

INDITEX

i+Cosmetics

2025

Inditex Precautions and Limits
for Users Safety for Cosmetics

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I. Definition of i+Cosmetics

Definition of i+Cosmetics

Inditex **Precautions and Limits for Users Safety for Cosmetics** (hereinafter i+Cosmetics) is defined as a product health and safety standard that:

- Has been developed by Inditex in compliance with the most demanding legislation in the area of cosmetic product health and safety.
- It includes the obligation for cosmetic products supplied to Inditex to be manufactured in accordance with Good Manufacturing Practices as a fundamental pillar to guarantee the safety of the products.
- Regulates those “Substances of Legally Limited Use” which if present in the product above certain levels, could be harmful to human health.
- Additionally, includes a section on the restrictions imposed on pH in cosmetic products and the corresponding labelling requirements associated with health and safety of products when they exist; and which do not exempt from compliance with the general labelling standards for products marketed by Inditex or from compliance with other standards that specifically regulate the labelling of consumer products.
- Considers the microbiological control of cosmetic products as a vital aspect in the health and safety product monitoring, so it contains a specific section with the respective requirements.
- Considers the efficacy of sunscreens or cosmetic products with sun protection as a vital aspect of the health and safety of these products, so it contains a specific mention of the corresponding requirements in the UV Filters section.
- Documentation requirements that must be enclosed with every Cosmetic Product in the process of marketing in the context of the European Union (Product Information File, PIF) are explained in detail in section IV of this standard. Inditex, will also require any other documents or certificates that are compulsory in other countries.
- It also includes REACH and CLP as mandatory European regulations for all Inditex suppliers. Additionally, it includes the obligation for suppliers to control and avoid endocrine disruptors included in French Decree No. 2021-1110; as well as the obligation to control and report on the presence of ingredients classified in the Australian Poisons Standard lists.

i+Cosmetics is a general application standard that is mandatory for all cosmetic products¹ that are supplied to Inditex. This standard prioritised the control of 11 families of chemical substances, taking into account their potential risk for human health and in accordance with the risk assessment carried out by Inditex. Compliance with the requirements of these 11 families does not exempt the manufacturer and/or supplier, under any circumstances, from complying with any- and all- substances and the limits which are laid down in the legislation in the field of cosmetic products in the markets covered by this standard i+Cosmetics.

The information contained in this document, or that which is accessed via this document, is shared by Inditex for general guidance purposes and must not be considered or used as a replacement for any legal requirement. Inditex has made every reasonable effort to guarantee the accuracy of the information available in this standard.

The information contained in this standard is subject to change and shall always prevail the latest version available at www.inditex.com.

The responsibility of the manufacturers and/or suppliers for guaranteeing compliance with the i+Cosmetics for products supplied to Inditex does not exempt them from complying with any other legislation that applies to cosmetic products, even if it is not specifically included in this standard. For more information about the commitment to comply with this standard see Annex XVI.

¹ “Cosmetic Product” being understood as meaning: any substance or mixture 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.

Regardless of the control commitment taken on by the suppliers of those parameters regulated by i+Cosmetics, Inditex will verify their correct implementation at any stage in the manufacturing process of those products manufactured, marketed and/or distributed, by carrying out: reviewing documents, audits at the production centres and random sampling and analysis of certain “Models/Quality” at any point in their manufacturing process.

Furthermore, the supplier shall let Inditex have all the documentation needed for the various import/export procedures that are required in each country where the Group has commercial dealings. The information contained in Inditex Logistics Manual must also be taken into consideration.

If you, as a supplier of Inditex, have doubts about any cosmetic ingredient not mentioned in this standard, please contact the Sustainability Department of Inditex to obtain further information on how to achieve conformity of your products with Inditex’s requirements for cosmetics (i+cosmetics@inditex.com).

Annex I details all information concerning the legislation consulted.

II. Legal Requirements of Production (GMP)

Legal requirements of production (GMP)

The manufacturing of cosmetic products takes place in compliance with good manufacturing practices (GMP); such compliance will be assumed when the manufacture adapts to the standards concerned (whose references have been published in the Official Journal of the European Union: within the scope of this standard, the reference norm is Norm ISO 22716:2007 (Cosmetics - Good Manufacturing Practices (GMP) and its respective General Training Document (ISO/TR 24475:2010)).

Standard ISO 22716:2007 (Cosmetics-Guidelines on GMP) is a set of guidelines aimed at providing a guide of the Good Manufacturing Practices (GMP) of cosmetic products considering the specific needs of the companies in the cosmetic industry. The Norm provides a series of practical and organizational tips designed to be applied following the path of the products, from their reception to their dispatch.

The final objective is to specify the activities that allow to obtain a cosmetic product that complies with certain defined characteristics establishing suitable control over their manufacture; and to guarantee the achievement and maintenance of the maximum quality applying that control throughout the entire production process; and at the storage, conservation and dispatch phases of the cosmetic products.

The basic objectives consist of establishing the following:

- The requirements and recommendations associated with the training of the personnel involved in the process; adapting the facilities and their equipment; the raw materials and the packaging materials; the production process; the finished products, their storage, dispatch and recall, if needed.
- The requirements and recommendations associated with all the aspects involving the quality control laboratory (personnel, facilities, equipment, subcontracts and documentation).
- The standard for dealing with products that do not comply with specifications.
- The waste management standard (not only for production but also for the laboratory quality control).
- The basic characteristics of the subcontracting agreements.
- The processing of the deviations and the respective corrective measures.
- The way of dealing with complaints and the withdrawal of products.
- Control over the changes that might affect the quality of the product.
- And, finally, the internal audits and documentation system.

The correct implementation of GMP is mandatory; Inditex reserves the right to conduct audits to check compliance with the GMP.

III. Legal Requirements of Product

Legal requirements of product

The cosmetic products to which standard applies belong to any of the following categories:

- A. Cosmetic products for the area around the eyes:** eye pencil, eyebrow pencil, eyeliner, eye shadow, eye make-up remover, mascara, other products for the area around the eyes.
- B. Cosmetic products for the lips:** lipstick, lip gloss, lip protector, lip liner, other products for the lips.
- C. Cosmetic products for the face:** make-up base (liquid, cream), blush, face powders, face cream, face lotion, face mask, facial corrector, make-up remover, facial cleansing product, other products for the face.
- D. Cosmetic products for the skin:** body make-up base, body cream, hands cream, body lotion, body oil, body powders, other products for the skin.
- E. Cosmetic products for washing and body hygiene:** soap, bath gel, bath foam, bath powders, bath oil, bath lotion, bath salts, aromatic bath tablet, talcum powders, moisturising towels and cloths, other products for washing and body hygiene.
- F. Deodorant and antiperspirant products.**
- G. Cosmetic products for the nails:** nail polish base, cuticle softener, nail cream, nail polish, nail polish remover, nail oil, nail gloss, other products for the nails.
- H. Cosmetic perfumery products:** eau de toilette, eau de cologne, eau de tender, eau de parfum, body mist, other perfumery products.
- I. Shave and after-shave products:** shave foam, shave lotion, shave cream, after-shave lotion, after-shave balm, other shave and after-shave products.
- J. Hair products:** shampoo, conditioner, fixative, hair mask, hair straightening product, hair curling product, hair dye (non-oxidative), other hair products.
- K. Cosmetic products for mouth and dental hygiene:** toothpaste, mouthwash, oral rinse, other oral and dental hygiene products.
- L. Sun protection and self-tanning products:** pre- and post-sun product, sun protection product, self-tanning product, other sun protection and self-tanning products.

In case of manufacturing cosmetic products not included in this list, please contact the Sustainability Department of Inditex (i+cosmetics@inditex.com).

For the purpose of this health and safety control standard for cosmetic products the following definitions are provided:

Rinse-off product: the cosmetic product which is intended to be removed after application on the skin, the hair or the mucous membranes.

Leave-on product: the cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes.

Product applied on mucous membranes: the cosmetic product which is intended to be applied on the mucous membranes of the oral cavity, on the rim of the eyes, or of the external genital organs.

Eye product: the cosmetic product which is intended to be applied in the vicinity of the eyes.

Lip product: the cosmetic product which is intended to be applied on the lips.

Types of substances and parameters regulated

A colour code has been established on the basis of the degree or type of regulation covering the chemical substances considered. This colour code will be used throughout the document, and it means the following:

Substances that must not form part of the composition of cosmetic products.

Substances subjected to certain restrictions and conditions of use.

Below, following the index proposed, the controlled substances, their origin in the cosmetic product, the legal limits that affect them, potential techniques for their analytical control and certain comments about the way that their use in the finished product can be prevented or how they can be replaced, are detailed.

Furthermore, a series of annexes are included summarising the main aspects covered in each section, but in Chart form, to facilitate their consultation and application.

III.1 Fragrances

a. Musks

1. What are they?

Musks are a group of chemical substances with a pungent and persistent aroma that are used in fragrances.

There are three classes of musks compounds that are chemically different, whose only common factor is their musk aroma:

- i. **Nitromusks**, also called **nitrated musks**, are a group of compounds derived from di- or tri-nitrobenzene.
- ii. **Polycyclic musks**, were developed later, with the aim of replacing the previous ones.
- iii. **Macrocyclic musks**, are a group formed by a mixture of chemically stable and biodegradable synthetic and natural compounds.

2. Where can they be found?

Synthetic musks are used as ingredients in many personal care products (lotions, soaps, perfumed cosmetics, etc.) and in perfume and colognes. Furthermore, they can act by “fixing” other more volatile aromatic notes to prevent them from evaporating rapidly.

3. What are their acceptable limits?

1. Nitromusks

There are five nitromusks that cannot form part of the composition of cosmetic products: **musk ambrette**, **musk moskene**, **musk tibetene**, **musk alpha²** and **musk KS²**.

There are two nitromusks that can form part of the composition of cosmetic products subject to the restrictions that are listed below; the MACs³ of these nitromusks in the finished cosmetic product are:

musk ketone^{4,5}

- 1.4% in fine fragrance
- 0.56% in eau de cologne
- 0.04% in other products

musk xylene^{4,5}

- 1% in fine fragrance
- 0.4% in eau de cologne
- 0.03% in other products

² According to the legislation of the United Mexican States (see Annex I).

³ MAC = Maximum Authorised Concentration in the ready for use preparation.

⁴ In the event of this substance being used as ingredient in the composition of a cosmetic product, contact the Sustainability Department of Inditex.

⁵ Not to be used in oral products.

2. Polycyclic musks

There is one polycyclic musk, **versalide**, which is prohibited. The polycyclic musks **tonalide** and **phantolide** are subject to the following restrictions:

tonalide⁵

- 0.1% in leave-on products, except:
 - 1.0% in hydroalcoholic products
 - 2.5% in fine fragrance
 - 0.5% in fragrance cream
- 0.2% in rinse-off products

phantolide

- 2.0% in leave-on products
- without limits in rinse-off products

3. Macrocyclic musks

This group of musks is currently exempt from any legal requirements.

4. How are they analysed?⁶

All the musks⁷ mentioned can be analysed by GC-MS or GC-MS/MS. Polycyclic musks can also be analysed by electrophoretic techniques (CE or NA-MEKC). As an alternative, nitromusks can be detected by means of GC-ECD or GC-AED (N line).

5. How can they be controlled?

By obtaining from our suppliers the undertaking and the guarantee that the cosmetic products supplied do not contain the prohibited nitromusks or the polycyclic musk versalide, which is also prohibited; and that the nitromusk ketone, the nitromusk xylene and the polycyclic musks tonalide and phantolide comply with the limits established in section 3 above. The musk ketone and the musk xylene, permitted but subject to restrictions, must be gradually replaced by polycyclic musks that are permitted and/or by macrocyclic musks.

Annex II details and extends all information concerning musks.

⁶ See Annex XIII to find out what the acronyms stand for each one of the analytic techniques.

⁷ The quantification limit for the selected method will be less than or equivalent to 0.0001% (1 ppm) for all musks considered.

b. Fragrance allergens

1. What are they?

There are 83 substances, classified as potential causes of allergic reactions and known as Fragrance Allergens, which may or may not correspond to a defined chemical substance, some of them are discrete molecules, while others are extracts and/or natural oils.

2. Where can they be found?

They are perfumed substances that are added as ingredients to cosmetic products to make the users feel good: cleaner, more comfortable or more attractive. They can be added directly or as constituents of fragrances, essential oils and natural extracts. However, they can also appear as impurities of other synthetic ingredients.

3. What are their acceptable limits?

Of the 83 fragrance allergens regulated, only two cannot be part of the composition of cosmetic products because they are prohibited: **Lyral (Hydroxyisohexyl 3-cyclohexene carboxaldehyde)** and **Lilial (Butylphenyl methylpropional)**.

The presence of any of the other **81** remaining **fragrance allergens** must be mentioned on the product label when they are in final cosmetic product in concentrations higher than: **0.001%** in leave-on cosmetics and **0.01%** in rinse-off cosmetics⁸.

Of the **81 fragrance allergens**, only the following have maximum authorised concentration limits: **3-propylidene-phthalide** (0.01%)⁹, **6-methylcoumarin** (0.003%)¹⁰, **rose ketones** (0.02%)⁹, **hydroxycitronellal** (1%)¹¹, **isoeugenol** (0.02%)¹¹, **lippia citriodora absolute** (0.2%), **methyl 2-octynoate** (0.01%)^{9,12}, **methyl salicylate**¹³, **myroxylon pereirae oil/extract** (0.4%), **menthol**¹⁴ and **camphor**¹⁵.

⁸ For the labelling of the new fragrance allergens included by the amendment Regulation EU 2023/1545, the following deadlines will apply to products that do not contain this new labelling: they may be placed on the market until 31 July 2026, and may be available until 31 July 2028.

⁹ These limits apply to all products except oral products (except in South Korea where it applies to all products).

¹⁰ Use only allowed in oral products. In South Korea, its use is prohibited (see Annex I).

¹¹ These limits apply to all products except oral products.

¹² MAC = 0.01% when it is used by itself. In combination with methyl octine carbonate (MOC), the combined level for the final product must not be > 0.01% (and of this, the % MOC, must not exceed 0.002%).

¹³ MAC = 0.06% in leave-on skin products (except face makeup, spray/aerosol body lotion, spray/aerosol deodorant, and hydroalcoholic-based fragrances). MAC = 0.06% in leave-on hair products (except spray/aerosol products). MAC = 0.05% in face makeup (except lip products, eye makeup and makeup removers). MAC = 0.002% in eye makeup and makeup removers. MAC = 0.009% in leave-on hair products (spray/aerosol). MAC = 0.003% in deodorant spray/aerosol. MAC = 0.04% in body lotion spray/aerosol. MAC = 0.06% in rinse-off skin products (except hand wash) and rinse-off hair products. MAC = 0.6% in hand wash products (0.2% in Argentina). MAC = 0.6% in hydroalcoholic-based fragrances (0.2% in Argentina). MAC = 0.03% in lip products. MAC = 2.52% in toothpastes (0.2% in Argentina, 1% in Canada and Taiwan and 2.5% in United Kingdom). MAC = 0.1% in mouthwashes intended for children between 6 and 10 years old. MAC = 0.6% in mouthwashes intended for children older than 10 years and adults (0.2% in Argentina and 0.4% in United Kingdom). MAC = 0.65% in mouth spray (0.2% in Argentina). Do not use in preparations for children under 6 years old (except for toothpastes). In the United Mexican States it can only be used in refreshing products with a MAC = 0.2%. In Taiwan for leave-on products, label should include "Consult physician or pharmacist before use with aspirin or salicylate idiosyncrasy", and for products which might be used for children under 2 years of age (exception of rinse-off products) label should include "Consult physician or pharmacist before uses to children under 2 years of age".

¹⁴ In Argentina MAC = 0.5% (mucous membranes); MAC = 0.5% (not mucous membranes and leave-on) and MAC = 1% (not mucous membranes and rinse-off). In Brazil MAC = 1%. In Indonesia for body powder MAC = 1%, prohibited in children under 3 years of age and label should include: "Contains Menthol. Do not use in children under 3 years old"; without restriction in other products. In Taiwan for products which might be used for children under 2 years of age (exception of rinse off products) label should include: "Consult physician or pharmacist before uses to children under 2 years of age". In India its use is prohibited in body and face powders.

¹⁵ In Canada and Taiwan MAC = 3%. In Indonesia for body powder MAC = 1.5%, prohibited in children under 3 years of age and label should include "Contains Camphor. Do not use in children under 3 years of age."; without restrictions in other products. In the United Mexican States can only be used in nail polish without restrictions and in refreshing products with MAC = 0.5%. In Taiwan for products which might be used for children under 2 years of age (exception of rinse off products) label should include: "Consult physician or pharmacist before uses to children under 2 years of age". In India its use is prohibited in body and face powders.

4. How are they analysed?¹⁶

Potentially allergenic volatile substances¹⁷ can be analysed by GC-MS or GC-MS/MS. As an alternative, there are analytical methods for fragrance allergens based on LC-MS/MS or HPLC-DAD.

5. How can they be controlled?

By obtaining from our suppliers the undertaking and the guarantee that the presence of fragrance allergens has been assessed and that, if their concentrations exceed the limits established, their presence will be suitably stated on the end-product label. Furthermore, if the cosmetic products that they supply contain any of the fragrance allergens with maximum authorised concentration limits, these comply with the restrictions described in section 3.

Annex III details and extends all information concerning fragrance allergens.

¹⁶ See Annex XIII to find out what the acronyms stand for each one of the analytical techniques.

¹⁷ The quantification limit for the selected method shall be lower than or equivalent to 0.0005% (5 ppm) for all the fragrance allergens considered.

III.2 Nitrosamines and nitrosating agents

1. What are they?

Nitrosamines (NNAs) are organic substances that are formed by a specific reaction between two substances that contain nitrogen, one of which is an amine that is provided with a second N by a substance known as nitrosating agent. NNAs are easily formed if the required precursors are present, mainly secondary amines (the most reactive) and nitrites as nitrosating agents.

2. Where can they be found?

NNAs can be found in a wide variety of cosmetic products and may, either be formed inside the product itself as a result of a reaction between the precursors, or by having been introduced into the product as a result of the use of contaminated raw materials. Nitrosation could take place both during the manufacturing process or when the product is in storage.

When cosmetics contain amines or their derivatives as ingredients, NNAs may be formed if they also contain any ingredient that could function as a nitrosating agent, generally under acidic conditions. Amines and their derivatives are mainly found in creams, lotions, shampoos and conditioners. Surfactants and emulsifiers based on ammonia or amine salts are frequently used in cosmetics and are potential sources of NNAs.

3. What are their acceptable limits?

Nitrosamines cannot form part of the composition of cosmetic products.

Furthermore, other limits associated with potential precursors of these compounds must be taken into account:

1. Amines and Amine-derivatives

Alkylamines and **secondary alkanolamines and their salts** are prohibited.

The following substances are regulated, and their maximum concentrations are indicated in brackets¹⁸:

Dialkylamides and **dialkanolamides of fatty acids**¹⁹ (0.5% as secondary amine).

Monoalkylamines, monoalkanolamines and their salts²⁰ (0.5% as secondary amine).

Trialkylamines, trialkanolamines and their salts²⁰ (2.5% in leave-on products and without limits in rinse-off products; 0.5% as secondary amine).

¹⁸ The restrictions listed below are general. The supplier must ensure that, when using any substance included in any of the following families, the substance can be used under the regulations included in this standard (see Annex I).

¹⁹ 1. Do not use with nitrosating agents.
2. Maximum secondary amine content: 5.0% (applied to raw materials).
3. Maximum nitrosamine content: 50 µg/kg.
4. Keep in nitrite-free containers.

²⁰ 1. Do not use with nitrosating agents.
2. Minimum purity: 99%.
3. Maximum secondary amine content: 0.5% (applied to raw materials).
4. Maximum nitrosamine content: 50 µg/kg.
5. Keep in nitrite-free containers.

2. Nitrosating agents

The nitrosating agents specified below, as well as any other nitrosating agent even if it is not included on this list, cannot be used in combination with amines or other substances that form NNAs, in any concentration:

Inorganic nitrites, except **sodium nitrite**²¹; **amyl nitrite**, **butyl nitrite**²², **isobutyl nitrite**, **isopropyl nitrite**²², **n-propyl nitrite**²² and **octyl nitrite**²².

5-Bromo-5-nitro-1,3-dioxane (Bronidox) and **2-Bromo-2-nitro-1,3-propanediol (Bronopol)**.

The following Table contains a summary of the combinations of the aforementioned substances²³, which have to be avoided in order to prevent the formation of nitrosamines in the final cosmetic product. This table contains a series of examples of known nitrosamines, but it is not an exhaustive list of them:

Nitrosamines ²⁴	Amines and amino-derivatives	Nitrosating agents	Combinations	
3-(N-Nitrosomethylamino)propionitrile	Secondary alkyl- and alkanolamines and their salts ²⁴ :	Inorganic nitrites	To prevent the formation of nitrosamines in the final cosmetic product, any combination of any of the substances contained in this chart is prohibited ²⁶	
4-Nitrosodiphenylamine		Sodium nitrite		
4-(N-Nitrosomethylamino)-1-(3-pyridyl)-1-butanone		Diethanolamine		Amyl nitrite ²⁵
Nitrosamide		Diisopropanolamine		Butyl nitrite ^{22,25}
N-Nitrosodibutylamine		Dimethylamine		Isobutyl nitrite ²⁵
N-Nitrosodiethanolamine				Isopropyl nitrite ^{22,25}
N-Nitrosodiethylamine				n-propyl nitrite ^{22,25}
N-Nitrosodiisopropanolamine				Octyl nitrite ^{22,25}
N-Nitrosodimethylamine				Bronidox
N-Nitrosodiphenylamine		Monoalkylamines, monoalkanolamines and their salts ²⁷ :		Bronopol
N-Nitrosodipropylamine				
N-Nitrosohexamethyleneimine				
N-Nitrosomethyl-N-butylamine		Trialkylamines, trialkanolamines and their salts ²⁷ :		
N-Nitrosomethyl-N-decylamine				
N-Nitrosomethyl-N-dodecylamine				
N-Nitrosomethyl-N-heptylamine				
N-Nitrosomethyl-N-hexylamine				
N-Nitrosomethyl-N-nonylamine		Triethanolamine		
N-Nitrosomethyl-N-octylamine				
N-Nitrosomethyl-N-pentylamine				
N-Nitrosomethyl-N-propylamine	Fatty acid dialkylamides and dialkanolamides ²⁷ :			
N-Nitrosomethyl-N-tetradecylamine				
N-Nitrosomethyl-N-undecylamine				
N-Nitroso-N-methylurea				
N-Nitroso-N-methylurethane				
N-Nitroso-N-methylvinylamine				
N-Nitrosomorpholine				
N-Nitrosornicotine				
N-Nitrosopiperidine				
N-Nitrosopyrrolidine				
N-Nitroso-para-amino benzoic acid esters	DEA-Cocamide			
N-Methyl-N-nitroso-ethanamine	DEA-Lauramide			
(etc.)	DEA-Oleamide			

²¹ Only allowed as a rust inhibitor with a MAC = 0.2% in the finished cosmetic product; for formulations that contain amides or amines it cannot be used in any concentration.

²² According to the legislation of Australia (see Annex I).

²³ To obtain detailed information about any of these substances, refer to Annex IV.

²⁴ All the substances that belong to this family are prohibited, the table list just some examples.

²⁵ Only these organic nitrites are mentioned, because they are the only ones that are specifically referred to in the legislations considered.

²⁶ For any doubt about these or other combinations of substances that could give rise to the formation of nitrosamines, contact the Sustainability Department of Inditex.

²⁷ All the substances that belong to this family are restricted, the table list just some examples.

4. How are they analysed?²⁸

The non-volatile NNAs²⁹ are analysed by LC-MS, LC-MS/MS, LC-TEA or HPLC-UV; and the volatile NNAs by GC-TEA, GC-MS or GC-MS/MS.

