 to 0.15 % calculated as F unless it is already labelled as contra-indicated for children (e.g. ‘for adult use only’) the following labelling is obligatory: ‘Children of 6 years and younger: use a pea-sized amount for supervised brushing to minimise swallowing. In case of intake of fluoride from other sources consult a dentist or doctor.’”

However, a SCCS Opinion from 2005 has been published on the safety of fluorine compounds in oral hygiene products for children under the age of 6 years¹⁰. Moreover, the World Health Organisation stress the need for sufficient fluoride intake for oral health and to minimize tooth decay.

Typical concentration of NaF in toothpaste is 1450 ppm. This substance is manufactured and/or imported in the European Economic Area in 1 000 – 10 000 tonnes per year.

Although alternative forms of fluoride exist, it might not always be possible to replace Sodium Fluoride or consider all sources of fluoride as interchangeable. The choice of a specific Fluoride source is in fact often dictated by the incompatibility with other ingredients in the formulation, that could make the fluoride itself no longer active. If that is the case the substitution with an alternative is not possible.

The anticaries benefit of Fluoride sources other than Sodium Fluoride is well known and accepted. The key parameter to be ensured for the anti-caries and enamel protection of fluoride is the delivery and bioavailability of the Fluoride ion on to tooth enamel, hence absence of reaction has to be ensured inside the formulation. Sodium Monofluorophosphate, Tin Fluoride and Olafluor have different chemistry and interactions, that must be assessed on a formulation by formulation base. Alternative

⁹ <https://echa.europa.eu/brief-profile/-/briefprofile/100.028.789>

¹⁰ https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_024.pdf

sources of fluoride might have impact on other product performances. For example, Tin Fluoride can stain teeth, making it not an easy replacement to be formulated or asking consumer to compromise on other benefit requested by a toothpaste like clean teeth.

Titanium dioxide (TiO₂)

Titanium Dioxide (TiO₂) is commonly used in cosmetic products as a UV filter that provides broad spectrum UVA/UVB protection up to 340 nm.

Titanium Dioxide (TiO₂) used as a UV-filter in a concentration up to 25% in cosmetic products is currently allowed under the Cosmetics Regulation (entry 27 in the Annex VI to this Regulation). This refers to all forms of TiO₂.

With respect to the nano-form of TiO₂, the SCCS (the Scientific Committee on Consumer Safety) published in recent years three opinions¹¹ on the safe use of nano-TiO₂ in cosmetics.

TiO₂ in inhalable powder form has been included as a Carc 2 (H351, only TiO₂ placed on the market in powder form and consisting of 1% or more of particles with an aerodynamic diameter ≤ 10µm) in the 14th ATP (adaptation to technical progress) to CLP, which adds a number of substances to Annex VI of CLP. The 14th ATP was adopted by the Commission on 4th of October 2019. The delegated act was published early 2020, with the changes becoming a legal requirement 18 months later. For mixtures, only mixtures placed on the market in powder form and containing 1% or more of TiO₂ which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10µm need to be classified as Carc.2., i.e. liquid and solid mixtures containing such TiO₂ do not need to be classified (but they do need to carry a warning statement)¹².

TiO₂ is used in sunscreen products in a concentration of less than 25%, with a typical concentration between 0.4 - 16.7%. This substance is manufactured and/or imported in the European Economic Area in more than 1 000 000 tonnes per year.

Zinc Oxide is the only inorganic or “physical” UV filter that is an alternative to Titanium Dioxide. However, according to the harmonised classification and labelling (CLP00) approved by the European Union, Zinc Oxide is very toxic to aquatic life (H400) and is very toxic to aquatic life with long lasting effects (H410). Additionally, the classification provided by companies to ECHA in REACH registrations identifies that this substance may damage fertility or the unborn child, is harmful if swallowed, is harmful if inhaled and may cause damage to organs through prolonged or repeated exposure¹³.

¹¹ SCCS Opinion on Titanium Dioxide (nano form), COLIPA n° S75, SCCS/1516/13, 2014, available online under:

https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf

SCCS Opinion on Titanium Dioxide (nano form) coated with Cetyl Phosphate, Manganese Dioxide or Triethoxycaprylylsilane as UV-filter in dermally applied cosmetic, SCCS/1580/16, 2018, available online under:

https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_202.pdf

SCCS Opinion on Titanium Dioxide (nano form) as UV-Filter in sprays.

https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_206.pdf

¹² <https://echa.europa.eu/brief-profile/-/briefprofile/100.033.327>

¹³ <https://echa.europa.eu/es/brief-profile/-/briefprofile/100.013.839>

Other alternatives to TiO₂ filter exist but may be potential endocrine disruptors. Of the substitutes identified by industry, only two are not potential endocrine disruptors.