Alkylamines and alkanolamines can be analysed by IC, both for the raw materials and finished cosmetic products.

Nitrites can also be analysed by IC. The other nitrosating agents that contain bromine, can be analysed by HPLC coupled to UV detection, EQ or an ICP-MS; alternatively, they can be determined by GC-ECD, GC-MS or GC-MS/MS.

5. How can they be controlled?

By obtaining from our suppliers the undertaking and the guarantee that the cosmetic products they supplied do not contain nitrosamines and that they take the required measures to ensure that they are not formed.

NNAs can be prevented using a suitable formulation: by not using amines or amine derivatives in combination with nitrosating agents and controlling the product under conditions of use that guarantee that NNAs have not formed under the habitual conditions of use.

Not only the raw materials but also the final formulations must be stored in nitrite-free containers.

In addition, the following further recommendations are suggested:

- Removal of accidental sources of nitrite and nitrogen oxides.
- Removal of the secondary amines that contaminate.
- Use of raw materials free of nitrosamines contamination. If any case, raw materials and formulated products containing alkylamines and alkanolamines must not be conserved with formaldehyde.
- Amines and ammonia derivatives must not be combined with nitrosating agents.
- The incorporation of an inhibitor that prevents the formation of nitrosamines when formulating the product.

Annex IV details and extends all information concerning nitrosamines and their precursors.

²⁸ See Annex XIII to find out what the acronyms stand for each of the analytical techniques.

²⁹ The quantification limit for the selected method will be less than or equivalent to 0.000001% (0.01 ppm) for all the NNAs considered.

III.3 Phthalates

1. What are they?

They are also referred to as esters of phthalic acid. They are chemical substances used in a wide variety of industrial applications, including plasticisers (they make plastics softer and more flexible); industrial solvents; additives; and as alcohol denaturants (ethanol).

2. Where can they be found?

In cosmetics, phthalates are used basically as plasticisers in the manufacture of nail varnishes, nail polish removers, nail extenders and nail polishes, to reduce cracking by making them less fragile. Furthermore, they are used as solvents and fixatives for fragrances in many other cosmetic products.

In the case of cosmetics, phthalates may also be present in containers, lids/tops, and in the sealing parts of the perfume and cologne flasks. Therefore, phthalates can migrate from the material that contains them to other parts and contaminate products that do not contain them as original ingredients. Furthermore, phthalates migration might also occur from the packaging machinery and its connections, or, from any other device that comes in contact with the cosmetic product during the manufacturing process.

3. What are their acceptable limits?

The following phthalates cannot form part of the composition of cosmetic products³⁰: **diethyl phthalate (DEP)**³¹, **dimethyl phthalate (DMP)**³², **dibutyl phthalate (DBP)**, **diisobutyl phthalate (DIBP)**, **dipentyl phthalate (DPP)**, **diisopentyl phthalate (DIPP)**, **n-pentyl-isopentyl phthalate (PIPP)**, **dihexyl phthalate (DnHP)**, **diisohexyl phthalate (DIHP)**, **dicyclohexyl phthalate (DCHP)**, **bis(2-ethylhexyl) phthalate (DEHP)**, **dioctyl phthalate (DOP)**³³, **diisooctyl phthalate (DIOP)**, **diisodecyl phthalate (DIDP)**³⁴, **diisononyl phthalate (DINP)**³⁴, **benzyl butyl phthalate (BBP)** and **bis(2-methoxyethyl) phthalate (DMEP)**.

Also, the following phthalates cannot form part of the composition of cosmetic products: **1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear**; **1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear**; **1,2-Benzenedicarboxylic acid, di-C6-8 branched alkylesters, C7 rich** and **1,2-Benzenedicarboxylic acid, di-C7-11, branched and linear alkyl esters**.

4. How are they analysed?³⁵

The analysis of phthalates³⁶ by HPLC-UV is a rapid approximation that is sufficiently sensitive for its determination in cosmetics. As an alternative, they can be analysed by GC-FID, GC-MS or GC-MS/MS.

³⁰ In the states of Washington, Vermont, and Oregon (see Annex I), all ortho-phthalates are prohibited. If any of them are not listed in the included prohibited phthalates list, contact the Sustainability Department of Inditex.

³¹ According to the legislation of Australia (see Annex I). In Australia, its use is prohibited in sunscreens, insect repellents, and body lotions.

³² According to the legislation of the United Mexican States, Argentina and Australia (see Annex I).

³³ According to the legislation of Taiwan (see Annex I).

³⁴ According to the legislation of California (see Annex I).

³⁵ See Annex XIII to find out what the acronyms stand for each one of the analytical techniques.

³⁶ The quantification limit for the selected method will be less than or equivalent to 0.0005% (5 ppm) for all the phthalates considered.

5. How can they be controlled?

There are replacements for this type of compounds that perform the same functions, so the trend should be towards the complete elimination of these substances in new products that are launched onto the market.

Avoiding their use as additives in cosmetic products.

Avoiding the use of plastic containers. In case of having to use this type of containers, make sure of the non-presence of phthalates.

Annex V details and extends all information concerning phthalates.

III.4 Metals, metalloids and non-metals

1. What are they?

Metals, metalloids and non-metals are chemical elements whose use in cosmetics may be regulated. This section also summarises the most essential information about the salts and compounds of these chemical elements.

2. Where can they be found?

Heavy metals are not accepted as ingredients in cosmetic products; however, they may occur as trace amounts due to the persistent nature of these substances and the fact that they occur naturally in the environment: in rocks, soil and water. Consequently, they can be found in pigments and other raw materials frequently used in the cosmetic industry. Some of these metals have been used as cosmetic ingredients in the past, but intended use in cosmetics is generally prohibited nowadays. Therefore, attention and control are now directed to the presence of these substances in trace amounts.

Cosmetic packaging, particularly flexible polyvinyl chloride (PVC) may contain heavy metals such as Cadmium (Cd), Lead (Pb), Mercury (Hg) and hexavalent Chromium (Cr(VI)), the first two being the most frequently detected. Historically, these metals have been used as dyes and inks, and as stabilisers to retard degradation of plastics exposed to heat and UV light.

3. What are their acceptable limits?

Chemical elements (metals, metalloids and non-metals) and their compounds have very different levels of regulation. For practical reference, this section provides a summary of the most relevant information that affects them.

A colour code has been established based on the degree or type of regulation covering the elements and/or its salts and/or compounds. This colour code will be used throughout this section and it means the following:

ELEMENT	Colour	SALTS AND/OR COMPOUNDS	Underlining	Example
Prohibited	red	all prohibited	without underlining	Element
		some prohibited	red underlining	Element
		some restricted	orange underlining	Element
Restricted	orange	some prohibited	red underlining	Element
		some restricted	orange underlining	Element
Not restrictions	black	some prohibited	red underlining	Element
		some restricted	orange underlining	Element

1. The following elements, their salts and their compounds cannot form part of the composition of cosmetic products: **Antimony, Arsenic, Beryllium, Cadmium, Mercury, Neodymium, Nickel, Lead, Selenium, Thallium, and Tellurium.**

The limit for these elements in the Final Cosmetic Products is no detection³⁷.

³⁷ The value of nd = < 0.0001 % = < 1 ppm for all the elements considered, with the exceptions of Nickel (nd = < 0.001 % = < 10 ppm) and Antimony and Lead (nd = < 0.0005 % = < 5 ppm). In Washington, the limit of Lead in Final Cosmetic Product is also non detection, to know the value associated with nd contact the Sustainability Department of Inditex. In the event of marketing baby toilet soaps in India, contact the Sustainability Department of Inditex. These limits are admitted only in the situation of technical unavailability associated with the presence of a specific ingredient that could contain that metal as an impurity.

2. The following elements, and/or their salts and/or their compounds may only form part of the composition of cosmetic products under the established limitations and conditions³⁸.

- 2.1. **Chromium**, chromic acid and chromic acid salts are prohibited. Chromium(III) oxide and chromium(III) hydroxide are allowed colorants.
- 2.2. **Cobalt** and the following compounds are prohibited: cobalt dichloride, cobalt sulphate, cobalt benzenesulphonate, cobalt di(acetate), cobalt dinitrate and cobalt carbonate. Cobalt aluminum oxide is an allowed colorant.
- 2.3. The metals **Barium**, **Strontium** and **Zirconium** are used together in lakes, salts and pigments associated with more than a dozen colorants and, under these conditions, their use is allowed. However, other salts of these three elements are either restricted or prohibited. Neither **Barium** nor **Strontium**³⁹ are prohibited as such, but **Zirconium** is prohibited.
- 2.4. The elements **Sulphur**⁴⁰, **Bismuth**, **Tin**, **Iron**, **Manganese**, **Molybdenum**, **Platinum**, **Vanadium** and **Zinc** are not prohibited as such, but their salts and compounds are either permitted (such as bismuth oxychloride (CI 77163) and oxides and other iron compounds allowed as colorants); or restricted or prohibited.
- 2.5. The following elements and some of their salts and/or compounds are used directly as metallic colorants: **Aluminium**, **Copper**, **Gold**⁴¹, **Silver** and **Titanium**⁴²; other salts and/or compounds of these elements, are restricted or prohibited.

Additionally, some metal salts of these elements are prohibited because of their anion ("non-metallic component of the salt")⁴³.

Traces of some of the chemical elements reviewed in this section may appear, either in raw materials used as ingredients for cosmetics (for example, colorants, see Annex X *bis*) or in the finished cosmetic products themselves (see Annex VI). As a general criterion: the presence of traces of prohibited substances must remain at a level that is as low as reasonably achievable (ALARA) following good manufacturing practices.

4. How are they analysed?⁴⁴

Metals⁴⁵ are analysed by ICP-MS. As an alternative, AAS, AES or XRFs can be used.

5. How can they be controlled?

By obtaining from our suppliers the undertaking and the guarantee that the cosmetic products they supply do not contain the prohibited substances indicated in section 3 above; or, that the salts and compounds of the different elements contemplated in section 3 comply with the restrictions specified in each case.

Annex VI details and extends all information associated with the presence of chemical elements as traces in the final cosmetic product.

Annex VI bis details and extends all the information associated with the restrictions and/or prohibitions concerning the elements, their salts and their compounds.

Annex X bis (Global List of metal impurities and Regionalised List of metal impurities) details the legislation that establishes the limits of metal impurities in colorants.

³⁸ The list of elements and/or their salts and/or their compounds with their respective restrictions can be seen in Annex VI *bis*.

³⁹ MAC = 2.1%; prohibited in aerosol products (see legislation of Canada, Annex I).

⁴⁰ MAC = 2%; use only permitted in anti-dandruff and antiacne products (see legislation of Taiwan and MERCOSUR, Annex I).

⁴¹ This element is not allowed as colorant (see legislation of the United States of America, Annex I).

⁴² TiO₂ (CI 77891) is a compound that is allowed as a colorant (see Annex X of colorants).

⁴³ For example: silver cyanide and copper cyanide are prohibited, but Silver and Copper are permitted; thus, the prohibition of the salt is due to the cyanide (both hydrogen cyanide and its salts are prohibited).

⁴⁴ See Annex XIII to find out what the acronyms stand for each one of the analytical techniques.

⁴⁵ The quantification limit for the selected method will be less than or equivalent to the limits proposed in this section and in Annexes X and X *bis* for each element considered.

III.5 Glycol-ethers

1. What are they?

Glycol-ethers are solvents with unusual properties, because they have the solubility characteristics of both ethers and alcohols. They are characterised by their miscibility with water and with many other organic solvents. They have many industrial applications including use as solvents for lacquers, inks, dyes and as surfactants.

2. Where can they be found?

In cosmetics, they are basically found as solvents and viscosity-reducing agents in nail products, facial cleaners and liquid soaps.

3. What are their acceptable limits?

The following substances cannot form part of the composition of cosmetic products: **2-ethoxyethanol (EGEE)**, **2-methoxyethanol (EGME)**, **2-methoxypropanol (1PG2ME)** and their respective **acetates (EGEEA, EGMEA and 1PG2MEA)**, **2-butoxyethanol (EGBE)**⁴⁶, **tert-butoxy-2-propanol (PGBE)**⁴⁷, **methyl and dimethyl ethers of diethylene glycol (DEGME, DEGDME)**, **dimethyl and diethyl ethers of ethylene glycol (EGDME, EGDEE)**, **dimethyl ethers of triethylene glycol (TEGDME)** and **tetraethylene glycol** and **monobutyl ether of diethylene glycol (DEGBE)**⁴⁸. In addition, **diethylene glycol (DEG)**⁴⁸ has been included in this section.

The glycol-ethers with restrictions are the following: **monoethyl ether of diethylene glycol (DEGEE)**^{49,50}, **1-methoxy-2-propanol (PGME)**⁵¹ and **its acetate (PGMEA)**⁵² and **polidocanol**⁵³.

4. How are they analysed?⁵⁴

These glycol-ethers⁵⁵ are analysed by HPLC-UV with prior derivatisation or by GC-FID or GC-MS.

5. How can they be controlled?

By obtaining from our suppliers the undertaking and the guarantee that they are not used as solvents in their products. In the event that the use of any of the restricted, but not prohibited, glycol-ethers is required, obtaining the undertaking and the guarantee that they comply with the restrictions specified in each case.

Annex VII details and extends all information concerning glycol-ethers.

⁴⁶ According to the legislation of South Korea (see Annex I).

⁴⁷ According to the legislation of California (see Annex I).

⁴⁸ The presence of DEG is prohibited in the final cosmetic product. Due to its technical inevitability as an impurity in raw materials, its presence is allowed as a trace in the final product up to a concentration of 0.1%, except in the markets of Japan and China, where no trace limit is established.

⁴⁹ MACs: oxidative hair dye (7%) and non-oxidative hair dyes (5%); rinse-off products (other than hair dyes) (10%); other cosmetic products and the following products in aerosol format: fine fragrances, hair sprays, antiperspirants and deodorants (2.6%). Not to be used in eye products and oral products.

⁵⁰ The level of ethylene glycol impurity in raw material must be $\leq 0.1\%$.

⁵¹ Its use is allowed, as long as it does not contain 2-methoxypropanol (1PG2ME) in concentration equal to or more than 0.5% (see legislation of Canada, Annex I).

⁵² Its use is allowed, as long as it does not contain 2-methoxypropanol (1PG2ME) and/or 2-methoxypropyl-1-acetate (1PG2MEA) in concentration equal to or more than 0.5% (see legislation of Canada, Annex I).

⁵³ MAC = 2%.

⁵⁴ See Annex XIII to find out what the acronyms stand for each one of the analytical techniques.

⁵⁵ The quantification limit for the selected method will be less than or equivalent to 0.0001% (1 ppm) for all the glycol-ethers considered.

III.6 Residual products from surfactants

1. What are they?

They come from ethoxylation reactions used in the synthesis of surfactants (ethoxylated surfactants are foaming agents, emulsifiers and moisturisers extensively used in cosmetics). Among the residual products generated in this synthesis are 1,4-dioxane and ethylene- and propylene oxides. Therefore, none of these compounds are cosmetic ingredients themselves, but are formed from the potential reactions of ingredients that are commonly used in cosmetic products; basically, in products that produce foam, such as shampoos, liquid soaps, etc. Aldehydes may also be formed in ethoxylation processes, such as formaldehyde which in aqueous solution will be in equilibrium with its hydrated form methylene glycol.

Alkylphenol ethoxylates (APEOs) are one of the families of non-ionic surfactants. The degradation of APEOs could give rise to the formation of alkylphenols (APs).

2. Where can they be found?

They may appear either in the raw materials or in cosmetics that containing them.

3. What are their acceptable limits?

The following substances cannot form part of the composition of cosmetic products: **1,4-dioxane**⁵⁶ (CAS 123-91-1; EC 204-661-8), **ethylene oxide** (CAS 75-21-8; EC 200-849-9), **propylene oxide** (CAS 75-56-9; EC 200-879-2), **alkylphenols**⁵⁷, **alkylphenol ethoxylates**⁵⁸, **formaldehyde** (CAS 50-00-0; EC 200-001-8) and **methylene glycol** (CAS 463-57-0; EC 207-339-5).

4. How are they analysed?⁵⁹

1,4-Dioxane⁶⁰, ethylene oxide and propylene oxide⁶¹ can be analysed by GC-MS or GC-FID.

Formaldehyde⁶¹ can be analysed by HPLC-DAD with post-column derivatisation.

Alkylphenols and alkylphenol ethoxylates⁶² can be analysed by liquid chromatography, either coupled to conventional detectors (HPLC-DAD or HPLC-FLD) or to mass spectrometry (LC-MS or LC-MS/MS); alternatively, the GC-MS technique can be used.

5. How can they be controlled?

By obtaining from our suppliers the undertaking and the guarantee that the surfactants used in the manufacture of the cosmetic products they supply do not contain these residual products (there are procedures for their removal from ethoxylated products).

Evaluating the use of alternative processes to ethoxylation.

⁵⁶ The limit for this substance in the Final Cosmetic Product is no detection: $nd \approx < 0.001\% \approx < 10$ ppm, except in New York, where the no detection limit for personal care products is $nd \approx < 0.0001\% \approx < 1$ ppm (see Annex I). In New York, personal care products are those intended for cleaning the skin and hair and including, but not limited to, hair shampoo, hair conditioner, soap, bath gels, and other bath products.

⁵⁷ Nonylphenol (CAS 25154-52-3; EC 246-672-0) and branched 4-nonylphenol (CAS 84852-15-3; EC 284-325-5) are expressly prohibited.

⁵⁸ Nonylphenol polyethylene glycol ether (CAS 127087-87-0; EC 500-325-8) is expressly prohibited (see legislation of Taiwan, Annex I).

⁵⁹ See Annex XIII to find out what the acronyms stand for each one of the analytical techniques.

⁶⁰ The quantification limit for the selected method will be less than or equivalent to 0.0001% (1 ppm).

⁶¹ The quantification limit for the selected method will be less than or equivalent to 0.001% (10 ppm).

⁶² The quantification limit for the selected method will be less than or equivalent to 0.00001% (0.1 ppm) for alkylphenols (APs) and less than or equivalent to 0.01% (100 ppm) for alkylphenol ethoxylates (APEOs).

III.7 Volatile organic compounds

1. What are they?

Volatile organic compounds (VOCs) are chemical compounds whose vapor pressures are high enough to evaporate into the atmosphere at room temperature. Within the scope of this standard, volatile organic compounds (VOCs) refer to any organic compound (containing at least one carbon atom) that participates in atmospheric photochemical reactions, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate. Additionally, those VOCs that have been determined to have insignificant photochemical reactivity are also excluded (see **Annex VIII bis**).

2. Where can they be found?

VOCs can be found in a wide variety of consumer products, including cosmetic products, with fragrances standing out among them, as well as other products such as hair care products, deodorants, and antiperspirants. When used, these products can inadvertently emit VOCs into the environment.

3. What are their acceptable limits?

The following tables specify the VOCs content limits based on the type of product.

The VOCs content limits established for Tables 1 and 3 do not include any VOC classified as low vapor pressure organic compounds (LVP-VOC), which are those that meet any of the following characteristics:

- It has a vapor pressure of less than 0.1 mm Hg at 20°C; or
- It has a boiling point above 216°C; or
- It consists of more than 12 carbon atoms, if the vapor pressure and boiling point are unknown.

Table 1. VOCs content limits in Personal Fragrance Products⁶³.

Product type	Maximum VOCs content limit (%) ⁶⁴
Personal Fragrance Product	Aerosol products: a) Products ≤ 20% fragrance: 70 b) Products > 20% fragrance: 65
	Non-aerosol products: a) Products ≤ 7% fragrance: 70 b) Products 7% < fragrance ≤ 20%: 75 c) Products > 20% fragrance: 65

⁶³ According to the legislation of California and Canada (see Annex I).

⁶⁴ For the calculation of VOCs content, fragrance is not considered. Fragrance is defined as any substance or complex mixture of aroma chemicals, nature essential oils, and other functional components with a combined vapor pressure not in excess of 2 mm Hg at 20°C, the sole purpose of which is to impart an odour or scent, or to counteract a malodour.

Table 2. VOCs content limits in deodorants and antiperspirants⁶⁵.

Product type	Maximum VOCs content limit (%) ⁶⁶
Antiperspirant	Aerosol: 40 HVOC⁶⁷ / 10 MVOC⁶⁸ Non-aerosol: 0 HVOC / 0 MVOC
Deodorant	Aerosol: 0 HVOC / 10 MVOC Non-aerosol: 0 HVOC / 0 MVOC

Table 3. VOCs content limits in cosmetic products (other than personal fragrance products, deodorants, and antiperspirants)⁶⁹.

Product type	Maximum VOCs content limit (%) ⁷⁰			
	California	USA	Canada	Hong-Kong
Astringent / Toner	35	Not restricted	35	Not restricted
Dry shampoo	55	Not restricted	Not restricted	Not restricted
Hair finishing spray	50	80	55	55
Hair mousse	6	16	6	Not restricted
Hair shine	55	Not restricted	55	Not restricted
Hair styling product (product for moulding, combing, sculpting hair)	Aerosol or pump spray: 6 Other forms: 2	6	Aerosol or pump spray: 6 Other forms: 2	Not restricted
Nail polish remover	1	85	1	Not restricted
Shaving cream (aerosol)	5	5	5	Not restricted
Shaving gel (aerosol)	4	Not restricted	4	Not restricted
Temporary hair color (aerosol)	55	Not restricted	55	Not restricted
Heavy-duty hand cleaner or soap	Non-aerosol: 1 Other forms: 8	Not restricted	Non-aerosol: 1 Other forms: 8	Not restricted

4. How are they analysed?

The volatile organic compound content is determined according to the CARB Method 310 "Determination of volatile organic compounds (VOCs) in consumer products and reactive organic compounds in aerosol coating products" by the California Environmental Protection Agency. The product formulation must be used to calculate the VOC content.

⁶⁵ According to the legislation of the USA, California and Canada (see Annex I).

⁶⁶ For the calculation of VOCs content, fragrance and colorants shall not be considered up to a combined level of 2% by weight. In addition, VOC compounds that contain more than 10 carbon atoms per molecule and for which the vapor pressure is unknown, or that have a vapour pressure of 2 mm Hg or less at 20°C shall also not be considered. The specified MVOC content shall not apply to ethanol.

⁶⁷ High Volatility Organic Compound (HVOC) means any organic compound that exerts a vapor pressure greater than 80 mm Hg when measured at 20°C.

⁶⁸ Medium Volatility Organic Compound (MVOC) means any organic compound that exerts a vapor pressure greater than 2 mm Hg and less than or equal to 80 mm Hg when measured at 20°C.

⁶⁹ According to the legislation of the USA, California, Canada and Hong Kong (see Annex I).

⁷⁰ For the calculation of VOCs content, fragrance is not considered (until 2% of concentration).

5. How can they be controlled?

By obtaining from our suppliers the undertaking and the guarantee that the raw materials and the manufacturing process ensure that the VOCs percentage in the final product does not exceed the established VOCs content limit.

Annex VIII details and extends all information concerning the VOCs.

Annex VIII bis details and extends all information concerning the VOCs excluded from the VOCs calculation.

III.8 Perfluoroalkyl and polyfluoroalkyl substances (PFAS)

1. What are they?

Perfluoroalkyl and polyfluoroalkyl substances (PFAS) are a large group of synthetic organic compounds that contain fluorine atoms bonded to carbon atoms. They are highly resistant to degradation, making them persistent and toxic in the environment and in the human body.

There are definitions of PFAS issued by various international organizations, such as the OECD, as well as by administrations like the European Union (ECHA) and the United States of America, both at the federal level and in certain states.

2. Where can they be found?

PFAS can be found in cosmetic products, both as intentionally added ingredients and as potential impurities from the raw material manufacturing process and/or as degradation products.

When they are intentionally added, PFAS can act as emulsifiers, antistatic, stabilisers, surfactants, film-formers, viscosity regulators, and solvents. Their properties enable the manufacture of cosmetic products that repel water and oil, among others. At the final product, intentionally added PFAS can be found in a wide range of cosmetic products, such as lotions, cleansers, nail polishes, shaving creams, lip and eye products, hair products, foundations, powders, and others. They may also be unintentionally present in the previously mentioned cosmetic categories, among others.

In the case of PFAS impurities, these may come from ingredients used as bulking agents, such as mica or talc, which may be coated with per- and polyfluoroalkyl substances to provide a hydrophobic characteristic that improves the durability and wear of the products. Another potential source is certain colorants added to cosmetic products. PFAS can also result from the degradation of ingredients with per- or polyfluorinated functional groups, such as methicone, dimethicone, acrylates, methacrylates or silicone polymers, among others.

3. What are their acceptable limits?

Perfluoroalkyl and **polyfluoroalkyl substances (PFAS)** cannot be part of the composition of cosmetic products.

4. How are they analysed?⁷¹

Individual PFAS can be analysed using LC-MS/MS, GC-MS or GC-MS/MS. The determination of total fluorine content can be used as a tool in a potential screening strategy.

5. How can they be controlled?

By obtaining from our suppliers the undertaking and the guarantee that the cosmetic products they supply do not contain per- or polyfluoroalkyl substances (PFAS), their precursors, raw materials treated with PFAS or other compounds related to PFAS.

Avoiding the use of packaging materials or machinery surfaces/connections treated with PFAS or PFAS-related compounds.

Annex IX details and extends all information concerning PFAS.

⁷¹ See Annex XIII to find out what the acronyms stand for each one of the analytical techniques.

III.9 Colorants

1. What are they?

They are substances whose sole or main purpose is to colour the cosmetic product, or the whole body or parts thereof (skin, lips, eyes, etc.) by absorbing or reflecting visible light. Colouring agents intended to colour hair are considered a different type of cosmetic ingredient and they have specific restrictions that are not contemplated in this standard⁷².

Colouring agents are classified into two major groups: colorants (or dyes), which are organic compounds that will dissolve in water or oils; and pigments, dyeing agents in the form of insoluble particles or crystals, that can be organic or mineral. They can be of natural origin (mineral, botanical or animal) or synthetic origin.

2. Where can they be found?

Water-soluble colorants are used in lotions, parfums, emulsions, soaps and bathroom products -shampoo, gel, etc.-, where a covering effect is not required, whereas liposoluble colorants are used in bath oils, tanning oils, etc.

Inorganic pigments or insoluble organic dyes (lakes) are commonly used in solid products such as make-up powder, eye pencils and shadows, lips and nails cosmetics and soaps and mascaras. The proportion of colorants and pigments in decorative cosmetics can range from 1 to 25% and are usually added as mixtures; other non-decorative cosmetic products, such as creams, tonics, gels, etc., contain much lower proportions (0.01-0.3%) to colour the product.

3. What are their acceptable limits?

Use of Colorants: only the colorants specified in the Global List of Colorants⁷³ (Annex X), can be used, with the limits and restrictions mentioned in each case. Additionally, a Regionalised List of Colorants⁷³ is included (with their respective limits and restrictions) that can only be used in exceptional circumstances and with prior approval of Inditex.

Impurities: the legislations that establish limit of impurities related with colorants can be found in Annex X *bis* (Global List of Metal Impurities and Regionalised List of Metal Impurities). Those legislations set the maximum limits for metals and other elements allowed for each of the colorants included in the corresponding Global and Regionalised List of Colorants mentioned in the previous paragraph.

4. How are they analysed?⁷⁴

Organic colorants⁷⁵ are analysed by liquid chromatography, either with conventional approximations (HPLC-UV-Vis or HPLC-DAD) or with selective detectors (LC-MS/MS); alternatively, CE can be used. The inorganic components can be determined by XRFS or AAS.

⁷² In the event that these substances are used as ingredients in the composition of a cosmetic product, contact the Sustainability Department of Inditex.

⁷³ Generally, and for the purpose of the information contained in the lists of colorants, a colorant shall include its salts and lakes, and, when expressed as a specific salt, its other salts and lakes shall also be included.

⁷⁴ See Annex XIII to find out what the acronyms stand for each one of the analytical techniques.

⁷⁵ The quantification limit will be less than or equivalent to 1% for all the compounds considered, with the exception of CI 59040 (0.01%), CI 60725 (0.3%), CI 75810 (0.1%), CI 42520 (0.0005%) and bromothymol blue (0.2%).

5. How can they be controlled?

By obtaining from the suppliers of chemical substances, the undertaking and the guarantee that the raw materials used in the manufacture of products destined to Inditex do not contain colorants or pigments that are not included in the Global List of Colorants (Annex X) referred to above.

Establishing a control system for raw materials and finished products that allows compliance with the mentioned provisions to be established.

Annex X (Global List of Colorants and Regionalised List of Colorants) contains the information concerning the use of colorants in cosmetic products.

Annex X bis (Global List of metal impurities and Regionalised List of metal impurities) contains the legislations which stated impurities' limits associated with each one of the colorants mentioned in the List concerned in **Annex X**.

III.10 Preservatives

1. What are they?

A variety of chemical substances that are added to cosmetics, exclusively or mainly, to inhibit the development of microorganisms in the cosmetic product. Preservatives are used to guarantee the effectiveness of the cosmetic product during the time it takes the consumer to finish it. However, the use of preservatives can also cause undesirable effects (irritation, allergies, etc.); therefore, the right choice of preservatives must guarantee the absence of undesirable side effects and, at the same time, comply with the requirements for guaranteeing the absence of microbial action.

2. Where can they be found?

The cosmetic manufacturing procedures and the raw materials can compromise the stability of the preservation process of a cosmetic. For this reason, preservatives are not only found in finished cosmetic products, but also in the raw materials used in their manufacture and in intermediate products of the process.

Among the final products, those with an aqueous base stand out, as microbial growth will be more likely, while there are others that can be classified as having a low risk of microbiological contamination.

3. What are their acceptable limits?

Use of Preservatives: only the preservatives specified in the Global List of Preservatives⁷⁶ (Annex XI), can be used, with the limits and restrictions mentioned in each case. Additionally, a Regionalised List of Preservatives⁷⁶ is included (with their respective limits and restrictions) that can only be used in exceptional circumstances and with prior approval of Inditex.

Warnings: these lists also contain the warnings that must be included in the product, when they exist. This does not exempt the manufacturer from complying with the general labelling standards for the products marketed by Inditex.

4. How are they analysed?⁷⁷

In general, preservatives⁷⁸ can be determined by GC or HPLC either coupled to conventional detectors or, preferably, to mass spectrometers (MS or MS/MS).

5. How can they be controlled?

By obtaining from the suppliers of chemical substances the undertaking and the guarantee that the raw materials used in the manufacture of products destined to Inditex do not contain preservatives that are not included in the Global List of Preservatives (Annex XI) referred to above.

Establishing a control system for raw materials and finished products that allows compliance with the mentioned provisions to be established.

Annex XI (Global List of Preservatives and Regionalised List of Preservatives) contains the information concerning the use of preservatives in cosmetic products.

⁷⁶ For the purposes of the information contained in the lists of preservatives, 'salts' is taken to mean salts from the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines; and salts from the anions chloride, bromide, sulphate and acetate; and 'esters' is taken to mean: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl and phenyl.

⁷⁷ See Annex XIII to find out what the acronyms stand for each one of the analytical techniques.

⁷⁸ The quantification limit will be considerably lower than the maximum allowable concentration for each compound considered.

III.11 UV Filters and sun protection

1. What are they?

- **UV Filters**

UV Filters are substances that have a high capacity to absorb UV radiation and are therefore generally used in sunscreen cosmetic products, although they can be added to other cosmetic products. This specific filtering capacity of certain radiations (UVA: 320-400 nm and UVB: 290-320 nm) is used to protect the skin against certain UV radiation by absorbing, reflecting or scattering UV radiation.

The restrictions established in this chapter do not generally apply to substances used as UV absorbers, which are those added to a product formulation solely to protect the product from UV radiation⁷⁹. UV filters included in this section (see Annex XII) may be used as UV absorbers.

- **Sun protection**

A sunscreen product is defined as any formulation (cream, oil, gel, or aerosol) applied to human skin with the exclusive or primary purpose of protecting it from UV radiation. Within sunscreen products, there are two different types:

- a) Primary sunscreens: these are products whose main function is to protect the skin from solar radiation and,
- b) Secondary sunscreens: these are products in which the function of protecting the skin from solar radiation is not the primary purpose of the product, but rather a secondary function.

This section applies to both types of products.

Sunscreen products, under various regulations, can be classified as either cosmetic product or as another type of product, falling between cosmetics and drugs.⁸⁰

2. Where can they be found?

In cosmetics, in addition to specific sunscreen products, they are often used in lipsticks, in make-up products, moisturising day creams and in after-shave products.

3. What are their acceptable limits?

Use of UV Filters: only the UV filters specified in the Global List of UV Filters (Annex XII), can be used, with the limits and restrictions mentioned in each case. Additionally, a Regionalised List of UV Filters is included (with their respective limits and restrictions) that can only be used in exceptional circumstances and with prior approval of Inditex.

Warnings: these lists also contain the warnings that must be included in the product when they exist. This does not exempt the manufacturer from complying with the general labelling standards for the products marketed by Inditex.

⁷⁹ In some markets, the definition of a UV Filter and a UV Absorber may differ from the one established here. If a substance is used as a UV Absorber and it is not included in the list of UV Filters, please contact the Inditex Sustainability Department of Inditex.

⁸⁰ For any doubt regarding the classification of this type of product in specific market, contact the Sustainability Department of Inditex.

Efficacy of sunscreen products: in general, sunscreens must protect against both UVB and UVA radiation. The limits are:

- Sun protection factor against radiation UVB (SPF): minimum 15.
- Sun protection factor against radiation UVA: minimum 1/3 of SPF.
- Critical wavelength⁸¹: greater than or equal to 370 nm.

4. How are they analysed?⁸²

In general, UV filters⁸³ can be determined by HPLC-UV/VIS or LC-MS/MS.

To analyse the efficacy of sunscreens, it is necessary to consider the available ISO standards, please contact the Sustainability Department of Inditex.

5. How can they be controlled?

By obtaining from the suppliers of chemical substances, the undertaking and the guarantee that the raw materials used in the manufacture of products destined to Inditex do not contain UV filters that are not included in the Global List of UV Filters (Annex XII) referred to above.

Establishing a control system for raw materials and finished products that allows compliance with the mentioned provisions to be established.

By obtaining from the suppliers the undertaking and the guarantee that the efficacy of sunscreens has been measured using standardised and reproducible methods.

Annex XII (Global List of UV Filters and Regionalised List of UV Filters) contains the information concerning the use of UV filters in cosmetic products.

⁸¹ Critical wavelength is defined as the wavelength at which the area under the optical density curve, starting at 290 nm, is equal to 90% of the area integrated between 290 and 400 nm.

⁸² See the Annex XIII to find out what the acronyms stand for each one of the analytical techniques.

⁸³ The quantification limit will be less or equivalent to 0.5% for all the compounds considered.

III.12 pH

1. What is it?

It is a parameter used to indicate the acidity or alkalinity (basicity) of a particular substance or a finished cosmetic product. Its value ranges from 0 (more acid) to 14 (more alkaline).

The pH is controlled through the use of buffers, which are chemical substances essential to preserve the stability of the formulations and the effectiveness of the finished cosmetic product.

2. Where is it measured?

In cosmetic products, in general.

3. What are their acceptable limits?

Cosmetic products supplied to Inditex shall have pH values ranging from 4 to 8. A pH value not within the proposed range may be accepted, if this value is essential to enable the cosmetic product to suitably comply with its function. In these cases, please contact with the Sustainability Department of Inditex beforehand.

The pH value of both the raw materials used in a given formulation and the finished cosmetic product are documentary requirements in the cosmetic product safety report (see PIF: Section IV of this standard, Part A, point 2).

4. How is it determined?

It is measured with a pH meter. The pH meter must be able to measure with a precision of ± 0.1 pH units and its minimum threshold must be 0.01 pH units.

5. How can it be controlled?

By obtaining from our suppliers the undertaking and the guarantee that buffers have been used in the manufacturing process whenever necessary; and that the finished cosmetic product complies with the pH limits established in this standard.

III.13 Microbiological control

1. Microbial contamination. What is it?

Cosmetic products must be properly preserved to prevent microbial contamination and deterioration, thus a suitable preservative system must be used when formulating the product (see section III.10 of preservatives). The different stages in the assessment of the design, manufacture, packaging and expected use of the cosmetic must consider the potential sources of microbial contamination that could affect the product, even after its commercialisation.

2. Microorganisms. Where can they be found?

All cosmetic products are exposed to microbiological contamination, but the degree of risk⁸⁴ depends on the ability of the product to sustain the growth of microorganisms and the probability that these microorganisms may cause harm to the user. Their source may come from the cosmetic manufacturing process or from the use by the consumer. Cosmetic products must not contain pathogenic microorganisms.

3. What are their acceptable limits?

The requirements that must be fulfilled in the microbiological control of the cosmetic products are summarised in the following table⁸⁵:

	Limits in cosmetic products
Total n° of Aerobic Mesophilic Microorganisms⁸⁶ (Bacteria, yeast and moulds)	< 100 CFU in 1 g (ml) ⁸⁷
Bacteria⁸⁸	
<i>Pseudomonas aeruginosa</i>	Absence in 1 g or 1 ml
<i>Staphylococcus aureus</i>	Absence in 1 g or 1 ml
<i>Escherichia coli</i> (Fecal coliforms)	Absence in 1 g or 1 ml
<i>Salmonella spp</i> ⁸⁹	Absence in 25 g or 25 ml
Yeast	
<i>Candida albicans</i>	Absence in 1 g or 1 ml

⁸⁴ The degree of risk is assessed in compliance with Standard ISO 29621:2017 Guidelines for the risk assessment and identification of microbiologically low risk products.

⁸⁵ When the cosmetics are in ampoules, these must be free of microorganisms (Sterility compliance), (see legislation of the Eurasian Customs Union, Annex I).

⁸⁶ Microorganisms that develop in the presence of free oxygen and at an optimum growth temperature ranging from 15 °C to 35 °C.

⁸⁷ CFU: Colony Forming Unit.

⁸⁸ In MERCOSUR (applicable only to talcum powders) and Thailand (applicable only to products containing herbs or plants), the presence of *Clostridium spp* must be monitored, with the established limit as follows: absence in 1 g or 1 ml (see Annex I).

⁸⁹ According to the legislation of the United Mexican States (see Annex I).

4. How are they analysed?

All the processes that involve a suitable microbiological control of the cosmetic products are regulated by ISO norms (International Organization for Standardization), which are required by this standard. For the correct microbiological risk assessment and microbiological control, please refer to Annex XIV⁹⁰.

Microbiological tests of cosmetic products also involve, as can be seen in the decision tree (Annex XIV), the detection (presence/absence) and enumeration of microorganisms as well as the identification of specific and non-specific microorganisms⁹¹. Most of those considered to be specific microorganism include one or more of the following species: *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus* and *Candida albicans*. Annex XIV also includes a diagram that summarises how to apply the ISO microbiology standards and the conclusions that can be derived from them.

5. How can it be controlled?

By obtaining from our suppliers the undertaking and the guarantee that the assessment and control over the microbiological risks involving their products have been suitably conducted, in accordance with the ISO norms concerned.

In addition, by obtaining the undertaking that the preservative systems used in their products are suitable and cover the useful life of the product, along with complying with the restrictions specified in each case.

Annex XIV (Microbiological Control) contains the information concerning the standard test procedures for controlling microorganisms in cosmetic products.

⁹⁰ The standards indicated below are essential for the application of all the standards explicitly mentioned in the text and/or the decision tree (Annex XIV).

ISO 22716:2007 Cosmetics. Good Manufacturing Practices (GMP). Guidelines on Good Manufacturing Practices.

ISO/TR 19838:2016 Guidelines for the application of ISO standards on Cosmetic Microbiology.

ISO 21148:2017 Cosmetics. Microbiology. General instructions for microbiological examination.

EN 12353:2021 Chemical disinfectants and antiseptics. Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity.

ISO 21322:2020 Cosmetics. Microbiology. Testing on impregnated or coated wipes and masks.

ISO 29621:2017 Cosmetics. Microbiology. Guidelines for the risk assessment and identification of microbiologically low risk products.

ISO 18415:2017/Amd 1:2022 Cosmetics. Microbiology. Detection of specified and non-specified microorganisms.

ISO 21149:2017/Amd 1:2022 Cosmetics. Microbiology. Enumeration and detection of aerobic mesophilic bacteria.

ISO 16212:2017/Amd 1:2022 Cosmetics. Microbiology. Enumeration of yeast and moulds.

⁹¹ Aerobic mesophilic microorganisms not defined in the specific microorganisms' section.

IV. Legal Documentation Requirements (PIF)

Documental requirements (PIF)

This section specifies the documentation that must accompany each Cosmetic Product (hereinafter referred to as, CP) in the marketing process. In the European Union, the Regulation requires the preparation of a Product Information File (PIF), the structure and content of which are detailed below. Inditex will require this PIF, among other documents or certificates that are also compulsory in other countries.

The existence of this documentation does not exempt from the fulfilment of any other documental requirements imposed by the applicable legislation, even when such requirements are not specifically mentioned in this section.

Summary of the EU legal framework

Cosmetic products made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use.

In order to demonstrate that a CP complies with the statement, prior to placing a CP on the market, the responsible person shall ensure that it has undergone a safety assessment on the basis of the relevant information, and that a cosmetic product safety report⁹² is set up in accordance with Annex I of Regulation (EC) N° 1223/2009 and with the guidelines established in the Commission Implementing Decision of 25th November 2013⁹³.

As a prerequisite for any cosmetic product on the market as from July 2013, a Product Information File (PIF) must be prepared for the cosmetic product, which the EU authorities may request for review at any time and that shall be kept for ten years following the date on which the last batch was placed on the market. Based on Royal Decree 85/2018 by which cosmetic products are regulated, the information contained in the product information file on the cosmetic product that is kept in Spanish territory must appear in Spanish language.

The Product Information File (PIF) shall contain the following information, which shall be updated as necessary. The information is structured into 5 parts: a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product; a description of the method of manufacturing and a statement on compliance with Good Manufacturing Practices (GMP); where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product; data on any animal testing which is prohibited in the EU (not only for finished products but also for ingredients and their combinations) and that must be replaced by alternative methods; and the element that is most important from the perspective of consumer safety: the cosmetic product safety report.

Product Information File

1	2	3	4	5
Description of the CP	Description of the Manufacturing Method + GMP	Proofs on the Effect Claimed for the CP	Data on Animal Testing	CP Safety Report (CPSR)

⁹² By virtue of article 11 of Regulation (EC) N° 1223/2009, a Product Information File must be prepared for the cosmetic product before it is placed on the market.

⁹³ The Commission, in close cooperation with all the interested parties, will adopt a series of suitable guidelines that will enable the companies, especially the small and medium-sized ones, to comply with the requirements established in Annex I. Commission Implementing Decision dated 25th November 2013 concerning the guidelines for Annex I of Regulation (EC) N° 1223/2009 issued by the European Parliament and Council on cosmetic products (Text relevant for the purpose of the EEE) (2013/674/EU). D.O. 26.11.2013.

Product Information File (PIF)

1. Description of the Cosmetic Product

The PIF begins with a description of the CP, which enables the Product Information File to be clearly attributed to the CP. This description must include: a) the presentation, including the certificate of having notified to the European portal CPNP and compliance with the Regulation EU 2023/988⁹⁴ concerning products which, appearing to be other than they are, endanger the health or safety of consumers and b) the labelling. A photograph of the packaging or the artwork may be enclosed in the PIF to show the presentation of the product and its intended use.

2. Description of the Manufacturing Method and Good Manufacturing Practices (GMP)

To ensure their safety, cosmetic products placed on the market should be produced according to Good Manufacturing Practices (GMP) (Regulation (EC) N° 1223/2009 [See Section II. Legal Requirements of Production]). A description of the manufacturing method as well as the declaration of conformity with GMP should be included.

3. Proofs on the Effect Claimed for the Cosmetic Product

Where justified by the nature or the effect of the cosmetic product, the proofs of the effect claimed for cosmetic product have to be included in the PIF.

4. Data on Animal Testing

Animal testing for the finished cosmetic products and for the cosmetic ingredients is prohibited⁹⁵.

The testing and marketing bans in the cosmetic regulation apply even in case alternative methods to animal testing are not yet available.

Any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries must be included in the PIF.

⁹⁴ The products to which this Regulation refers are those that, without being food products have a shape, and odour, a colour, an appearance, a presentation, a labelling, a volume or a size that are such that it is likely that the consumers, especially children, could mistake them for food products and put them in their mouths, lick them or swallow them. Their commercialisation, manufacture, import and export are prohibited.

⁹⁵ COM (2013) 135 final: Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics.

5. Cosmetic Product Safety Report (CPSR)

This report is structured into two parts, and must include⁹³:

Part A: Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product

- Complete product composition, stating the name and the identity (qualitative) of each raw material (including chemical name, INCI, CAS, EINECS/ELINCS, where possible), and the amount of each raw material, stating the weight percentage (quantitative). Ranges should not be used, unless this can be justified.
- It may also be useful to indicate the supplier(s) of the raw materials.
- All substances entering into the composition of commercial mixtures supplied as raw materials (including directly added preservatives, antioxidants, chelators, buffering agents, solvents, other additives, etc.) are to be identified and quantified in the formula of the finished product. This also applies to all substances indirectly added to the product, such as preservatives used for preserving raw materials.
- The intended function of each substance is to be indicated.
- When chemically well-defined substances are present, their quantity and molecular formula should be given together with their analytical specifications (degree of purity, identification of major impurities, criteria and test methods used).
- When complex ingredients are present (for example, of mineral, botanical, animal or biotechnological origin), their nature and quantity together with a clear definition of the mixture and the material(s) used should be given in order to identify the substances with regard to their composition and effects (manufacturing and purification processes, including physical, chemical, enzymatic, biotechnological and microbiological steps). The purity criteria and test methods used should be provided.
- In the case of fragrance (or flavour) compounds, their identification is to include: the name, their code number, the identity of the supplier, the safety assessment, the IFRA certificate and the declaration of fragrance allergens.

2. Physical/chemical characteristics and stability of the cosmetic product

- Physical and chemical characteristics of the raw materials and of the finished cosmetic product (pH, odour, density, viscosity, etc.).
- Stability of the cosmetic product.
- Assessment and determination of its minimum durability or period after opening of the product (PAO).

3. Microbiological quality

- The microbiological quality of the raw materials and of the finished cosmetic product.
- Products with a “low microbiological risk” do not require preservation challenge test nor microbiological quality tests, but the “low microbiological risk” has to be justified⁹⁶.

⁹⁶ Guidelines for the risk assessment and identification of microbiologically low risk products ISO 29621:2017.

- Single-use products, and products that cannot be opened (e.g. for which the packaging allows dosing the product without it coming in contact with the air), no preservation challenge test is required; but a scientific explanation must be given as to why it is not necessary to conduct this test. However, microbiological quality tests will be required⁹⁷.
- For all other products, both the preservation challenge test and the microbiological quality tests on the finished product are required.
- For the detection and identification of specific microorganisms in cosmetic products, or of other types of non-specified microorganisms, the general guidelines concerned must be followed⁹⁸.

4. Impurities, traces and information about the packaging material

Impurities are unintended substances in raw materials. A trace is a small quantity of an unintended substance in the finished product. The presence of impurities and traces can be assessed in several ways:

- Through the specifications/technical data for each raw material.
- Through a physicochemical analysis of possible impurities in raw materials and, if necessary, in the final product.
- If there are any traces of prohibited substances in the final product⁹⁹, their toxicological effects must be assessed.
- The presence of traces of prohibited substances must remain as low as reasonably achievable level in keeping with good manufacturing practice (ALARA)¹⁰⁰.
- The relevant characteristics of packaging material must also be taken into consideration (composition of the packaging material and technically unavoidable impurities), including the possible migration of substances from the packaging to the product. The correct packaging-product compatibility must be ensured.

5. Normal and reasonably foreseeable use

- A clear explanation of the normal intended use and the reasonably foreseeable use should be provided. The intended use should be appropriately communicated to the consumer in order to avoid misuse of the product.
- Warnings and other explanations on the labelling should be consistent with the identified normal and reasonably foreseeable use, and the reasoning justifying their inclusion is to be given.

6. Exposure to the cosmetic product

The amount of cosmetic product coming into contact with the external parts of the human body or the teeth and the mucous membranes of the oral cavity under normal or reasonably foreseeable use for each use and the frequency of use shall be quantified. It should take the following parameters into account: product type; area of application; amount per application; duration and frequency; possible routes of exposure; target group for use; and impact of particle size on exposure.

⁹⁷ Evaluation of the antimicrobial protection of a cosmetic product ISO 11930:2019/Amd 1:2022.

⁹⁸ Detection of specified and non-specified microorganisms ISO 18415:2017/Amd 1:2022.

⁹⁹ By virtue of article 17 of Regulation (EC) N° 1223/2009, traces of prohibited substances are only permitted if they are technically unavoidable and if they do not affect the safety of the cosmetic products. In this case, the cosmetics manufacturers are required to provide evidence of the technical unavoidability. That means that they have to justify the presence of those traces by all necessary means.

¹⁰⁰ ALARA: As low as reasonably achievable.

7. Exposure to the substances

The amount of each substance coming into contact with the external parts of the human body or the teeth and the mucous membranes of the oral cavity under normal or reasonably foreseeable use, for each use, shall be determined. Exposure to each of the substances in the cosmetic product is calculated from the exposure to the final product and the concentration of the individual substances in the final product.

8. Toxicological profile of the substances

- Describe the toxicological hazard of each of the substances in the finished product, determine the potential exposure, and draw up a risk characterisation.
- The endpoints to be considered include the routes of exposure, the conditions of use of the product, the physicochemical characteristics and the possible absorption of the substances.
- Ensure that the experimental data complies with the requirements concerning prohibition of animal testing¹⁰¹.
- Endpoints that may be relevant for the toxicological profile for each substance are the following¹⁰²: acute toxicity via relevant routes of exposure; irritation and corrosivity; skin irritation and skin corrosivity; mucous membrane irritation (eye irritation); skin sensitisation; dermal/percutaneous absorption; repeated dose toxicity; mutagenicity/genotoxicity; carcinogenicity; reproduction toxicity; toxicokinetic; photo-induced toxicity.
- All the significant routes of absorption must be considered.
- The systemic effects must be considered, and the margin of safety (MoS) must be calculated.

9. Undesirable effects and serious undesirable effects

- Monitor the safety of the product after it has been placed on the market and to take corrective action, if necessary.
- The responsible person (in collaboration with the distributors) is required to set up a system to collect, document, establish the causality of and manage the undesirable effects caused by the product after its use; and to notify the competent authority when the undesirable effects are serious.
- Information on undesirable effects and serious undesirable effects is to be included in the cosmetic product safety report.

10. Information on the cosmetic product

- Skin compatibility studies carried out with the cosmetic product must be included to ensure the safety of the cosmetic product.
- This section of the cosmetic product safety report allows the inclusion of any additional information¹⁰³ that is considered relevant in order to carry out the safety assessment of the product.

¹⁰¹ COM (2013) 135 final: Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics.

¹⁰² For the required studied parameters, the most relevant concentrations or the No Observed Adverse Effect Level (NOAEL) or the Lowest Observed Adverse Effect Levels (LOAEL) must be identified to be used in the process of risk characterization. When a NOAEL is not available, other reference toxicology values such as No Observed Effect Level (NOEL) or Lowest Observed Effect Level (LOEL), can be used to calculate the margin of safety.

¹⁰³ Information not covered under the other headings of part A of Annex I of Regulation (EC) N° 1223/2009.

Part B: Cosmetic product safety assessment

Part B of the cosmetic product safety report consists of:

1. The **assessment conclusion:** it should state whether the product is safe, safe with restrictions or not safe for human health when used under normal or reasonably foreseeable conditions of use. Regulation (EC) N° 1223/2009 should be explicitly mentioned.
2. The **labelled warnings and instructions of use:** explicitly list the particular precautions to be observed in use, including at least those listed in Annexes III to VI to Regulation (EC) N° 1223/2009 which should appear on the labelling.
3. The **reasoning:** a clear and accurate explanation about how the safety assessor reaches his or her conclusions on the safety of the cosmetic product from the data gathered. It is the result of an expert evaluation of the available data.
4. The **credentials of the safety assessor and their final approval:** the name and address of the safety assessor must be specified and must be dated and signed. The result of the safety assessment is to be signed stating the date of preparation.

Annex XV contains "checklists" to facilitate the verification of the documentary content required in the PIF.

V. Other Mandatory Legislations

Other mandatory legislations

REACH

1. What is it?

REACH is a regulation of the European Union concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) N° 1907/2006 of the European Parliament and of the Council).

2. Is it of mandatory compliance?

REACH is a mandatory regulation for those suppliers that manufacture, distribute and/or supply cosmetic products, labels, containers and packaging (hereinafter, the “Products”) for any of Inditex’s “formats” and that, later, are set aside for sale in any of the European Union Member States.

To do so, the mentioned Suppliers, should control and manage properly any phase (their own and/or subcontracted) of “the manufacturing cycle” of the “Products” with the aim of: (1) detecting and, as a result, avoiding the presence of substances included in the list “Candidate List of Substances of Very High Concern for Authorisation”¹⁰⁴ in amounts higher than 0.1% of the total weight of the “Products” and (2) justifying the presence of SVHC to any external agency and/or the Sustainability Department of Inditex.

If the mentioned SVHC were detected in amounts higher than the above mentioned limit in the “Products” before their importation to any of the Member States of the European Union, Suppliers should notify immediately its existence to the Sustainability Department of Inditex, as well as the corresponding “Corrective Action Plan” for its appropriate elimination.

CLP

1. What is it?

CLP is a regulation of the European Union concerning the Classification, Labelling and Packaging of substances and mixtures (Regulation (EC) N° 1272/2008 of the European Parliament and of the Council).

2. Is it of mandatory compliance?

Regulation (EC) N° 1223/2009 on cosmetic products contains in its article 15 provisions on the use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR substances) under Part 3 of Annex VI to Regulation (EC) N° 1272/2008 and it indicates the following:

1. The use in cosmetic products of substances classified as **CMR substances of category 2**, under Part 3 of Annex VI to Regulation (EC) N° 1272/2008 shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by SCCS¹⁰⁵ and found safe for use in cosmetic products.
2. The use in cosmetic products of substances classified as **CMR substances of category 1A or 1B** under Part 3 of Annex VI to Regulation (EC) N° 1272/2008 shall be prohibited.

¹⁰⁴ Article 57 of REACH defines “Substances of Very High Concern” (SVHC) as those substances that are carcinogenic, mutagenic and/or toxic to human reproduction (CMR 1A and CMR 1B), those substances that are persistent, bioaccumulative and toxic (PBT), those substances that are very persistent and very bioaccumulative (vPvB) or those substances (such as those having endocrine disrupting properties or sensitizing substances) for which there is scientific evidence of potential serious effects to human health or the environment which give rise to an equivalent level of concern to the substances listed above and which are identified on a case-by-case basis in accordance with the procedure set out in article 59 of REACH. The list of SVHC substances can be consulted on the ECHA website (<http://echa.europa.eu/es/candidate-list-table>).

¹⁰⁵ Scientific Committee on Consumer Safety (SCCS).

The CLP regulation does not directly apply to cosmetic products as defined under Regulation (EC) N° 1223/2009, but it is necessary to take into account Part 3 of Annex VI of this regulation due to the prohibition of the use of CMR substances in cosmetic products established in the Regulation (EC) N° 1223/2009.

French Decree on endocrine disruptors in consumer products

Suppliers should control and manage properly any phase (their own and/or subcontracted) of "the manufacturing cycle" of the "Products" with the aim of: (1) detecting and, as a result, avoiding the presence of Endocrine Disruptors Substances (EDS) included in the list of Annex I of the NOR: TREP2323345A¹⁰⁶, in amounts higher than 0.1% of the total weight of the "Products" and (2) justifying the presence of EDS to any external agency and/or the Sustainability Department of Inditex.

Therapeutic Goods (Poisons Standard of Australia)

Suppliers should control and manage properly any phase (their own and/or subcontracted) of "the manufacturing cycle" of the "Products" with the aim of: (1) identifying the presence of any ingredient listed in the Poisons Standard in a concentration that classifies it in any of its lists for which additional labelling and/or packaging actions are required, and (2) communicating this situation to the Sustainability Department of Inditex.

¹⁰⁶ The list of endocrine disruptors can be found on the following website: https://www.legifrance.gouv.fr/loda/id/JORFTEXT000048193237?init=true&page=1&query=TREP2323345A&searchField=ALL&tab_selection=a

VI. Annexes

Annex I. List of the Documents Consulted to Prepare the Global Strategy for Comparing Legislations

Markets	Legislation
European Union	1907/2006/EC 1272/2008/EC 1223/2009/EC 231/2012/EU 2019/1021/EU and its corresponding amendments, adaptations, and error corrections
Saudi Arabia	SFDA – Lists of prohibited and restricted cosmetic ingredients, colorants, preservatives and UV filters
Argentina	Disposition 5930/1999 Disposition 5572/2005 Disposition 6544/2012 Disposition 7529/2013 Dispositions 11276/2016 and 13832/2016 Disposition 249/2017 Disposition 7078/2019 Disposition 8504/2021 Disposition 5978/2023 and its corresponding amendments, adaptations, and error corrections
Association of Southeast Asian Nations (ASEAN) (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam)	ASEAN Cosmetic Directive ASEAN Guidelines on Limits of Contaminants for Cosmetics
Australia	Australian Inventory of Chemical Substances (AICS) Industrial Chemicals Act 2019 Therapeutic Goods (Poisons Standard) and its corresponding amendments Australian regulatory guidelines for sunscreens (version 3.0, May 2023)
Brazil	RDC N° 638 (24-3-2022) RDC N° 752 (19-9-2022) RDC N° 645 (24-3-2022) IN N° 220 (13-4-2023) RDC N° 814 (1-9-2023)
Canada	Cosmetic Ingredient Hotlist Guidance on Heavy Metal Impurities in Cosmetics Prohibition of Certain Toxic Substances Regulations, 2022 Primary Sunscreen Monograph (2022-11-25) Secondary Sunscreen Monograph (2022-11-25) Volatile Organic Compound Concentration Limits for Certain Products Regulations (SOR 2021-268)
China	Safety and Technical Standards for Cosmetics 2015 (STSC 2015) and its corresponding amendments, adaptations, and error corrections Inventory of Prohibited Cosmetic Ingredients Inventory of Prohibited Plant (Animal) Ingredients for Cosmetics Inventory of Existing Cosmetic Ingredients in China - IECIC

Markets	Legislation
Andean Community (Bolivia, Colombia, Ecuador, and Peru)	Decision 833: Harmonization of Legislation on Cosmetic Products Resolution 1905: Prohibition on the use of long-chain parabens as ingredients in cosmetic products in the Andean Community Resolution 1953: Restriction and prohibition of the use of ingredients in cosmetic soaps for body cleaning and hygiene that have antibacterial or antimicrobial actions Resolution 2120 Andean Technical Regulation on Microbiological Technical Specifications for Cosmetic Products
Gulf Cooperation Council (GCC) (United Arab Emirates, Bahrain, Saudi Arabia, Oman, Qatar, Kuwait and Yemen)	Cosmetic Products - Safety Requirements of Cosmetics and Personal Care Products GSO 1943:2024
South Korea	Cosmetic Act; Cosmetic Act Decree; Cosmetic Act Enforcement Rules Regulations on safety standards for cosmetics Types and standards of pigments in cosmetics Regulations on precautions when using cosmetics and labelling of allergenic ingredients
Denmark	Statutory Order No. 1217 of 11 October 2013
Egypt	Decision No 122 (2022) ES 3570/2022 ES 7323/2011
Spain	Royal Decree 85/2018
United States of America	FEDERAL LAWS Food and Drug Administration. Title 21 CFR, Part 250, 700 Food and Drug Administration. Title 21 CFR, Part 310 Food and Drug Administration. Title 21 CFR, Part 73 (Color Additives Listed for Use in Cosmetics) Food and Drug Administration. Title 21 CFR, Part 74 (Color Additives Listed for Use in Cosmetics) Food and Drug Administration. Title 21 CFR, Part 82.51 (Lakes (FD&C)) Food and Drug Administration. Title 21 CFR, Part 82.1051 (Lakes (D&C)) Food and Drug Administration. Title 21 CFR, Part 82.2051 (Lakes (Ext D&C)) Food and Drug Administration. Title 21 CFR, Part 352 (Sunscreen Drug Products for Over-The-Counter Human Use) Food and Drug Administration. Title 40 CFR, Part 59 (National Volatile Organic Compound Emissions Standards for Consumer and Commercial Products) Modernization of Cosmetics Regulation Act of 2022 (MoCRA) STATE LAWS California: Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) Regulation for reducing volatile organic emissions from antiperspirants and deodorants Regulation for reducing emissions from consumer products Health and Safety Code – HSC. Division 104 – Chapter 14 Cosmetic safety Colorado: Colorado Revised Statutes, Title 25. Environmental Control. Article 15. Part 6 Connecticut: Public Act No. 24-59 Hawaii: Haw. Rev. Stat. §342-D-21 Maine: Title 38, Chapter 16, §1614 Maryland: Health – General. Section 21-259-2 New Hampshire: RSA 149-M Consumer Products; Per and Polyfluoroalkyl Substance Use Restricted Minnesota: Chapter 60—H.F.No.2310 New York: Environmental Conservation Law (ECL). Article 37. Title 1. Section 37-0117 New Mexico: Per- and Poly-Fluoroalkyl Substances Protection Act Oregon: Toxic-Free Act Rhode Island: Title 23 Health and Safety. Chapter 18.18 Comprehensive PFAS Ban Act of 2022 Vermont: 9 V.S.A chapter 63, subchapter 12 Chemicals in Cosmetic and Menstrual Products Washington: Chapter 70A.560 RCW Toxic-Free Cosmetics Act (TFCA)

Markets	Legislation
United Mexican States	Regulation of Health Control of Products and Services, DOF 12-2-2016 Ministry of Health, DOF 21-05-2010 Ministry of Health, DOF 11-03-2014 and its corresponding amendments NOM-141-SSA1/SCFI-2012 and its corresponding amendments
France	Decree N° 2021-1110 Law N° 2025-188
Hong-Kong	Consumer Goods Safety Ordinance (Cap. 456) (CGS) Consumer Goods Safety Regulation (Cap. 456 Section 30(1)(a)) (CGSR) Air Pollution Control (Volatile Organic Compounds) Regulation
India	2020 Cosmetic Rules Drugs and Cosmetics Act, 1940 and its corresponding amendments IS 4707 Part 1 (2020) IS 4707 Part 2 (2017) IS 4707 Part 4 (2022)
Indonesia	BPOM Regulation No. 17 of 2022 BPOM Regulation No. 479 of 2023 BPOM Regulation No. 16 of 2024
Israel	Pharmacists' Regulations (Cosmetics)
Japan	Standards for Cosmetics (Ministry of Health and Welfare Notification No. 331 of 2000) Ministerial Ordinance by the Ministry of Health, Labour & Welfare No. 87, 2014 Ministry of Health and Welfare Ordinance No. 30 of August 1966 Ministry of Health and Welfare Ordinance No. 15 of February 1961 Japanese Pharmacopoeia Japanese Pharmaceutical Excipients
Southern Common Market (MERCOSUR) (Argentina, Brazil, Paraguay, Uruguay and Venezuela)	MERCOSUR/GMC/RES N° 51/98 MERCOSUR/GMC/RES N° 24/11 MERCOSUR/GMC/RES N° 16/12 MERCOSUR/GMC/RES N° 62/14 MERCOSUR/GMC/RES N° 44/15 MERCOSUR/GMC/RES N° 35/20 MERCOSUR/GMC/RES N° 37/20 MERCOSUR/GMC/RES N° 14/21 MERCOSUR/GMC/RES N° 35/22
United Kingdom	Schedule 34 of the Product Safety and Metrology Statutory Instrument and its corresponding amendments UK Cosmetic Products Enforcement Regulations 2013
Thailand	Cosmetic Act B.E 2558 and its corresponding amendments
Taiwan	Cosmetic Hygiene and Safety Act
Turkey	Cosmetics Law N° 5324 and its corresponding amendments Regulation on Cosmetics N° 32184 and its corresponding amendments Guide to Heavy Metals in Cosmetic Products
Eurasian Customs Union (Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia)	On Safety of Perfumes and Cosmetics, TP TC 009/2011 and its corresponding amendments
Venezuela	Administrative Provision No 230-2018

Annex II. Summary Chart of Musk

Name of Common Ingredients Glossary	Chemical Name	CAS Number	EC Number	Limits ¹⁰⁷
NITROMUSKS				
Musk ambrette	4- <i>tert</i> -Butyl-3-methoxy-2,6-dinitrotoluene	83-66-9	201-493-7	nd
Musk moskene	1,1,3,3,5-Pentamethyl-4,6-dinitroindane	116-66-5	204-149-4	nd
Musk tibetene	5- <i>tert</i> -Butyl-1,2,3-trimethyl-4,6-dinitrobenzene	145-39-1	205-651-6	nd
Musk alpha ¹⁰⁸	1,3-dibromo-4-methoxy-2-methyl-5-nitrobenzene	61827-59-6		nd
Musk KS ¹⁰⁸	1,3-dibromo-2-methoxy-4-methyl-5-nitrobenzene	62265-99-0	263-479-7	nd
Musk ketone ^{109,110}	4'- <i>tert</i> -Butyl-2',6'-dimethyl-3',5'-dinitroacetophenone	81-14-1	201-328-9	1.4% in fine fragrance, 0.56% in eau de toilette, 0.04% in other products
Musk xylene ^{109,110}	5- <i>tert</i> -Butyl-2,4,6-trinitro- <i>m</i> -xylene	81-15-2	201-329-4	1% in fine fragrance, 0.4% in eau de toilette, 0.03% in other products
POLYCYCLIC MUSKS				
Versalide	3'-Ethyl-5',6',7',8'-tetrahydro-5',5',8',8'-tetramethyl-2'-acetonaphthone or 7-acetyl-6-ethyl-1,1,4,4-tetramethyl-1,2,3,4-tetrahydronaphthalen (AETT)	88-29-9	201-817-7	nd
Tonalide ¹¹⁰ ; acetyl hexamethyl tetralin; AHTN	1-(5,6,7,8-Tetrahydro- 3,5,5,6,8,8-hexamethyl -2-naphthyl)ethan-1-one	21145-77-7/ 1506-02-1	244-240-6/ 216-133-4	leave-on products: 0.1% except: hydroalcoholic products: 1.0% fine fragrance: 2.5% fragrance cream: 0.5% rinse-off products: 0.2%
Phantolide; acetyl hexamethyl indan; AHMI; Musk indane	1,1,2,3,3,6-Hexamethylindan-5-yl methyl ketone	15323-35-0	239-360-0	leave-on products: 2.0% rinse-off products: no restrictions

¹⁰⁷ nd = < 0.0001% ≈ < 1 ppm.

¹⁰⁸ According to the legislation of the United Mexican States (see Annex I).

¹⁰⁹ In the event of this substance being used as ingredient in the composition of a cosmetic product, contact the Sustainability Department of Inditex.

¹¹⁰ Not to be used in oral products.

Annex III. Summary Chart of Fragrance Allergens^{111, 112}

Name of Common Ingredients Glossary	Chemical Name ¹¹³	Label name ¹¹⁴	CAS Number	EC Number
3-Propylidenephthalide ¹¹⁵	3-Propylidene-1-(3H)-isobenzofuranone 3-Propylidenephthalide	3-Propylidenephthalide	17369-59-4	241-402-8
6-Methylcoumarin ¹¹⁶	6-Methylcoumarin	6-Methylcoumarin	92-48-8	202-158-8
Acetyl Cedrene	[3R-(3 α ,3a β ,7 β ,8a α)]-1-(2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-1H-3a,7-methanoazulen-5-yl)ethan-1-one	Acetyl Cedrene	32388-55-9	251-020-3
Alpha-Damascone cis-Rose ketone 1 trans-Rose ketone 1 ¹¹⁷	1-(2,6,6-Trimethyl-2-cyclohexen-1-yl)-2-buten-1-one	Rose Ketones	43052-87-5 / 23726-94-5 / 24720-09-0	245-845-8 / 246-430-4
Rose ketone 4 (Damascone) ¹¹⁷	1-(2,6,6-Trimethylcyclohexa-1,3-dien-1-yl)-2-buten-1-one		23696-85-7	245-833-2
Rose ketone 3 (delta-Damascone) trans-Rose ketone-3 ¹¹⁷	1-(2,6,6-Trimethyl-3-cyclohexen-1-yl)-2-buten-1-one		57378-68-4 / 71048-82-3	260-709-8 / 275-156-8
cis-Rose ketone 2 (cis-beta-Damascone) ¹¹⁷	(Z)-1-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2-buten-1-one		23726-92-3	245-843-7
trans-Rose ketone 2 (trans-beta-Damascone) ¹¹⁷	(E)-1-(2,6,6-Trimethyl-1-cyclohexen-1-yl)-2-buten-1-one		23726-91-2	245-842-1
alpha-Isomethyl ionone	3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	alpha-Isomethyl ionone	127-51-5	204-846-3
Alpha-Terpinene ¹¹⁸	p-Mentha-1,3-diene	Alpha-Terpinene	99-86-5	202-795-1
Amyl cinnamal	2-Benzylideneheptanal	Amyl cinnamal	122-40-7	204-541-5
Amylcinnamyl alcohol	2-Pentyl-3-phenylprop-2-en-1-ol	Amylcinnamyl alcohol	101-85-9	202-982-8
Amyl Salicylate	Pentyl-2-hydroxybenzoate	Amyl Salicylate	2050-08-0	218-080-2
Anethole	1-Methoxy-4-(1E)-1-propen-1-yl-benzene (trans-Anethole)	Anethole	104-46-1 / 4180-23-8	203-205-5 / 224-052-0

¹¹¹ The presence of any of the restricted substances listed in this table must be indicated on the list of ingredients when its concentration exceeds: 0.001% for leave-on products and 0.01% in rinse-off products.

¹¹² For the labelling of the new fragrance allergens included by the amendment Regulation EU 2023/1545, the following deadlines will apply to products that do not contain this new labelling: they may be placed on the market until 31 July 2026, and may be available until 31 July 2028.

¹¹³ In cases where there are inconsistencies between the Name of Common Ingredients Glossary and the Chemical Name column, particularly for natural ingredients, the Chemical Name column should be used to define the scope.

¹¹⁴ The name for labelling provided corresponds to the one established by the European Union Regulation.

¹¹⁵ MAC = 0.01% for all products with the exception of oral products (except in South Korea where it applies to all products).

¹¹⁶ MAC = 0.003%; use only allowed in oral products. In South Korea, its use is prohibited (see Annex I).

¹¹⁷ MAC = 0.02% for all products with the exception of oral products (except in South Korea where it applies to all products). The sum of the substances used in combination must not exceed the indicated limits.

¹¹⁸ Peroxide level lower than 10 mmol/L; this limit is applied to the substance and not to the finished cosmetic product.

Name of Common Ingredients Glossary	Chemical Name ¹¹³	Label name ¹¹⁴	CAS Number	EC Number
Anise alcohol	4-Methoxybenzyl alcohol	Anise alcohol	105-13-5	203-273-6
Benzaldehyde	Benzaldehyde	Benzaldehyde	100-52-7	202-860-4
Benzyl alcohol ¹¹⁹	Benzyl alcohol	Benzyl alcohol	100-51-6	202-859-9
Benzyl benzoate	Benzyl benzoate	Benzyl benzoate	120-51-4	204-402-9
Benzyl cinnamate	2-Propenoic acid, 3-phenyl-, phenylmethyl ester	Benzyl cinnamate	103-41-3	203-109-3
Benzyl salicylate	Benzyl salicylate	Benzyl salicylate	118-58-1	204-262-9
Beta-Caryophyllene	(1R,4E,9S)-4,11,11-Trimethyl-8-methylenebicyclo[7.2.0]undec-4-ene	Beta-Caryophyllene	87-44-5	201-746-1
Butylphenyl methylpropional / Lilial	2-(4-tert-Butylbenzyl)propionaldehyde; BMHCA		80-54-6	201-289-8
Camphor ¹²⁰	Bornan-2-one; 1,7,7-Trimethylbicyclo[2.2.1]-2-heptanone	Camphor	76-22-2 / 21368-68-3 / 464-49-3 / 464-48-2	200-945-0 / 244-350-4 / 207-355-2 / 207-354-7
Cananga Odorata Flower Extract Cananga Odorata Flower Oil	Cananga odorata flower oil and extract Ylang Ylang flower oil and extract	Cananga Odorata Oil/ Extract	83863-30-3 / 8006-81-3 / 68606-83-7 / 93686-30-7	281-092-1 / 297-681-1
Carvone	2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one	Carvone	99-49-0	202-759-5
	(5R)-2-Methyl-5-prop-1-en-2-ylcyclohex-2-en-1-one		6485-40-1	229-352-5
	(5S)-2-Methyl-5-prop-1-en-2-ylcyclohex-2-en-1-one		2244-16-8	218-827-2
Cedrus Atlantica Bark Extract ¹¹⁸ Cedrus Atlantica Bark Oil ¹¹⁸ Cedrus Atlantica Bark Water ¹¹⁸ Cedrus Atlantica Leaf Extract ¹¹⁸ Cedrus Atlantica Wood Extract ¹¹⁸ Cedrus Atlantica Wood Oil ¹¹⁸	<i>Cedrus atlantica</i> oil and extract	Cedrus Atlantica Oil/ Extract	92201-55-3 / 8023-85-6	295-985-9
Cinnamal	2-Propenal, 3-phenyl-	Cinnamal	104-55-2	203-213-9
Cinnamomum Cassia Leaf Oil	Cinnamomum cassia leaf oil	Cinnamomum Cassia Leaf Oil	8007-80-5 / 84961-46-6	284-635-0

¹¹⁹ For purposes other than inhibiting the development of microorganisms in the product, this purpose has to be apparent from the presentation of the product.

¹²⁰ In Canada and Taiwan MAC = 3%. In Indonesia for body powder MAC = 1.5%, prohibited in children under 3 years of age and label should include "Contains camphor. Do not use in children under 3 years of age."; without restrictions in other products. In the United Mexican States can only be used in nail polish without restrictions and in refreshing products with MAC = 0.5%. In Taiwan for products which might be used for children under 2 years of age (exception of rinse off products) label should include: "Consult physician or pharmacist before uses to children under 2 years of age". In India its use is prohibited in body and face powders.

Name of Common Ingredients Glossary	Chemical Name ¹¹³	Label name ¹¹⁴	CAS Number	EC Number
Cinnamomum Zeylanicum Bark Oil	Cinnamomum zeylanicum bark oil	Cinnamomum Zeylanicum Bark Oil	8015-91-6 / 84649-98-9	283-479-0
Cinnamyl alcohol	Cinnamyl alcohol	Cinnamyl alcohol	104-54-1	203-212-3
Citral	3,7-Dimethyl-2,6-octadienal	Citral	5392-40-5	226-394-6
Geranial	(E)-3,7-Dimethylocta-2,6-dienal		141-27-5	205-476-5
Neral	(Z)-3,7-Dimethylocta-2,6-dienal		106-26-3	203-379-2
Citronellol	Citronellol/ (±)3,7-Dimethyl-6-octen-1-ol	Citronellol	106-22-9 / 26489-01-0	203-375-0 / 247-737-6
	(3R)-3,7-Dimethyloct-6-en-1-ol		1117-61-9	214-250-5
	(3S)-3,7-Dimethyloct-6-en-1-ol		7540-51-4	231-415-7
Citrus Aurantium Amara Flower Oil	Citrus aurantium amara and dulcis flower oil	Citrus Aurantium Flower Oil	72968-50-4	277-143-2
Citrus Aurantium Dulcis Flower Oil			8028-48-6 / 8016-38-4	232-433-8
Citrus Aurantium Amara Peel Oil	Citrus aurantium amara and dulcis peel oil	Citrus Aurantium Peel Oil	68916-04-1 / 72968-50-4	277-143-2
Citrus Aurantium Dulcis Peel Oil			97766-30-8 / 8028-48-6 / 8008-57-9	307-891-8 / 232-433-8
Citrus Sinensis Peel Oil				
Citrus Aurantium Bergamia Peel Oil	Citrus aurantium bergamia oil (Bergamot oil)	Citrus Aurantium Bergamia Peel Oil	8007-75-8 / 89957-91-5 / 68648-33-9 / 85049-52-1	616-915-9 / 289-612-9
Citrus Limon Peel Oil	Citrus limon oil	Citrus Limon Peel Oil	84929-31-7 / 8008-56-8	284-515-8
Coumarin	2H-1-Benzopyran-2-one	Coumarin	91-64-5	202-086-7
Cymbopogon Schoenanthus Oil	Cymbopogon citratus / schoenanthus/flexuosus oils	Lemongrass Oil	8007-02-1 / 89998-16-3	289-754-1
Cymbopogon Flexuosus Oil			91844-92-7	295-161-9
Cymbopogon Citratus Leaf Oil			8007-02-1 / 91844-92-7	295-161-9
Dimethyl Phenethyl Acetate	2-Methyl-1-phenyl-2-propyl acetate Dimethylbenzyl Carbiny Acetate	Dimethyl Phenethyl Acetate	151-05-3	205-781-3
Eucalyptus Globulus Leaf Oil ¹²¹	Eucalyptus globulus oil	Eucalyptus Globulus Oil	97926-40-4 / 8000-48-4	308-257-3 / 616-775-9
Eucalyptus Globulus Leaf/ Twig Oil ¹²¹			8000-48-4	616-775-9

¹²¹ In Canada, cosmetic products other than cosmetics in solid form and with concentration greater than 0.022%, label should include "Keep out of reach of children" and "In case of accidental ingestion, call a Poison Control Centre or doctor immediately and advise them this product contains eucalyptus oil" (see Annex I).

Name of Common Ingredients Glossary	Chemical Name ¹¹³	Label name ¹¹⁴	CAS Number	EC Number
Eugenia Caryophyllus Leaf Oil	Eugenia caryophyllus oil	Eugenia Caryophyllus Oil	8000-34-8 / 8015-97-2 / 84961-50-2	616-772-2 / 284-638-7
Eugenia Caryophyllus Flower Oil			84961-50-2	284-638-7
Eugenia Caryophyllus Steam Oil			84961-50-2	284-638-7
Eugenia Caryophyllus Bud Oil			84961-50-2	284-638-7
Eugenol	Phenol, 2-methoxy-4-(2-propenyl)	Eugenol	97-53-0	202-589-1
Eugenyl Acetate	Phenol, 2-methoxy-4-(2-propenyl)-, acetate	Eugenyl Acetate	93-28-7	202-235-6
Evernia furfuracea extract	Treemoss extract	Evernia furfuracea extract	90028-67-4	289-860-8
Evernia prunastri extract	Oak moss extract	Evernia prunastri extract	90028-68-5	289-861-3
Farnesol	2,6,10-Dodecatrien-1-ol, 3,7,11-trimethyl-	Farnesol	4602-84-0	225-004-1
Geraniol	2,6-Octadien-1-ol, 3,7-dimethyl-, (2E)-	Geraniol	106-24-1	203-377-1
Geranyl Acetate	2,6-Octadien-1-ol, 3,7-dimethyl-,1-acetate, (2E)-	Geranyl Acetate	105-87-3	203-341-5
Hexadecanolactone	Oxacycloheptadecan-2-one	Hexadecanolactone	109-29-5	203-662-0
Hexamethylindanopyran	1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta- γ -2-benzopyran	Hexamethylindanopyran	1222-05-5	214-946-9
Hexyl cinnamal	2-Benzylideneoctanal	Hexyl cinnamal	101-86-0	202-983-3
Hydroxycitronellal ¹²²	7-Hydroxycitronellal	Hydroxycitronellal	107-75-5	203-518-7
Hydroxyisohexyl 3-cyclohexene carboxaldehyde / Lyral	3 and 4-(4-Hydroxy-4-methylpentyl) cyclohex-3-ene-1-carbaldehyde (HICC)		51414-25-6/ 31906-04-4	257-187-9 / 250-863-4
Isoeugenol ¹²³	Phenol, 2-methoxy-4-(1-propenyl)	Isoeugenol	97-54-1	202-590-7
	(E)-2-Methoxy-4-(prop-1-enyl)phenol (trans-Isoeugenol)		5932-68-3	227-678-2
	(Z)-2-Methoxy-4-(prop-1-enyl)phenol (cis-Isoeugenol)		5912-86-7	227-633-7
Isoeugenyl Acetate	2-Methoxy-4-prop-1-enylphenyl acetate	Isoeugenyl Acetate	93-29-8	202-236-1

¹²² MAC = 1.0% for all products with the exception of oral products.

¹²³ MAC = 0.02% for all products with the exception of oral products.

Name of Common Ingredients Glossary	Chemical Name ¹¹³	Label name ¹¹⁴	CAS Number	EC Number
Jasminum Grandiflorum Flower Extract	Jasminum grandiflorum / officinale oil and extract	Jasmine Oil/ Extract	84776-64-7 / 90045-94-6 / 8022-96-6	283-993-5 / 289-960-1
Jasminum Officinale Oil			8024-43-9	
Jasminum Officinale Flower Extract			90045-94-6	289-960-1
Juniperus Virginiana Oil	Juniperus virginiana oil	Juniperus Virginiana Oil	8000-27-9	
Juniperus Virginiana Wood Oil			85085-41-2	285-370-3
Laurus Nobilis Leaf Oil ¹²⁴	Laurus nobilis oil	Laurus Nobilis Leaf Oil	8002-41-3 / 8007-48-5 / 84603-73-6	283-272-5
Lavandula Hybrida Oil Lavandula Hybrida Extract Lavandula Hybrida Flower Extract	Lavandula hybrida oil/extract	Lavandula Oil/ Extract	91722-69-9 / 8022-15-9 / 93455-96-0 / 93455-97-1 / 92623-76-2	294-470-6 / 296-408-3
Lavandula Intermedia Flower/ Leaf/Stem Extract Lavandula Intermedia Flower/ Leaf/Stem Oil Lavandula Intermedia Oil	Lavandula intermedia oil/extract		84776-65-8 / 8000-28-0 / 90063-37-9	283-994-0 / 289-995-2
Lavandula Angustifolia Oil Lavandula Angustifolia Flower/Leaf/Stem Extract	Lavandula angustifolia oil/extract		84776-65-8 / 8000-28-0 / 90063-37-9	283-994-0 / 289-995-2
Limonene ¹²⁵	1-methyl-4-prop-1-en-2-yl-cyclohexene; dl limonene (racemic) Dipentene		Limonene	138-86-3 / 7705-14-8
	(R)-p-Mentha-1,8-diene (d-limonene)	5989-27-5		227-813-5
	(S)-p-Mentha-1,8-diene (l-limonene)	5989-54-8		227-815-6
Linalool	1,6-Octadien-3-ol, 3,7-dimethyl-	Linalool	78-70-6	201-134-4
Linalyl Acetate	3,7-Dimethyl octa-1,6-diene-3-yl acetate	Linalyl Acetate	115-95-7	204-116-4
Lippia citriodora absolute ¹²⁶	Verbena absolute	Lippia citriodora absolute	8024-12-2 / 85116-63-8	285-515-0
Mentha Piperita Oil	Mentha piperita oil	Mentha Piperita Oil	8006-90-4 / 84082-70-2	282-015-4
Mentha Viridis Leaf Oil	Mentha spicata oil (spearmint oil)	Mentha Viridis Leaf Oil	8008-79-5 / 84696-51-5	616-927-4 / 283-656-2

¹²⁴ The use of *Laurus nobilis* L. seed oil is prohibited in cosmetic products.

¹²⁵ Peroxide level lower than 20 mmol/L; this limit is applied to the substance and not to the finished cosmetic product.

¹²⁶ MAC = 0.2%. Verbena essential oils (*Lippia citriodora* Kunth) and derivatives, other than absolute, are prohibited when used as a fragrance ingredient (in Taiwan, this prohibition applies to all products). In South Korea, Verbena oils is prohibited in all products, and in the United Mexican States, Verbena oil is prohibited in fragrances (see Annex I).

Name of Common Ingredients Glossary	Chemical Name ¹¹³	Label name ¹¹⁴	CAS Number	EC Number
Menthol ¹²⁷	Menthol	Menthol	89-78-1	201-939-0
	dI-Menthol		1490-04-6	216-074-4
	l-Menthol		2216-51-5	218-690-9
	d-Menthol		15356-60-2	239-387-8
Methyl 2-Octynoate ¹²⁸	Methyl Oct-2-ynoate Methyl heptine carbonate	Methyl 2-Octynoate	111-12-6	203-836-6
Methyl Salicylate ¹²⁹	Methyl-2-hydroxybenzoate	Methyl Salicylate	119-36-8	204-317-7
Myroxylon Balsamum Pereirae Balsam Extract ¹³⁰ Myroxylon Balsamum Pereirae Balsam Oil ¹³⁰ Myroxylon Pereirae Oil ¹³⁰ Myroxylon Pereirae Resin Extract ¹³⁰ Myroxylon Pereirae Resin ¹³⁰	<i>Myroxylon balsamum</i> var. <i>pereirae</i> ; extracts and distillates; Balsam Peru oil, absolute and anhydrol (Balsam Oil Peru)	Myroxylon Pereirae Oil/ Extract	8007-00-9	232-352-8
Narcissus Poeticus Extract	Narcissus poeticus/pseudonarcissus/jonquilla/tazetta extract	Narcissus Extract	90064-26-9 / 68917-12-4	290-087-3
Narcissus Pseudonarcissus Flower Extract			90064-27-0	290-088-9
Narcissus Jonquilla Extract			90064-25-8	290-086-8
Narcissus Tazetta Extract				

¹²⁷ In Argentina MAC = 0.5% (mucous membranes); MAC = 0.5% (not mucous membranes and leave-on) and MAC = 1% (not mucous membranes and rinse-off). In Brazil MAC = 1%. In Indonesia for body powder MAC = 1%, prohibited in children under 3 years of age and label should include: "Contains menthol. Do not use in children under 3 years old"; without restriction in other products. In Taiwan for products which might be used for children under 2 years of age (exception of rinse off products) label should include: "Consult physician or pharmacist before uses to children under 2 years of age". In India its use is prohibited in body and face powders.

¹²⁸ MAC = 0.01% when it is used by itself. In combination with methyl octine carbonate (MOC), the combined level for the final product must not be > 0.01% (and of this, the % MOC, must not exceed 0.002%). These limits apply to all the products with the exception of oral products (except in South Korea where it applies to all products).

¹²⁹ MAC = 0.06% in leave-on skin products (except face makeup, spray/aerosol body lotion, spray/aerosol deodorant, and hydroalcoholic-based fragrances). MAC = 0.06% in leave-on hair products (except spray/aerosol products). MAC = 0.05% in face makeup (except lip products) and makeup removers. MAC = 0.002% in eye makeup and makeup removers. MAC = 0.009% in leave-on hair products (spray/aerosol). MAC = 0.003% in deodorant spray/aerosol. MAC = 0.04% in body lotion spray/aerosol. MAC = 0.06% in rinse-off skin products (except hand wash) and rinse-off hair products. MAC = 0.6% in hand wash products (0.2% in Argentina). MAC = 0.6% in hydroalcoholic-based fragrances (0.2% in Argentina). MAC = 0.03% in lip products. MAC = 2.52% in toothpastes (0.2% in Argentina, 1% in Canada and Taiwan and 2.5% in United Kingdom). MAC = 0.1% in mouthwashes intended for children between 6 and 10 years old. MAC = 0.6% in mouthwashes intended for children older than 10 years and adults (0.2% in Argentina and 0.4% in United Kingdom). MAC = 0.65% in mouth spray (0.2% in Argentina). Do not use in preparations for children under 6 years old (except for toothpastes). In the United Mexican States it can only be used in refreshing products with a MAC = 0.2%. In Taiwan for leave-on products, label should include "Consult physician or pharmacist before use with aspirin or salicylate idiosyncrasy", and for products which might be used for children under 2 years of age (exception of rinse-off products) label should include "Consult physician or pharmacist before uses to children under 2 years of age".

¹³⁰ MAC = 0.4%. The exudation of *Myroxylon pereirae* (Royle) Klotzsch (Peru balsam, crude) is prohibited when used as a fragrance ingredient. In South Korea, Balsam of Peru (resin of *Myroxylon pereirae*) is prohibited in all products (see Annex I).

Name of Common Ingredients Glossary	Chemical Name ¹¹³	Label name ¹¹⁴	CAS Number	EC Number
Pelargonium Graveolens Flower Oil	Pelargonium graveolens oil	Pelargonium Graveolens Flower Oil	90082-51-2 / 8000-46-2	290-140-0
Pinene ¹¹⁸	2,6,6-Trimethylbi-cyclo[3.1.1]hept-2-ene (alpha-Pinene)	Pinene	80-56-8 / 7785-70-8	201-291-9 / 232-087-8
	6,6-Dimethyl-2-methylenebicyclo[3.1.1]heptane (beta-Pinene)		127-91-3 / 18172-67-3	204-872-5 / 242-060-2
Pinus Mugo Leaf Oil ¹¹⁸ Pinus Mugo Twig Leaf Extract ¹¹⁸ Pinus Mugo Twig Oil ¹¹⁸	<i>Pinus mugo</i> leaf and twig oil and extract	Pinus Mugo	90082-72-7	290-163-6
Pinus Pumila Needle Extract ¹¹⁸ Pinus Pumila Twig Leaf Extract ¹¹⁸ Pinus Pumila Twig Leaf Oil ¹¹⁸	<i>Pinus pumila</i> leaf and twig oil and extract	Pinus Pumila	97676-05-6	307-681-6
Pogostemon Cablin Oil	Pogostemom cablin oil	Pogostemon Cablin Oil	8014-09-3 / 84238-39-1	282-493-4
Rosa Damascena Flower Oil Rosa Damascena Flower Extract	Rosa damascena flower oil/extract	Rose Flower Oil/Extract	8007-01-0 / 90106-38-0	290-260-3
Rosa Alba Flower Oil Rosa Alba Flower Extract	Rosa alba flower oil/extract		93334-48-6	297-122-1
Rosa Canina Flower Oil	Rosa canina flower oil		84696-47-9	283-652-0
Rosa Centifolia Flower Oil Rosa Centifolia Flower Extract	Rosa centifolia oil/extract		84604-12-6	283-289-8
Rosa Gallica Flower Oil	Rosa gallica flower oil		84604-13-7	283-290-3
Rosa Moschata Flower Oil	Rosa moschata flower oil			
Rosa Rugosa Flower Oil	Rosa rugosa flower oil		92347-25-6	296-213-3
Salicylaldehyde	o-Hydroxy-benzaldehyde	Salicylaldehyde	90-02-8	201-961-0
Santalol	5-(2,3-Dimethyl-tricyclo[2.2.1.0 ^{2,6}]-hept-3-yl)-2-methylpent-2-en-1-ol (alpha-Santalol)	Santalol	11031-45-1 / 115-71-9	234-262-4 / 204-102-8
	(1S-(1a,2a(Z),4a))-2-Methyl-5-(2-methyl-3-methylenebicyclo[2.2.1]hept-2-yl)-2-penten-1-ol (beta-Santalol)		77-42-9	201-027-2
Santalum Album Oil	Santalum album oil	Santalum Album Oil	8006-87-9 / 84787-70-2	284-111-1
Sclareol	[1R-(1alpha)]-alpha-Ethenyldecahydro-2-hydroxy-a,2,5,5,8a-pentamethyl-1-naphthalenepropanol	Sclareol	515-03-7	208-194-0

Name of Common Ingredients Glossary	Chemical Name ¹¹³	Label name ¹¹⁴	CAS Number	EC Number
Terpineol	2-(4-methylcyclohex-3-en-1-yl)propan-2-ol	Terpineol	8000-41-7	232-268-1
	p-Menth-1-en-8-ol (alpha-Terpineol)		98-55-5	202-680-6
	1-methyl-4-(1-methylvinyl)cyclohexan-1-ol (beta-Terpineol)		138-87-4	205-342-6
	1-methyl-4-(1-methylethylidene)cyclohexan-1-ol (gamma-Terpineol)		586-81-2	209-584-3
Terpinolene ¹¹⁸	p-Mentha-1,4(8)-diene	Terpinolene	586-62-9	209-578-0
Tetramethyl acetyloctahydronaphthalenes	1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	Tetramethyl acetyloctahydronaphthalenes	54464-57-2	259-174-3
	1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthyl)ethan-1-one		54464-59-4	259-175-9
	1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one		68155-66-8	268-978-3
	1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one		68155-67-9	268-979-9
Trimethylbenzenepropanol	3-(2,2-Dimethyl-3-hydroxypropyl)toluene	Trimethylbenzenepropanol	103694-68-4	403-140-4
Trimethylcyclopentenyl Methylisopentenol	3-Methyl-5-(2,2,3-Trimethyl-3-Cyclopentenyl)pent-4-en-2-ol	Trimethylcyclopentenyl Methylisopentenol	67801-20-1	267-140-4
Turpentine ¹¹⁸	Turpentine gum (<i>Pinus</i> spp.)	Turpentine	9005-90-7	232-688-5
	Turpentine oil and rectified oil		8006-64-2	232-350-7
	Turpentine, steam distilled (<i>Pinus</i> spp.)		8052-14-0	
Vanillin	4-Hydroxy-3-methoxybenzaldehyde	Vanillin	121-33-5	204-465-2

Annex IV. Summary Chart of Nitrosamines and Nitrosating Agents¹³¹

Name of Common Ingredients Glossary	Chemical Name	Acronym	CAS Number	EC Number	Limits ¹³²
3-(N-Nitrosomethylamino) propionitrile			60153-49-3		nd
4-Nitrosodiphenylamine			156-10-5	205-848-7	nd
4-(N-Nitrosomethylamino)-1-(3-pyridyl)-1-butanone			64091-91-4		nd
Nitrosamide			35576-91-1		nd
N-Nitrosodibutylamine			924-16-3		nd
N-Nitrosodiethanolamine	2,2-(Nitrosoimino) bisethanol	NDELA	1116-54-7	214-237-4	nd
N-Nitrosodiethylamine	N-Nitrosodiethylamine	NDEA	55-18-5	200-226-1	nd
N-Nitrosodiisopropanolamine	N-Nitroso-bis (2-hydroxypropylamine)	NBHPA	53609-64-6		nd
N-Nitrosodimethylamine	N-Methyl-N-nitrosomethanamine	NDMA	62-75-9	200-549-8	nd
N-Nitrosodiphenylamine	Diphenylnitrosamine		86-30-6	201-663-0	nd
N-Nitrosodipropylamine	N-Nitroso-N-propyl-1-propanamine	NDPA	621-64-7	210-698-0	nd
N-Nitrosohexamethyleneimine			932-83-2	213-258-6	nd
N-Nitrosomethyl-N-butylamine			7068-83-9		nd
N-Nitrosomethyl-N-decylamine			75881-22-0		nd
N-Nitrosomethyl-N-dodecylamine	N-Nitroso-N-methyl-N-dodecylamine		55090-44-3		nd
N-Nitrosomethyl-N-heptylamine			16338-99-1		nd
N-Nitrosomethyl-N-hexylamine			28538-70-7		nd
N-Nitrosomethyl-N-nonylamine			75881-19-5		nd
N-Nitrosomethyl-N-octylamine			34423-54-6		nd
N-Nitrosomethyl-N-pentylamine			13256-07-0		nd
N-Nitrosomethyl-N-propylamine			924-46-9		nd
N-Nitrosomethyl-N-tetradecylamine			75881-20-8		nd
N-Nitrosomethyl-N-undecylamine			68107-26-6		nd
N-Nitroso-N-methylurea			684-93-5	211-678-4	nd
N-Nitroso-N-methylurethane			615-53-2	210-432-3	nd
N-Nitroso-N-methylvinylamine			4549-40-0		nd
N-Nitrosomorpholine	4-Nitrosomorpholine	NMOR	59-89-2		nd
N-Nitrosornicotine			16543-55-8		nd
N-Nitrosopiperidine			100-75-4	202-886-6	nd
N-Nitrosopyrrolidine	1-Nitrosopyrrolidine	NPYR	930-55-2	213-218-8	nd
N-Nitroso-para-amino benzoic acid esters		NPABA			nd
N-Methyl-N-nitroso-ethanamine			10595-95-6	204-825-9	nd
Diethanolamine	2,2'-Iminodiethanol	DEA	111-42-2	203-868-0	nd
Diisopropanolamine	1,1'-Iminodipropan-2-ol	DIPA	110-97-4	203-820-9	nd
Dimethylamine			124-40-3	204-697-4	nd

¹³¹ To prevent the formation of Nitrosamines in the cosmetic product, the concurrent use of amines, amino-derivatives and nitrosating agents is prohibited as ingredients of the cosmetics in one specific cosmetic, even if these substances have a MAC limit.

¹³² nd = < 0.000001% = < 0.01 ppm.

Name of Common Ingredients Glossary	Chemical Name	Acronym	CAS Number	EC Number	Limits ¹³²
Ethanolamine ¹³³	2-Aminoethanol	MEA	141-43-5	205-483-3	0.5% (as secondary amine)
Triethanolamine ¹³³	2,2',2"-Nitrilotriethanol	TEA	102-71-6	203-049-8	leave-on products: 2.5% rinse-off products: no restrictions
DEA-Cocamide ¹³⁴	N,N-bis(Hydroxyethyl)cocamide		68603-42-9	271-657-0	0.5% (as secondary amine)
DEA-Lauramide ¹³⁴	N,N-bis(2-Hydroxyethyl)dodecanamide		120-40-1	204-393-1	0.5% (as secondary amine)
DEA-Oleamide ¹³⁴	N,N-bis(2-Hydroxyethyl)oleamide		93-83-4	202-281-7	0.5% (as secondary amine)
Inorganic nitrites			14797-65-0	231-963-7	nd
Sodium nitrite ¹³⁵			7632-00-0	231-555-9	0.2% (only as rust inhibitor)
Amyl nitrite			110-46-3	203-770-8	nd
Butyl nitrite ¹³⁶			544-16-1	208-862-1	nd
Isobutyl nitrite			542-56-3	208-819-7	nd
Isopropyl nitrite ¹³⁶			541-42-4	208-779-2	nd
n-propyl nitrite ¹³⁶			543-67-9	208-848-5	nd
Octyl nitrite ¹³⁶			629-46-9	211-092-9	nd
Bronidox	5-Bromo-5-nitro-1,3-dioxane		30007-47-7	250-001-7	nd
Bronopol	2-Bromo-2-nitropropane-1,3-diol		52-51-7	200-143-0	nd

¹³³ Maximum content of secondary amine in final cosmetic product = 0.5%. Not to be used with nitrosating systems. Minimum purity 99%. Maximum content of secondary amine in raw material = 0.5%. Maximum nitrosamine content = 50 µg/kg. Keep in nitrite-free containers.

¹³⁴ Maximum content of secondary amine in final cosmetic product = 0.5%. Not to be used with nitrosating systems. Maximum content of secondary amine in raw material = 5%. Maximum nitrosamine content = 50 µg/kg. Keep in nitrite-free containers.

¹³⁵ For formulations that contain amides or amines it cannot be used in any concentration.

¹³⁶ According to Australian legislation (see Annex I).

Annex V. Summary Chart of Phthalates¹³⁷

Name of Common Ingredients Glossary	Chemical Name	Acronym	CAS Number	EC Number	Limits ¹³⁸
1,2-Benzenedicarboxylic acid; di-C6-8 branched alkylesters, C7-rich			71888-89-6	276-158-1	nd
1,2-Benzenedicarboxylic acid, di-C7-11, branched and linear alkyl esters			68515-42-4	271-084-6	nd
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear			68515-50-4	271-093-5	nd
1,2-Benzenedicarboxylic acid, dipentyl ester, branched and linear			84777-06-0	284-032-2	nd
Benzyl butyl phthalate		BBP	85-68-7	201-622-7	nd
Dibutyl phthalate		DBP	84-74-2	201-557-4	nd
Dicyclohexyl phthalate		DCHP	84-61-7	201-545-9	nd
Diethylhexyl phthalate	bis(2-Ethylhexyl) phthalate	DEHP	117-81-7	204-211-0	nd
Diethyl phthalate ¹³⁹		DEP	84-66-2	201-550-6	nd
Dihexyl phthalate		DnHP	84-75-3	201-559-5	nd
Diisobutyl phthalate		DIBP	84-69-5	201-553-2	nd
Diisodecyl phthalate ¹⁴⁰		DIDP	68515-49-1 / 26761-40-0	201-884-2 / 247-977-1	nd
Diisohexyl phthalate		DIHP	71850-09-4	276-090-2	nd
Diisononyl phthalate ¹⁴⁰		DINP	28553-12-0	249-079-5	nd
Diisooctyl phthalate		DIOP	27554-26-3	248-523-5	nd
Diisopentyl phthalate		DIPP	605-50-5	210-088-4	nd
Dimethoxyethyl phthalate	bis(2-Methoxyethyl) phthalate	DMEP	117-82-8	204-212-6	nd
Dimethyl phthalate ¹⁴¹		DMP	131-11-3	205-011-6	nd
Diocetyl phthalate ¹⁴²	di-n-Octyl phthalate	DOP	117-84-0	204-214-7	nd
Dipentyl phthalate	di-n-Pentyl phthalate	DPP	131-18-0	205-017-9	nd
Pentyl-isopentylphthalate	n-Pentyl-isopentylphthalate	PIPP	776297-69-9		nd

¹³⁷ In the states of Washington, Vermont, and Oregon (see Annex I), all ortho-phthalates are prohibited. If any of them are not listed in the included prohibited phthalates list, contact the Sustainability Department of Inditex.

¹³⁸ nd = < 0.0005% ≈ < 5 ppm.

¹³⁹ According to the legislation of Australia (see Annex I). In Australia, its use is prohibited in sunscreens, insect repellents, and body lotions.

¹⁴⁰ According to the legislation of California (see Annex I).

¹⁴¹ According to the legislation of the United Mexican States, Argentina and Australia (see Annex I).

¹⁴² According to the legislation of Taiwan (see Annex I).

Annex VI. Summary Chart of Chemical Elements as Traces in Final Cosmetic Product

The limit for the following elements and their compounds in the Final Cosmetic Product is shown in Table 1:

Table 1

Element	Symbol	CAS Number	EC Number	Limits as traces in Final Cosmetic Product
Antimony	Sb	7440-36-0	231-146-5	Not detected ¹⁴³
Arsenic	As	7440-38-2	231-148-6	
Beryllium	Be	7440-41-7	231-150-7	
Cadmium	Cd	7440-43-9	231-152-8	
Lead	Pb	7439-92-1	231-100-4	
Mercury	Hg	7439-97-6	231-106-7	
Neodymium	Nd	7440-00-8	231-109-3	
Nickel	Ni	7440-02-0	231-111-4	
Selenium	Se	7782-49-2	231-957-4	
Tellurium	Te	13494-80-9	236-813-4	
Thallium	Tl	7440-28-0	231-138-1	

Table 2 shows the limit of chromium(VI) salts in the Final Cosmetic Product:

Table 2

Substance	Symbol	CAS Number	Limits as traces in Final Cosmetic Product
Chromium(VI)	Cr(VI)	18540-29-9	Not detected

Table 3 shows the considerations about the presence of other elements in the Final Cosmetic Product:

Table 3

Element	Symbol	CAS Number	EC Number	Comments on traces in Final Cosmetic Products
Cobalt	Co	7440-48-4	231-158-0	Cobalt and the following compounds are forbidden in Final Cosmetic Product: cobalt dichloride, cobalt sulphate, cobalt benzenesulphonate, cobalt di(acetate), cobalt dinitrate and cobalt carbonate.
Zirconium ¹⁴⁴	Zr	7440-67-7	231-176-9	Zirconium is forbidden for those cosmetics that do not contain zirconium lakes, salts and pigments of permitted colorants and/or permitted zirconium and aluminium complexes.

¹⁴³ The limit for these elements in the Final Cosmetic Product is not detection: nd ≈ < 0.0001% ≈ < 1 ppm for all the elements considered prohibited, with the exceptions of Nickel (nd ≈ < 0.001% ≈ < 10 ppm) and Antimony and Lead (nd ≈ < 0.0005% ≈ < 5 ppm). In Washington, the limit of Lead in Final Cosmetic Product is also non detection, to know the value associated with nd contact the Sustainability Department of Inditex. In the event of marketing baby toilet soaps in India, contact the Sustainability Department of Inditex. These limits are admitted only in the situation of technical unavoidability associated with the presence of a specific ingredient that could contain that metal as an impurity.

¹⁴⁴ For those cosmetics that do not contain zirconium lakes, salts and pigments of permitted colorants and/or permitted zirconium and aluminium complexes (see Annex VI bis).

Annex VI bis. Summary Chart of Elements, their Salts and their Compounds

Elements	Colorants ¹⁴⁵		Prohibited	Restricted ¹⁴⁶
Chromium	CI 77289	Chromium(III) hydroxide	Chromic acid	
	CI 77288	Chromium(III) oxide	Chromic acid salts	
	CI 18690 ¹⁴⁷	Hydrogen bis[2-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]benzoato(2-)]1-chromate	Trisodium bis(7-acetamido-2-(4-nitro-2-oxidophenylazo)-3-sulfonato-1-naphtholato) chromate (1-)	
	CI 18736 ¹⁴⁷	Disodium hydrogen bis[5-chloro-3-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]-2-hydroxybenzenesulphonato(3)]3- chromate		
Cobalt	CI 77346 ¹⁴⁷	Cobalt aluminum oxide	Cobalt dichloride	
			Cobalt sulphate	
			Cobalt benzenesulphonate	
			Cobalt di(acetate)	
			Cobalt dinitrate	
			Cobalt carbonate	
Barium	CI 77120 ¹⁴⁷	Barium sulphate	Barium salts	
	CI 15580 ¹⁴⁷	Barium bis[4-[(2-hydroxy-1-naphthyl)azo]-2-methylbenzenesulphonate]	Barium sulphide	
	Lakes, salts and pigments of colorants ¹⁴⁸		Barium diboron tetraoxide	
Strontium ¹⁴⁹	Lakes, salts and pigments of colorants ¹⁴⁸		Strontium compounds ¹⁵⁰	Strontium salts ¹⁵¹
			Strontium lactate	Strontium acetate
			Strontium nitrate	Strontium chloride
			Strontium nitrite	Strontium hydroxide
			Strontium polycarboxylate	Strontium peroxide
Zirconium	Lakes, salts and pigments of colorants ¹⁴⁸		Zirconium compounds	Aluminium zirconium salts ¹⁵²
				Aluminium zirconium complexes ¹⁵¹
				Aluminium zirconium chloride hydroxide complexes Al _x Zr(OH) _y Cl _z
				Aluminium zirconium chloride hydroxide glycine complexes

¹⁴⁵ For the specifications of the colorants, refer to the section III.9 and to the corresponding annexes (Annex X and Annex X bis).

¹⁴⁶ For any doubt about the restricted substances that appear in this column, contact the Sustainability Department of Inditex.

¹⁴⁷ For the specifications of these colorants, refer to Regionalised Chart of Colorants (section III.9 and to the corresponding annexes X and X bis).

¹⁴⁸ The colorants in which the use of these lakes, salts and pigments is permitted are: CI 10316, CI 12085, CI 15510, CI 15850, CI 15985, CI 17200 (in South Korea the Barium, Strontium and Zirconium lakes of this colorant are prohibited), CI 19140, CI 45370, CI 45380 and CI 45410 (Global Chart of Colorants, Annex X); CI 15630 (in South Korea the Barium, Strontium and Zirconium lakes of this colorant are prohibited), CI 15865, CI 16255, CI 42051 and CI 45430 (Regionalised Chart of Colorants, Annex X).

¹⁴⁹ MAC = 2.1%; prohibited in aerosol cosmetic products (see legislation of Canada, Annex I).

¹⁵⁰ According to the legislation of Japan, Taiwan and South Korea (see Annex I).

¹⁵¹ According to the legislation of Canada (see Annex I).

¹⁵² According to the legislation of Taiwan (see Annex I).

Elements	Colorants ¹⁴⁵		Prohibited	Restricted ¹⁴⁶
Sulfur ¹⁵³			Alkali sulphides	Inorganic sulfites ¹⁵⁴
			Alkali earth sulphides	Hydrogen-sulphites ¹⁵⁴
Bismuth	CI 77163	Bismuth chloride oxide	Bismuth compounds ¹⁵⁵	Bismuth subnitrate ¹⁵²
Tin			Bis(tri-n-butyltin)oxide ¹⁵²	Tin difluoride
			Dibutylbis(pentane-2,4-dionato-O,O')tin	
			Dibutyltin bis(2-ethylhexanoate)	
			Dibutyltin diacetate	
			Dibutyltin dichloride	
			Dibutyltin dilaurate	
			Dibutyltin hydrogen borate	
			Dibutyltin maleate	
			Dibutyltin oxide	
			Dichlorodioctylstannane	
			Dimethyltin dichloride	
			Dioctyltin dilaurate	
			Stannane, dioctyl-,bis (coco acyloxy) derivs.	
			Tributyltin compounds	
			Trichloromethylstannane	
			Tricyclohexylhydroxytin ¹⁵²	
			Triphenyltin acetate	
			Triphenyltin hydroxide	
		2-Ethylhexyl 10-ethyl-4-((2-ethylhexyl)oxy)-2-oxoethyl)thio)-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate		
		2-Ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate		
		2-Ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate		

¹⁵³ MAC= 2%; use only permitted in anti-dandruff and antiacne products (see legislation of Taiwan and MERCOSUR, Annex I). The list of sulphur compounds and/or its salts, restricted and banned, is not exhaustive.

¹⁵⁴ For the specifications of preservatives, refer to the section III.10 of preservatives and to the corresponding annex XI.

¹⁵⁵ According to the legislation of Japan and South Korea (see Annex I).

Elements	Colorants ¹⁴⁵		Prohibited	Restricted ¹⁴⁶
Iron ¹⁵⁶	CI 10006 ¹⁴⁷	Sodium tris(1,2-naphthoquinone-1-oximato-O,O')ferrate(1-)	Alkali pentacyanonitrosylferrate (2-)	
	CI 10020 ¹⁴⁷	Trisodium tris[5,6-dihydro-5-(hydroxyimino)-6-oxonaphthalene-2-sulphonato(2-)- N5,O6]ferrate(3-)		
	CI 77004 ¹⁴⁷	Natural hydrated aluminium silicate, Al ₂ O ₃ .2SiO ₂ .2H ₂ O, containing calcium, magnesium or iron carbonates, ferric hydroxide, quartz-sand, mica, etc. as impurities		
	CI 77015 ¹⁴⁷	Aluminum silicate coloured with ferric oxide		
	CI 77489	Iron oxide		
	CI 77491	Iron oxide Red		
	CI 77492	Iron oxide Yellow		
	CI 77499	Iron oxide Black		
	CI 77510	Ferric Ammonium Ferrocyanide Ferric Ferrocyanide		
Manganese	CI 77742	Ammonium manganese(3+) diphosphate	Manganese ethylenebis (dithiocarbamate) (polymeric)	
	CI 77745 ¹⁴⁷	Trimanganese bis(orthophosphate)	Manganese ethylenebis (dithiocarbamate) (polymeric) complex with zinc salt	
Molybdenum			Molybdenum trioxide	
Platinum			Platinum (nano)	
			Colloidal Platinum (nano)	
			Acetyl tetrapeptide-17 Colloidal Platinum (nano)	
Vanadium			Divanadium pentaoxide	
Zinc	-----	Zinc stearate ¹⁴⁷	Silver zinc zeolite	Water-soluble zinc salts
			Zinc borate	
			Zinc dimethyldithio carbamate	
	Zinc pyrithione			
	CI 77947	Zinc oxide	Manganese ethylenebis(dithiocarbamate) (polymeric) complex with zinc salt	Zinc oxide (as UV Filter) ¹⁵⁷

¹⁵⁶ In India, the limit for iron content in baby toilet soaps is 10 ppm (see Annex I).

¹⁵⁷ For the specifications of UV filters, refer to section III.11 of UV filters and to the corresponding annex XII.

Elements	Colorants ¹⁴⁵		Prohibited	Restricted ¹⁴⁶
Aluminium	CI 77000	Aluminium	Silver zinc zeolite	Aluminium sulphate buffered ¹⁵⁸
	CI 77002 ¹⁴⁷	Aluminium hydroxide sulphate		Aluminium potassium bis(sulfate) ¹⁵²
	CI 77004 ¹⁴⁷	Natural hydrated aluminium silicate, Al ₂ O ₃ .2SiO ₂ .2H ₂ O containing calcium, magnesium or iron carbonates, ferric hydroxide, quartz-sand, mica, etc. as impurities		Aluminium chloride
				Aluminium chlorohydrate, its salts and its associated complexes
	CI 77015 ¹⁴⁷	Aluminum silicate coloured with ferric oxide		Aluminium chlorhydroxy allantoinate ¹⁵⁰
				Aluminium chlorhydroxide, its salts and complexes ¹⁵⁸
				Aluminium fluoride
	CI 77346 ¹⁴⁷	Cobalt aluminum oxide		Aluminium sesquichlorohydrate and its derivatives
-----	Aluminum stearate ¹⁴⁷	Aluminium zirconium complexes ¹⁵¹		
		Aluminium zirconium salts ¹⁵²		
		Aluminium zirconium chloride hydroxide complexes Al _x Zr(OH) _y Cl _z		
		Aluminium zirconium chloride hydroxide glycine complexes		

¹⁵⁸ According to the legislation of MERCOSUR (see Annex I).

Elements	Colorants ¹⁴⁵		Prohibited	Restricted ¹⁴⁶
Copper ¹⁵⁹	CI 77400	Copper	Trisodium [4'-(8-acetylamino-3,6-disulfonato-2-naphthylazo)-4'-(6-benzoylamino-3-Sulfonato-2-naphthylazo)-biphenyl-1,3',3'',1'''-tetraolato-O,O',O'',O'''] copper(II)	
	CI 75810	Trisodium (2S-trans)-[18-carboxy-20-(carboxymethyl)-13-ethyl-2,3-dihydro-3,7,12,17-tetramethyl-8-vinyl-21H,23H-porphine-2-propionato(5-)-N21,N22,N23,N24]cuprate(3-)	Disodium[5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulphophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]salicylato(4-)] cuprate(2-)	
	CI 74160 ¹⁴⁷	(29H,31H-Phthalocyaninato(2-)-N29,N30,N31,N32) copper	(μ-((7,7'-Iminobis(4-hydroxy-3-(2-hydroxy-5-(N-methylsulphamoyl)phenyl)azo)naphthalene-2-sulphonato))(6-))dicuprate(2-) and its salts	
	CI 74180 ¹⁴⁷	Disodium [29H,31H-phthalocyaninedisulphonato(4-)-N29,N30,N31,N32] cuprate(2-)	Slimes and sludges, copper electrolyte refining, decopperised	
	CI 74260 ¹⁴⁷	Polychloro copper phthalocyanine	Copper (nano) Colloidal copper (nano)	
Gold	CI 77480 ¹⁴⁷	Gold	Gold salts Gold (nano) Colloidal gold (nano) Gold thioethylamino hyaluronic acid (nano) Acetyl heptapeptide-9 colloidal gold (nano)	
Silver	CI 77820	Silver	Silver nitrate Colloidal silver (nano) Silver zinc zeolite	Silver chloride deposited on titanium dioxide ¹⁵⁴ Citric acid (and) silver citrate (as Preservative) ¹⁵⁴
Titanium	CI 77891	Titanium dioxide	Bis(Cyclopentadienyl)-bis(2,6-difluoro-3-(pyrrol-1-yl)-phenyl)titanium Potassium titanium oxide	Titanium dioxide (as UV Filter) ¹⁵⁷

¹⁵⁹ In India, the limit for copper content in baby toilet soaps is 3 ppm (see Annex I).

Annex VII. Summary Chart of Glycol-Ethers

Name of Common Ingredients Glossary	Chemical Name	Acronym	CAS Number	EC Number	Limits ¹⁶⁰
Diethylene glycol	2,2'-Oxydiethanol	DEG	111-46-6	203-872-2	nd ¹⁶¹
Diethylene glycol dimethyl ether	bis(2-Methoxyethyl) ether	DEGDME	111-96-6	203-924-4	nd
Diethylene glycol monobutyl ether ¹⁶²	2-(2-Butoxyethoxy)ethanol	DEGBE	112-34-5	203-961-6	nd
Diethylene glycol monomethyl ether	2-(2-Methoxyethoxy)ethanol	DEGME	111-77-3	203-906-6	nd
Ethylene glycol dimethyl ether	1,2-Dimethoxyethane	EGDME	110-71-4	203-794-9	nd
Ethylene glycol monobutyl ether ¹⁶²	2-Butoxyethanol	EGBE	111-76-2	203-905-0	nd
Ethylene glycol monoethyl ether	2-Ethoxyethanol	EGEE	110-80-5	203-804-1	nd
Ethylene glycol monoethyl ether acetate	2-Ethoxyethyl acetate	EGEEA	111-15-9	203-839-2	nd
Ethylene glycol monomethyl ether	2-Methoxyethanol	EGME	109-86-4	203-713-7	nd
Ethylene glycol monomethyl ether acetate	2-Methoxyethyl acetate	EGMEA	110-49-6	203-772-9	nd
Ethylene glycol diethyl ether	1,2-Diethoxyethane	EGDEE	629-14-1	211-076-1	nd
Propylene glycol t-butyl ether ¹⁶³	tert-Butoxy-2-propanol	PGBE	57018-52-7	406-180-0	nd
Triethylene glycol dimethyl ether	1,2-bis(2-Methoxyethoxy)ethane	TEGDME	112-49-2	203-977-3	nd
Tetraethylene glycol dimethyl ether	Bis(2-(2-methoxyethoxy)ethyl)ether		143-24-8	205-594-7	nd
	2-Methoxypropanol	1PG2ME	1589-47-5	216-455-5	nd
	2-Methoxypropyl-1-acetate	1PG2MEA	70657-70-4	274-724-2	nd
Propylene glycol monomethyl ether	1-Methoxy-2-propanol	PGME	107-98-2	203-539-2	¹⁶⁴
Propylene glycol monomethyl ether acetate	1-Methoxy-2-propyl acetate	PGMEA	108-65-6 / 84540-57-8	203-603-9	¹⁶⁵
Diethylene glycol monoethyl ether	2-(2-Ethoxyethoxy)ethanol	DEGEE	111-90-0	203-919-7	2.6-10% ^{166,167}
Nonaethylene glycol monododecyl ether	Polidocanol		3055-99-0	221-284-4	2%

¹⁶⁰ nd ≈ < 0.0001% ≈ < 1 ppm.

¹⁶¹ The presence of DEG is prohibited in final cosmetic products. Due to its technical inevitability as an impurity in raw materials, its presence is allowed as a trace in the final product up to a concentration of 0.1%, except in the markets of Japan and China, where no trace limit is established.

¹⁶² According to the legislation of South Korea (see Annex I).

¹⁶³ According to the legislation of California (see Annex I).

¹⁶⁴ Its use is allowed as long as it does not contain 2-methoxypropanol (1PG2ME) in concentration equal to or more than 0.5% (see legislation of Canada, Annex I).

¹⁶⁵ Its use is allowed as long as it does not contain 2-methoxypropanol (1PG2ME) and/or 2-methoxypropyl-1-acetate (1PG2MEA) in concentration equal to or more than 0.5% (see legislation of Canada, Annex I).

¹⁶⁶ The limits refer to: oxidative hair dyes (7%) and non-oxidative hair dyes (5%); rinse-off products (other than hair dyes) (10%); other cosmetic products and the following products in aerosol: fine fragrances, hair sprays, antiperspirants and deodorants (2.6%). Not to be used in eye product and oral products.

¹⁶⁷ The level of ethylene glycol impurity in raw material must be ≤ 0.1%.

Annex VIII. Summary Chart of Volatile Organic Compounds (VOCs)

Table 1. VOCs content limits in Personal Fragrance Products¹⁶⁸.

Product type	Maximum VOCs content limit (%) ¹⁶⁹
Personal Fragrance Product	Aerosol products: a) Products ≤ 20% fragrance: 70 b) Products > 20% fragrance: 65
	Non-aerosol products: a) Products ≤ 7% fragrance: 70 b) Products 7% < fragrance ≤ 20%: 75 c) Products > 20% fragrance: 65

Table 2. VOCs content limits in deodorants and antiperspirants¹⁷⁰.

Product type	Maximum VOCs content limit (%) ¹⁷¹
Antiperspirant	Aerosol: 40 HVOC¹⁷² / 10 MVOC¹⁷³ Non aerosol: 0 HVOC / 0 MVOC
Deodorant	Aerosol: 0 HVOC / 10 MVOC Non aerosol: 0 HVOC / 0 MVOC

¹⁶⁸ According to the legislation of California and Canada (see Annex I).

¹⁶⁹ For the calculation of VOCs content, fragrance is not considered. Fragrance is defined as any substance or complex mixture of aroma chemicals, nature essential oils, and other functional components with a combined vapor pressure not in excess of 2 mm Hg at 20°C, the sole purpose of which is to impart an odour or scent, or to counteract a malodour.

¹⁷⁰ According to the legislation of the USA, California and Canada (see Annex I).

¹⁷¹ For the calculation of VOCs content, fragrance and colorants shall not be considered up to a combined level of 2% by weight. In addition, VOC compounds that contain more than 10 carbon atoms per molecule and for which the vapor pressure is unknown, or that have a vapour pressure of 2 mm Hg or less at 20°C shall also not be considered. The specified MVOC content shall not apply to ethanol.

¹⁷² High Volatility Organic Compound (HVOC) means any organic compound that exerts a vapor pressure greater than 80 mm Hg when measured at 20°C.

¹⁷³ Medium Volatility Organic Compound (MVOC) means any organic compound that exerts a vapor pressure greater than 2 mm Hg and less than or equal to 80 mm Hg when measured at 20°C.

Table 3. VOCs content limits in cosmetics products (other than personal fragrance products, deodorants, and antiperspirants)¹⁷⁴.

Product type	Maximum VOCs content limit (%) ¹⁷⁵			
	California	USA	Canada	Hong-Kong
Astringent / Toner	35	Not restricted	35	Not restricted
Dry shampoo	55	Not restricted	Not restricted	Not restricted
Hair finishing spray	50	80	55	55
Hair mousse	6	16	6	Not restricted
Hair shine	55	Not restricted	55	Not restricted
Hair styling product (product for moulding, combing, sculpting hair)	Aerosol or pump spray: 6 Other forms: 2	6	Aerosol or pump spray: 6 Other forms: 2	Not restricted
Nail polish remover	1	85	1	Not restricted
Shaving cream (aerosol)	5	5	5	Not restricted
Shaving gel (aerosol)	4	Not restricted	4	Not restricted
Temporary hair color (aerosol)	55	Not restricted	55	Not restricted
Heavy-duty hand cleaner or soap	Non-aerosol: 1 Other forms: 8	Not restricted	Non-aerosol: 1 Other forms: 8	Not restricted

¹⁷⁴ According to the legislation of the USA, California, Canada and Hong Kong (see Annex I).

¹⁷⁵ For the calculation of VOCs content, fragrance is not considered (until 2% of concentration).

Annex VIII *bis*. Summary Chart of Volatile Organic Compounds excluded from the calculation of VOCs

The list of VOCs that are excluded because it has been determined that they have negligible photochemical reactivity is listed below.

Chemical name	Acronym	CAS number	EC number
1,1,2,2-Tetrafluoroethane	HFC-134	359-35-3	206-628-3
1,1-Difluoroethane	HFC-152a	75-37-3	200-866-1
Acetone		67-64-1	200-662-2
Cyclic, branched or linear completely methylated siloxanes		Various	Various
Ethane		74-84-0	200-814-8
Methane		74-82-8	200-812-7
Methyl acetate		79-20-9	201-185-2
Trifluoromethane	HFC-23	75-46-7	200-872-4

Annex IX. Summary Chart of Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)^{176, 177}

Chemical name / Name of Common Ingredients Glossary	CAS number	Limits
(-)-Perfluoro(2-propoxypropionic) acid	75579-40-7	nd
(1H,1H,2H,2Hperfluorooctyl)1H,1H,2H,2Hperfluorodecyl)phosphate		nd
(2R)-2,3,3,3-tetrakis(fluoranyl)-2-[1,1,2,2,3,3,3-heptakis(fluoranyl)propoxy]propanoic acid	75579-39-4	nd
(n:2) Fluorotelomer phosphate ester derivates		nd
(n:2) Fluorotelomer phosphate triester		nd
1-(Perfluorooctyl)-3,6,9,12,15,18,21,24-octaooxatetracontan-25-one	67549-47-7	nd
1,2-Propanediol, 3-[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)oxy]-	126814-93-5	nd
1,2-Propanediol, 3-[(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl)oxy]-	121500-31-0	nd
10:2 Polyfluoroalkyl phosphate monoester	91338-38-2	nd
11-Chloroeicosafluoro-3-oxaundecane-1-sulfonic acid	763051-92-9	nd
1-Butanesulfonic acid, 1,1,2,2,3,3,4,4,4-nonafluoro-, ammonium salt	68259-10-9	nd
1-Chloro-3,3,3-trifluoropropene	2730-43-0	nd
1-Decanesulfonamide, N-ethyl-1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heneicosafluoro-N-[2-(phosphonooxy)ethyl]-	61481-05-8	nd
1-Dodecane sulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-pentacosafuoro-N-methyl-N-[2-(sulfooxy)ethyl]-	61481-06-9	nd
1H,1H,2H,2Hperfluorodecylphosphate		nd
1H,1H,2H,2Hperfluorooctylphosphate		nd
1-Octanesulfonamide, N-ethyl-1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluoro-N-[2-(phosphonooxy)ethyl]-	3820-83-5	nd
1-Octanethiol, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-	34451-26-8	nd
1-Propanaminium, 3-[[1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-heptadecafluorooctyl)sulfonyl]amino]-N,N,N-trimethyl-, iodide (1:1)	1652-63-7	nd
1-Propanaminium, N-(2-carboxyethyl)-3-[(2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluoro-1-oxooctyl)amino]-N,N-dimethyl-, inner salt	5158-52-1	nd
2-(Perfluoroalkyl)ethanol	65545-80-4	nd
2,3,3,3-Tetrafluoro-2-(heptafluoropropoxy)propanoic acid	13252-13-6	nd
2,3,3,3-Tetrafluoro-2-(perfluoropropoxy)propanoyl fluoride	2062-98-8	nd
2,3,3,3-Tetrafluoropropene	754-12-1	nd
2-Propanol, 1,3-bis[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)thio]-	160819-46-5	nd
2-Propanol, 1,3-bis[(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl)thio]-	160819-47-6	nd
2-Propanol, 1-[(2-decyltetradecyl)oxy]-3-[(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl)thio]-	160819-49-8	nd
2-Propanol, 1-[(2-dodecylhexadecyl)oxy]-3-[(3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl)thio]-	160819-50-1	nd
2-Propanol, 1-[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)oxy]-3-[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)thio]-	155604-47-0	nd
2-Propenoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluorooctyl ester, homopolymer	26337-50-8	nd
2-Propenoic acid, 2,2,3,3,4,4,5,5,6,6,7,7-dodecafluoroheptyl ester, homopolymer	26246-67-3	nd
2-Propenoic acid, 2-methyl-, 2,2,3,3,4,4,5,5,6,6,7,7-dodecafluoroheptyl ester, homopolymer	25656-09-1	nd
2-Propenoic acid, 2-methyl-, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluorooctyl ester, homopolymer	29014-57-1	nd
4,8-dioxa-3H-perfluorononanoate	2250081-67-3	nd
4:2 Fluorotelomer phosphate diester	135098-69-0	nd

¹⁷⁶ This table consists of a non-exhaustive list of PFAS substances and/or related substances.

¹⁷⁷ Additionally, all PFAS and/or related substances explicitly banned by the cosmetic product regulations in the legislations included in this standard are prohibited. PFAS and/or related substances regulated by European REACH legislation (Regulation (EC) No 1907/2006) and the Persistent Organic Pollutants Regulation (Regulation (EU) 2019/1021) are also prohibited, as well as those included in equivalent legislation in the markets covered by this standard.

Chemical name / Name of Common Ingredients Glossary	CAS number	Limits
4:2 Fluorotelomer phosphate monoester	150065-76-2	nd
4:2 Fluorotelomer sulfonate anion	414911-30-1	nd
4:2 Fluorotelomer sulfonic acid	757124-72-4	nd
4:2 Fluorotelomer sulfonic acid (4:2 FTS)	757124-72-4	nd
4:2 Polyfluoroalkyl phosphate monoester	16627-70-6	nd
4:2/6:2 Fluorotelomer phosphate diester	1158182-59-2	nd
4:2/6:2 Polyfluoroalkyl phosphate diester	142076-17-5	nd
4:2-Fluorotelomer alcohol	2043-47-2	nd
6:2 Chlorinated perfluoroether sulfonic acid	73606-19-6	nd
6:2 Fluorotelomer acrylate	17527-29-6	nd
6:2 Fluorotelomer carboxylic acid	53826-12-3	nd
6:2 Fluorotelomer methacrylate	2144-53-8	nd
6:2 Fluorotelomer sulfonate anion	425670-75-3	nd
6:2 Fluorotelomer sulfonic acid (6:2 FTS)	27619-97-2	nd
6:2 Fluorotelomer thiohydroxy ammonium chloride	88992-45-4	nd
6:2 Polyfluoroalkyl phosphate diester	57677-95-9	nd
6:2 Polyfluoroalkyl phosphate monoester	57678-01-0	nd
6:2/10:2 Fluorotelomer phosphate diester	1578186-50-1	nd
6:2/10:2 Polyfluoroalkyl phosphate diester	168635-85-8	nd
6:2/12:2 Fluorotelomer phosphate diester	1578186-69-2	nd
6:2/14:2 Fluorotelomer phosphate diester		nd
6:2/6:2 Polyfluoroalkyl phosphate diester	94350-12-4	nd
6:2/8:2 Fluorotelomer phosphate diester	943913-15-3	nd
6:2-Fluorotelomer alcohol	647-42-7	nd
7H-Dodecafluoroheptanoic acid / Ω -Hydroperfluoroalkanoate	1546-95-8	nd
8:2 Chlorinated perfluoroether sulfonic acid	83329-89-9	nd
8:2 Fluorotelomer sulfonate anion	481071-78-7	nd
8:2 Fluorotelomer sulfonic acid (8:2 FTS)	39108-34-4	nd
8:2 Fluorotelomer thioether hydroxyammonium chloride	71940-07-3	nd
8:2 polyfluoroalkyl phosphate diester		nd
8:2 polyfluoroalkyl phosphate monoester	74538-63-7	nd
8:2/10:2 Fluorotelomer phosphate diester	1158182-60-5	nd
8:2/12:2 Fluorotelomer phosphate diester	1578186-42-1	nd
8:2/8:2 Polyfluoroalkyl phosphate diester		nd
8-Chloroperfluoro-1-octanesulfonic acid	777011-38-8	nd
Acetyl trifluoromethylphenyl valylglycine	379685-96-8	nd
Acrylates/methoxy PEG-23 methacrylate/perfluorooctyl ethyl acrylate copolymer		nd
Acrylates/perfluorohexylethyl methacrylate copolymer	1557087-30-5	nd
Acrylates/trifluoropropylmethacrylate/polytrimethyl siloxymethacrylate copolymer		nd
Acrylic acid/perfluorohexylethyl acrylate crosspolymer	1820790-78-0	nd
Adamantanylcarboxamido Trifluoromethylbenzotrile		nd
Ammonium (n:2) fluorotelomer phosphate diester		nd
Ammonium C6-16 perfluoroalkylethyl phosphate	65530-72-5 / 65530-71-4 / 65530-70-3	nd
Ammonium C9-10 perfluoroalkylsulfonate		nd
Ammonium perfluoroheptanoate	6130-43-4	nd
Ammonium perfluorohexyl ethylphosphates		nd
Amp-C8-18 perfluoroalkylethyl phosphate		nd

Chemical name / Name of Common Ingredients Glossary	CAS number	Limits
Behenyl methacrylate/perfluorooctylethyl methacrylate copolymer		nd
Bis(1H,1H,2H,2Hperfluorooctyl)phosphate		nd
Bis(4-tert-butylphenyl)iodonium perfluoro-1-butanedisulfonate	194999-85-4	nd
Butyl acrylate/C6-14 perfluoroalkylethyl acrylate/mercaptopropyl dimethicone copolymer		nd
C12-16 Alkyl PEG-7 methacrylate/perfluorohexylethyl methacrylate copolymer		nd
C20-28 alkyl perfluorodecylethoxy dimethicone		nd
C4-14 perfluoroalkylethoxy dimethicone		nd
C4-18 perfluoroalkylethyl thiohydroxypropyltrimonium chloride	70983-60-7	nd
C6-12 perfluoroalkylethanol		nd
C6-14 Perfluoroalkylethyl acrylate		nd
C6-14 perfluoroalkylethyl acrylate/hema copolymer		nd
C8-18 Fluoroalcohol phosphate		nd
C9-13 Fluoroalcohol		nd
C9-15 Fluoroalcohol phosphate	223239-92-7	nd
Chlorinated polyfluorinated ether sulfonate	756426-58-1	nd
Chlorotrifluoropropene	102687-65-0	nd
Cis-1,1,1,4,4,4-hexafluoro-2-butene	692-49-9	nd
Cloflucarban	369-77-7	nd
DEA-C8-18 Perfluoroalkylethyl phosphate	223239-91-6	nd
DEA-Perfluorohexyl ethylphosphates		nd
DEA-Polyperfluoroethoxymethoxy PEG-2 phosphate		nd
Decafluoropentane	138495-42-8	nd
Diammonium (n:2) fluorotelomer phosphate monoester		nd
Diethanolamine bis(C8-C18 perfluoroalkylethyl phosphate)	65530-64-5	nd
Diethylaminoethyl methacrylate/hema/perfluorohexylethyl methacrylate crosspolymer		nd
Difluorocyclohexyloxyphenol	2001566-55-6	nd
Dimethiconol fluoroalcohol dilinoleic acid		nd
Dimethyl(phenyl)sulfonium nonafluorobutane-1-sulfonate	220133-51-7	nd
Dioctyldodecyl fluoroheptyl citrate	214334-16-4	nd
Ethanaminium, 2-carboxy-N,N-diethyl-N-[2-[[[(1,1,2,2,3,3,3,4,4,5,5,6,6,7,7,8,8,8-heptafluorooctyl)sulfonyl]amino]ethyl]-, inner salt	61481-08-1	nd
Ethanol, 2,2'-iminobis-, compd. with alpha-fluoro-omega-(2-(phosphonooxy)ethyl)poly(difluoromethylene) (2:1)	65530-63-4	nd
Ethyl nitrotrifluoromethylphenyl citramalamide	1081953-87-8	nd
Ethyl perfluorobutyl ether	163702-05-4	nd
Ethyl perfluoroisobutyl ether	163702-06-5	nd
Ethyl tafluprostamide / Dechloro dihydroxy difluoro ethylcloprostenolamide	1185851-52-8	nd
Ethyl travoprostamide / Trifluoro dechloro ethylcloprostenolamide	1005193-64-5	nd
Europium tris(trifluorothienylbutanedione) bis(triphenylphosphine oxide)	120851-64-1	nd
Fluoro C2-8 alkyldimethicone		nd
Fluoro octyldodecyl meadowfoamate		nd
Fluoroalcohol n = 9 – 13		nd
Fluoroalcohol phosphate n = 9 – 15		nd
Fluoroaliphatic polymeric esters		nd
Fluorosalan	4776-06-1	nd
Fluridil	260980-89-0	nd
Gen X / Ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate	62037-80-3	nd
HC Yellow no. 13	10442-83-8	nd

Chemical name / Name of Common Ingredients Glossary	CAS number	Limits
Hexafluoropropene, oxidized, oligomers, reduced, reaction products with methanol, reduced, reaction products with ethylene oxide and phosphoryl trichloride, hydrolyzed, salts with 2,2'-nitrilodiethanol	162567-75-1	nd
Hexafluoropropylene/tetrafluoroethylene copolymer		nd
Hydrofluorocarbon 134A / Tetrafluoroethane	811-97-2	nd
Hydrofluorocarbon 227EA / Heptafluoropropane	431-89-0	nd
Hydrogen trifluoropropyl dimethicone	766542-38-5	nd
Isobutylmethacrylate/trifluoroethylmethacrylate/bis-hydroxypropyl dimethicone acrylate copolymer	321735-42-6	nd
Isododecyl/perfluorononylethyl dimer dilinoleate/citrate		nd
Isopropyl titanium triisostearate/perfluorooctyl triethoxysilane crosspolymer		nd
Ketotravoprost / Methyl travoprost	404830-45-1	nd
Lithium nonafluoro-1-butanefluorobutanesulfonate	131651-65-5	nd
Magnesium nonafluorobutanefluorobutanesulfonate	507453-86-3	nd
Methacrylic acid, 2-(diethylamino)ethyl ester, polymer with 2,2,3,3,4,4,4-heptafluorobutyl methacrylate	34438-55-6	nd
Methacrylic acid, 2-(diethylamino)ethyl ester, polymer with 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluorooctyl acrylate	34482-03-6	nd
Methacrylic acid, 2-(diethylamino)ethyl ester, polymer with 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9-hexadecafluorononyl acrylate	34514-87-9	nd
Methacrylic acid, 2-(diethylamino)ethyl ester, polymer with 2,2,3,3,4,4,5,5,6,6,7,7-dodecafluoroheptyl acrylate	34438-56-7	nd
Methacrylic acid, 2-(diethylamino)ethyl ester, polymer with butyl methacrylate and 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluorooctyl acrylate	34482-04-7	nd
Methacrylic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluorooctyl ester, polymer with 2-(diethylamino)ethyl methacrylate	34438-51-2	nd
Methacrylic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9-hexadecafluoroheptadecyl ester, polymers	34482-06-9	nd
Methacrylic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9-hexadecafluorononyl ester, polymer with 2-(diethylamino)ethyl methacrylate	34447-80-8	nd
Methacrylic acid, 2,2,3,3,4,4,5,5,6,6,7,7-dodecafluoroheptyl ester, polymer with 2-(diethylamino)ethyl methacrylate	34438-59-0	nd
Methyl perfluoro butyl/isobutyl ether	163702-07-6 /	nd
Methyl perfluoroalkyl ether	163702-08-7	
Methyl perfluorobutyl ether /		nd
Methyl perfluoroalkyl ether	163702-07-6	
Methyl perfluoroisobutyl ether	163702-08-7	nd
N,N,N,-Triethylethanaminium 1,1,2,2,3,3,4,4,4-nonafluorobutane-1-sulfonate	25628-08-4	nd
N-Ethyl perfluoroalkane sulfonamidoacetic acid	2991-50-6	nd
N-Ethyl perfluorodecane sulfonamidoacetic acid	61481-04-7	nd
N-Morpholinium nonafluorobutanefluorobutanesulfonate	503155-89-3	nd
Nonanamide, N-[3-(diethylamino)propyl]-2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,9-heptadecafluoro-	61481-09-2	nd
Nortafuprost	209860-89-9	nd
Octafluoropentyl methacrylate	355-93-1	nd
Oxirane, 2-[[[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)oxy]methyl]-	122193-68-4	nd
PEG-10 acrylate/perfluorohexylethyl acrylate copolymer		nd
PEG-10 nonafluorohexyl dimethicone copolymer		nd
PEG-10 trifluoropropyl dimethicone copolymer / trifluoropropyl dimethicone/PEG-10 crosspolymer		nd
PEG-4 trifluoropropyl dimethicone copolymer		nd
PEG-8 trifluoropropyl dimethicone copolymer		nd
Pentafluorobutane	144377-42-4	nd
Pentafluoropropane	460-73-1	nd
Perfluoro dimethylethylpentane	50285-18-2	nd
Perfluoro t-butylcyclohexane	84808-64-0	nd

Chemical name / Name of Common Ingredients Glossary	CAS number	Limits
Perfluoro-1- propanesulfonic acid	59933-66-3	nd
Perfluoro-1-butanefulfonamide	1338-42-1	nd
Perfluoro-3,7-dimethyloctanoic acid	172155-07-6	nd
Perfluoro-4- ethylcyclohexanesulfonic acid	335-24-0	nd
Perfluoro-4-ethylcyclohexane	646-83-3	nd
Perfluoroalkyl dimethicone (n= 2-8)		nd
Perfluoroalkylethyl thiohydroxypropyl trimonium chloride		nd
Perfluorobutane sulfonamide	30334-69-1	nd
Perfluorobutanefulfonate	45187-15-3	nd
Perfluorobutanefulfonic acid	375-73-5	nd
Perfluorobutanoate	45048-62-2	nd
Perfluorobutanoic acid	375-22-4	nd
Perfluorobutoxydiglycol difluoroethoxy propyl trimethoxysilane		nd
Perfluorobutylcyclohexane	374-60-7	nd
Perfluorobutylethyl dimethicone		nd
Perfluorobutylethyl stearyl dimethicone	915223-67-5	nd
Perfluorocaprylyl bromide	423-55-2	nd
Perfluorocaprylyl triethoxysilylethyl methicone		nd
Perfluorocyclohexylmethanol	28788-68-3	nd
Perfluorodecalin	306-94-5	nd
Perfluorodecanefulfonate	126105-34-8	nd
Perfluorodecanefulfonate (CAS from acid)	335-77-3	nd
Perfluorodecanoate	73829-36-4	nd
Perfluorodecylphosphonate	145962-55-8	nd
Perfluorodecylphosphonate (CAS from acid)	52299-26-0	nd
Perfluorodimethylcyclohexane / Perfluoro-1,3- dimethylcyclohexane	335-27-3	nd
Perfluorododecanoate	171978-95-3	nd
Perfluoroester		nd
Perfluoro-ethoxymethoxy difluoromethyl distearamide		nd
Perfluoroheptane	335-57-9	nd
Perfluoroheptanefulfonate	146689-46-5	nd
Perfluoroheptanefulfonate (CAS from acid)	375-92-8	nd
Perfluoroheptanoate	120885-29-2	nd
Perfluorohexadecanoate	1214264-30-8	nd
Perfluorohexadecanoic acid	67905-19-5	nd
Perfluorohexane	355-42-0	nd
Perfluorohexane sulfonamide	41997-13-1	nd
Perfluorohexanefulfonate	108427-53-8	nd
Perfluorohexanoate	92612-52-7	nd
Perfluorohexyl ethylphosphonic acid	252237-40-4	nd
Perfluorohexylethoxy dimethicone		nd
Perfluorohexylethyl dimethylbutyl ether	210896-25-6	nd
Perfluorohexylphosphonate	754-34-7	nd
Perfluorohexylphosphonate (CAS from acid)	40143-76-8	nd
Perfluoroisohexane / Perfluoro-2-methylpentane	355-04-4	nd
Perfluoromethylcyclohexane	355-02-2	nd
Perfluoromethylcyclopentane	1805-22-7	nd
Perfluoromethyldecalin	51294-16-7	nd
Perfluorononane sulfonic acid	474511-07-4	nd

Chemical name / Name of Common Ingredients Glossary	CAS number	Limits
Perfluorononanesulfonate	68259-12-1	nd
Perfluorononanoate	72007-68-2	nd
Perfluorononyl dimethicone		nd
Perfluorononyl dimethicone crosspolymer	259725-95-6	nd
Perfluorononyl dimethicone/methicone/amodimethicone crosspolymer		nd
Perfluorononyl octyldodecyl glycol		nd
Perfluorononyl octyldodecyl glycol grapeseedate		nd
Perfluorononyl octyldodecyl glycol meadowfoamate		nd
Perfluorononylethyl carboxy PEG-7 dimethicone phosphate		nd
Perfluorononylethyl carboxydecyl behenyl dimethicone		nd
Perfluorononylethyl carboxydecyl hexacosyl dimethicone		nd
Perfluorononylethyl carboxydecyl lauryl dimethicone		nd
Perfluorononylethyl carboxydecyl lauryl/behenyl dimethicone		nd
Perfluorononylethyl carboxydecyl PEG-10 dimethicone		nd
Perfluorononylethyl carboxydecyl PEG-8 dimethicone		nd
Perfluorononylethyl dimethicone/methicone copolymer		nd
Perfluorononylethyl PEG-8 dimethicone		nd
Perfluorononylethyl PEG-8 phenylisopropyl dimethicone		nd
Perfluorononylethyl stearyl dimethicone		nd
Perfluorooctadecanoic acid	16517-11-6	nd
Perfluorooctane sulfonamidoacetic acid	2806-24-8	nd
Perfluorooctanesulfonamide	754-91-6	nd
Perfluorooctanesulfonate	45298-90-6	nd
Perfluorooctanoate	45285-51-6	nd
Perfluorooctylethyl triethoxysilane	101947-16-4	nd
Perfluorooctylethyl trimethoxysilane	83048-65-1	nd
Perfluorooctylethyl trisiloxane	163921-85-5	nd
Perfluorooctylethyl/diphenyl dimethicone copolymer		nd
Perfluorooctylphosphonate	145964-09-6	nd
Perfluorooctylphosphonate (CAS from acid)	40143-78-0	nd
Perfluoropentadecanoic acid	141074-63-7	nd
Perfluoropentanesulfonate (CAS from acid)	2706-91-4	nd
Perfluoropentanoate	45167-47-3	nd
Perfluoropentanoic acid	2706-90-3	nd
Perfluoroperhydrobenzyl tetralin	116265-66-8	nd
Perfluoroperhydrofluorene	307-08-4	nd
Perfluoroperhydrophenanthrene	306-91-2	nd
Perfluoropolyether		nd
Perfluoropropane	76-19-7	nd
Perfluoropropane sulfonic acid	423-41-6	nd
Perfluoropropanoate	44864-55-3	nd
Perfluoropropanoic acid	422-64-0	nd
Perfluoropropylene	116-15-4	nd
Perfluoropropylene/vinylidene difluoride copolymer	9011-17-0	nd
Perfluorotetradecanoate	365971-87-5	nd
Perfluorotetralin	2342-07-6	nd
Perfluorotridecanoate	862374-87-6	nd
Perfluoroundecane sulfonic acid	749786-16-1	nd
Perfluoroundecanoate	196859-54-8	nd

Chemical name / Name of Common Ingredients Glossary	CAS number	Limits
Phosphonic acid, perfluoro-C6-12-alkyl derivs / Perfluoroalkyl phosphate	68412-68-0	nd
Poly(difluoromethylene), .alpha.-[2-[(2-carboxyethyl)thio]ethyl]- omega.-fluoro-, lithium salt	65530-69-0	nd
Poly(difluoromethylene), α,α' -[phosphinobis(oxy-2,1-ethanediy)]bis[Ω -fluoro- // bis(3,3,3-trifluoropropyl) hydrogen phosphate	65530-62-3	nd
Poly(difluoromethylene), α -fluoro- Ω -[2-(phosphonooxy)ethyl]- // 3,3,3-trifluoropropyl dihydrogen phosphate	65530-61-2	nd
Poly(oxy-1,2-ethanediy), α -(perfluoroalkyl)- Ω -hydroxy-		nd
Polyacrylate-37		nd
Polyacrylate-48		nd
Polychlorotrifluoroethylene	9002-83-9	nd
Polyfluoroalkyl phosphonic acids		nd
Polyperfluoroethoxymethoxy difluoroethyl PEG diisostearate		nd
Polyperfluoroethoxymethoxy difluoroethyl PEG ether / Tetrafluoroethylene, oxidized, oligomers, reduced, methyl esters, reduced	162492-15-1 / 88645-29-8	nd
Polyperfluoroethoxymethoxy difluoroethyl PEG phosphate		nd
Polyperfluoroethoxymethoxy difluorohydroxyethyl ether		nd
Polyperfluoroethoxymethoxy difluoromethyl distearamide / Tribehenin PEG-20 esters	220207-10-3	nd
Polyperfluoroethoxymethoxy difluoromethyl ether	161075-02-1	nd
Polyperfluoroethoxymethoxy PEG-2 phosphate	162567-74-0	nd
Polyperfluoroisopropyl ether		nd
Polyperfluoromethylisopropyl ether	69991-67-9	nd
Polyperfluoroperhydrophenanthrene	159182-00-0	nd
Polysilicone-10		nd
Polysilicone-7	146632-08-8	nd
Polytetrafluoroethylene (PTFE)	9002-84-0	nd
Polytetrafluoroethylene acetoxypopyl betaine	123171-68-6	nd
Polyurethane-26	328389-90-8	nd
Polyurethane-27	328389-91-9	nd
Polyvinylidene difluoride (PVDF)	24937-79-9	nd
Potassium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionate	67118-55-2	nd
Potassium N-ethyl perfluorooctane sulfonamidoacetate	2991-51-7	nd
Potassium nonafluoro-1-butanefulfonate	29420-49-3	nd
Potassium perfluoroheptanoate	21049-36-5	nd
Potassium perfluorohexyl ethylphosphate / Potassium 6:2 fluorotelomer phosphonate	1224952-82-2	nd
Sodium formylhippurate trifluoroacetylisobutyl dipeptide-42 amide	144055-55-0	nd
Sodium perfluoroheptanoate	20109-59-5	nd
Sodium perfluorohexyl ethylphosphonate / Sodium 6:2 fluorotelomer phosphonate	1189052-95-6	nd
Stearyl methacrylate/perfluorooctylethyl methacrylate copolymer		nd
Tafuprost	209860-87-7	nd
TEA-C8-18 perfluoroalkylethyl phosphate		nd
TEA-perfluorohexyl ethylphosphates		nd
Tetrabutyl-phosphonium nonafluoro-butane-1-sulfonate	220689-12-3	nd
Tetrafluoropropene / trans-1,3,3,3-tetrafluoropropene	29118-24-9	nd
Trifluoroacetic acid and its salts (trifluoroacetate)	76-05-1	nd
Trifluoroacetyl tripeptide-2	64577-63-5	nd
Trifluoroethyl methacrylate	352-87-4	nd
Trifluoromethyl C1-4 alkyl dimethicone		nd
Trifluoromethyl dehydrolatanoprost	157283-68-6	nd
Trifluoromethylbipyridyl bromobenzimidazole		nd
Trifluoromethylphenethyl mesalazine	927685-43-6	nd

Chemical name / Name of Common Ingredients Glossary	CAS number	Limits
Trifluoropropyl cyclopentasiloxane	2063-78-7	nd
Trifluoropropyl cyclotetrasiloxane	429-67-4	nd
Trifluoropropyl cyclotrisiloxane	2374-14-3	nd
Trifluoropropyl dimethicone		nd
Trifluoropropyl dimethicone/PEG -10 crosspolymer		nd
Trifluoropropyl dimethicone/trifluoropropyl divinyl dimethicone crosspolymer		nd
Trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer		nd
Trifluoropropyl dimethiconol		nd
Trifluoropropyl methicone		nd
Trifluoropropyldimethyl/trimethylsiloxysilicate		nd
Trifluoropropyldimethylsiloxy/trimethylsiloxy silsesquioxane		nd
Trifluoropropylmethyl dimethicone	115361-68-7	nd
Trimethyl trifluoromethylindolino piperidinylspironaphthooxazine	172208-34-3	nd
Triphenylsulfonium nonaflate	144317-44-2	nd
Undecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heneicosafuoro-, ethyl ester	41506-11-0	nd

Annex X. Summary Chart of Colorants

Global Chart of Colorants¹⁷⁸

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ¹⁷⁹	Not to be used in eye products ¹⁸⁰	Not to be used in lip products ¹⁸¹	Not to be used in products applied on mucous membranes ¹⁸²	General notes
CI 10316	Yellow	Disodium 5,7-dinitro-8-oxidonaphthalene-2-sulphonate	Ext. D&C Yellow No.7		846-70-8	212-690-2			X	X ¹⁸³	X ¹⁸⁴	185,186
USA: Straight colour: Ext. D&C Yellow No.7 (Na salt); Lakes: ¹⁸⁷ Na, K, Al, Ba, Ca, Sr, Zr. Japan: Yellow No. 403(1); Salt: Na/ Lakes: Al.												
CI 12085	Red	1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol	D&C Red No.36		2814-77-9	220-562-2	3%		X ^{188,189}		X ¹⁸⁸	185,186
USA: Straight colour: D&C Red No.36; Lakes: ¹⁹⁰ Na, K, Al, Ba, Ca, Sr, Zr. Japan: Red No. 228; Salt: -/ Lakes: -.												

¹⁷⁸ Without prejudice to other provisions, a colorant shall include its salts and lakes and when a colorant is expressed as a specific salt, its other salts and lakes shall also be included (in the USA and Japan, only the salts and lakes specified in the table for each colorant shall be used). All colorants used must meet the purity criteria established in the regulations included in this standard (see Annex I).

¹⁷⁹ Leave-on product means a cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes.

¹⁸⁰ Eye product means a cosmetic product which is intended to be applied in the vicinity of the eyes.

¹⁸¹ Lip product means a cosmetic product which is intended to be applied on the lips.

¹⁸² Product applied on mucous membranes means a cosmetic product which is intended to be applied on the mucous membranes of the oral cavity, on the rim of the eyes, or on the external genital organs.

¹⁸³ According to the legislation of the USA and South Korea (see Annex I).

¹⁸⁴ According to the legislation of the USA and Japan (see Annex I).

¹⁸⁵ This colorant includes the insoluble barium, strontium and zirconium lakes, salts and pigments.

¹⁸⁶ This colorant must be batch certified by FDA if it is to be used in cosmetic products marketed in the USA.

¹⁸⁷ The permitted lakes must comply with the provisions of 21 CFR 82.2051 (Lakes Ext. D&C). The lakes will be formed from a straight colour (or a derived salt) by depositing it onto the substrates listed below and using the radicals also indicated below. Substrate: alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, resin, aluminum benzoate, calcium carbonate, or any combination of two or more of these. Basic radical: sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

¹⁸⁸ According to the legislation of the USA (see Annex I).

¹⁸⁹ In India, the use of this colorant and its lakes in eye pencils is prohibited (see Annex I).

¹⁹⁰ The permitted lakes must comply with the provisions of 21 CFR 82.1051 (Lakes D&C). The lakes will be formed from a straight colour (or a derived salt) by depositing it onto the substrates listed below and using the radicals also indicated below. Substrate: alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, resin, aluminum benzoate, calcium carbonate, or any combination of two or more of these. Basic radical: sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ¹⁷⁹	Not to be used in eye products ¹⁸⁰	Not to be used in lip products ¹⁸¹	Not to be used in products applied on mucous membranes ¹⁸²	General notes
CI 14700	Red	Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulphonate	FD&C Red No.4		4548-53-2	224-909-9			X ^{183,189}	X ¹⁸³	X ¹⁸⁴	186,191
USA: Straight colour: FD&C Red No.4 (Na salt); Lakes ^{190,192} FD&C Red No.4: Al, Ca; D&C Red No.4: Na, K, Al, Ba, Ca, Sr, Zr. Japan: Red No. 504; Salt: Na/ Lakes: Al.												
CI 15510	Orange	Sodium 4-[(2-hydroxy-1-naphthyl)azo] benzenesulphonate	D&C Orange No.4		633-96-5	211-199-0			X	X ¹⁸⁸	X ¹⁸⁸	185,186
USA: Straight colour: D&C Orange No.4 (Na salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Orange No. 205; Salt: Na/ Lakes: Al, Ba, Zr.												
CI 15800	Red	Calcium bis[3-hydroxy-4-(phenylazo)-2-naphthoate]	D&C Red No.31		6371-76-2	228-899-7			X ^{183,189}	X ¹⁸³	X	186,191,193
USA: Straight colour: D&C Red No.31 (Ca salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Red No. 219; Salt: Ca/ Lakes: -.												
CI 15850	Red	Disodium 3-hydroxy-4-[(4-methyl-2-sulphonatophenyl)azo]-2-naphthoate	D&C Red No.6 D&C Red No.7	E 180	5858-81-1	227-497-9			X ^{189,194}			185,186
USA: Straight colour: D&C Red No.6 (Na salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Red No. 201; Salt: Na/ Lakes: -. USA: Straight colour: D&C Red No.7 (Ca salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Red No. 202; Salt: Ca/ Lakes: -.												

¹⁹¹ Barium, strontium and zirconium lakes of this colorant are prohibited (see legislation of South Korea, Annex I).

¹⁹² The permitted lakes must comply with the provisions of 21 CFR 82.51 (Lakes FD&C). The lakes will be formed from a straight colour (or a derived salt) by depositing it onto the substrates listed below and using the radicals also indicated below. Substrate: alumina. Basic radical: aluminum or calcium.

¹⁹³ Use only in cosmetic products that are applied to the nails and hair (see legislation of Japan, Annex I).

¹⁹⁴ According to the legislation of the USA (see Annex I). The prohibition of eye products includes products applied on the rim of the eyes.

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ¹⁷⁹	Not to be used in eye products ¹⁸⁰	Not to be used in lip products ¹⁸¹	Not to be used in products applied on mucous membranes ¹⁸²	General notes
CI 15880	Red	Calcium 3-hydroxy-4-[(1-sulphonato-2-naphthyl)azo]-2-naphthoate	D&C Red No.34		6417-83-0	229-142-3			X ^{188,189}	X ¹⁸⁸	X ¹⁸⁸	186,191
USA: Straight colour: D&C Red No.34 (Ca salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Red No. 220; Salt: Ca/ Lakes: -.												
CI 15985	Yellow	Disodium 6-hydroxy-5-[(4-sulphonatophenyl)azo]naphthalene-2-sulphonate	FD&C Yellow No.6	E 110	2783-94-0	220-491-7			X ^{189,194}			185,186
USA: Straight colour: FD&C Yellow No.6 (Na salt); Lakes ^{190,192} : FD&C Yellow No.6: Al, Ca; D&C Yellow No.6: Na, K, Al, Ba, Ca, Sr, Zr. Japan: Yellow No. 5; Salt: Na/ Lakes: Al, Ba, Zr.												
CI 17200	Red	Disodium 5-amino-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulphonate	D&C Red No.33		3567-66-6	222-656-9	3% ¹⁹⁵		X ^{189,194}			186,196,197
USA: Straight colour: D&C Red No.33 (Ca salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Red No. 227; Salt: Na/ Lakes: Al.												
CI 19140	Yellow	Trisodium 5-hydroxy-1-(4-sulphophenyl)-4-((4-sulphophenyl)azo)pyrazole-3-carboxylate	FD&C Yellow No.5	E 102	1934-21-0	217-699-5			X ¹⁸⁹			185,186,198
USA: Straight colour: FD&C Yellow No.5 (Na salt); Lakes ^{190,192} : FD&C Yellow No.5: Al, Ca; D&C Yellow No.5: Na, K, Al, Ba, Ca, Sr, Zr. Japan: Yellow No. 4; Salt: Na/ Lakes: Al, Ba, Zr.												

¹⁹⁵ This numerical limit applies to lip cosmetics (see legislation of the USA and South Korea, Annex I).

¹⁹⁶ This colorant includes the insoluble barium, strontium and zirconium lakes, salts and pigments; except in South Korea where barium, strontium and zirconium lakes of this colorant are prohibited (see Annex I).

¹⁹⁷ In products applied on mucous membranes, it can only be used in mouthwashes and dentifrices (see legislation of the USA, Annex I).

¹⁹⁸ In eye products, can only be used this colorant or its aluminium lake (see legislation of the USA, Annex I).

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ¹⁷⁹	Not to be used in eye products ¹⁸⁰	Not to be used in lip products ¹⁸¹	Not to be used in products applied on mucous membranes ¹⁸²	General notes
CI 40800	Orange	β-carotene (Synthetic; Food Orange 5)	β-Carotene	E 160a	7235-40-7	230-636-6			X ¹⁸⁹			
CI 42053	Green	Benzene-methanaminium, N-ethyl-N-(4-((4-(ethyl((3-sulfophenyl)methyl)amino)phenyl)(4-hydroxy-2-sulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-3-sulfo-, hydroxide, inner salt, disodium salt	FD&C Green No.3		2353-45-9	219-091-5			X ^{189,194}			186
USA: Straight colour: FD&C Green No.3 (Na salt); Lakes ^{190, 192} : FD&C Green No.3: Al, Ca; D&C Green No.3: Na, K, Al, Ba, Ca, Sr, Zr. Japan: Green No. 3; Salt: Na/ Lakes: Al.												
CI 42090	Blue	Benzene-methanaminium, N-ethyl-N-(4-((4-(ethyl((3-sulfophenyl)methyl)amino)phenyl)(2-sulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-3-sulfo-, hydroxide, inner salt, disodium salt	FD&C Blue No.1 D&C Blue No.4	E 133	3844-45-9	223-339-8			X ^{189,199}	X ¹⁹⁹	X ¹⁹⁹	186,191
USA: Straight colour: FD&C Blue No.1 (Na salt); Lakes ^{190, 192} : FD&C Blue No.1: Al, Ca; D&C Blue No.1: Na, K, Al, Ba, Ca, Sr, Zr. Japan: Blue No. 1; Salt: Na/ Lakes: Al, Ba, Zr. USA: Straight colour: D&C Blue No.4 (NH ₄ salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Blue No. 205; Salt: NH ₄ / Lakes: Al.												
CI 45350	Yellow	Disodium 2-(3-oxo-6-oxidoxanthen-9-yl)benzoate	D&C Yellow No.7 D&C Yellow No.8		2321-07-5 / 518-47-8	219-031-8 / 208-253-0	6%		X ^{183,189}	X ¹⁸³	X ¹⁸⁸	186,191

¹⁹⁹ According to the legislation of the USA (see Annex I), in eye products, only FD&C Blue No. 1 and FD&C Blue No. 1-Aluminum Lake can be used. In lip products and products applied to mucous membranes, only FD&C Blue No. 1 and its lakes can be used.

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ¹⁷⁹	Not to be used in eye products ¹⁸⁰	Not to be used in lip products ¹⁸¹	Not to be used in products applied on mucous membranes ¹⁸²	General notes
USA: Straight colour: D&C Yellow No.7; Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Yellow No. 201; Salt: -/ Lakes: -. USA: Straight colour: D&C Yellow No.8 (Na salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Yellow No. 202(1); Salt: Na/ Lakes: Al// Yellow No. 202(2); Salt: K/ Lakes: Al.												
CI 45370	Orange	4',5'-Dibromo-3',6'-dihydroxyspiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one	D&C Orange No.5		596-03-2 / 4372-02-5	209-876-0 / 224-468-2	5% ²⁰⁰		X ^{189,201}			185,186,197
USA: Straight colour: D&C Orange No.5; Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Orange No. 201; Salt: -/ Lakes: -.												
CI 45380	Red	Disodium 2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxanthen-9-yl)benzoate	D&C Red No.21 D&C Red No.22		17372-87-1	241-409-6			X ^{189,201}			185,186
USA: Straight colour: D&C Red No.21; Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Red No. 223; Salt: -/ Lakes: -. USA: Straight colour: D&C Red No.22 (Na salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Red No. 230(1); Salt: Na/ Lakes: Al// Red No. 230(2); Salt: K/ Lakes: -.												
CI 45410	Red	3,4,5,6-Tetrachloro-2-(1,4,5,8-tetrabromo-6-hydroxy-3-oxoxanthen-9-yl)benzoic acid	D&C Red No.27 D&C Red No.28		18472-87-2	242-355-6			X ^{189,201}			185,186
USA: Straight colour: D&C Red No.27; Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Red No. 218; Salt: -/ Lakes: -. USA: Straight colour: D&C Red No.28 (Na salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Red No. 231; Salt: K/ Lakes: -.												

²⁰⁰ This numerical limit applies to lip cosmetics (see legislation of the USA, Annex I).

²⁰¹ According to the legislation of the USA and South Korea (see Annex I). The prohibition of eye products includes products applied on the rim of the eyes.

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ¹⁷⁹	Not to be used in eye products ¹⁸⁰	Not to be used in lip products ¹⁸¹	Not to be used in products applied on mucous membranes ¹⁸²	General notes
CI 47000	Yellow	1,3-Isobenzofurandione, reaction products with methylquinoline and quinoline	D&C Yellow No.11		8003-22-3	232-318-2			X ^{183,189}	X ¹⁸³	X	186,191,193
USA: Straight colour: D&C Yellow No.11; Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Yellow No. 204; Salt: -/ Lakes: -.												
CI 47005	Yellow	1H-Indene-1,3(2H)-dione, 2-(2-quinolinyl)-, sulfonated, sodium salts	D&C Yellow No.10	E 104	95193-83-2 / 8004-92-0	305-897-5			X ^{189,201}			186
USA: Straight colour: D&C Yellow No.10 (Na salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Yellow No. 203; Salt: Na/ Lakes: Al, Ba, Zr.												
CI 59040	Green	Trisodium 8-hydroxyppyrene-1,3,6-trisulphonate	D&C Green No.8		6358-69-6	228-783-6	0.01% ¹⁸³		X ^{183,189}	X ¹⁸³	X	186,191
USA: Straight colour: D&C Green No.8 (Na salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Green No. 204; Salt: Na/ Lakes: Al.												
CI 60725	Violet	1-Hydroxy-4-(p-toluidino)anthraquinone	D&C Violet No.2		81-48-1	201-353-5	0.3% ²⁰²		X ^{188,189}	X ¹⁸⁸	X ¹⁸⁸	186,191
USA: Straight colour: D&C Violet No.2; Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Violet No. 201; Salt: -/ Lakes: -.												
CI 60730	Violet	Sodium 4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]toluene-3-sulphonate	Ext. D&C Violet No.2		4430-18-6	224-618-7			X ^{183,189}	X ¹⁸³	X	186,191
USA: Straight colour: Ext. D&C Violet No.2 (Na salt); Lakes ¹⁸⁷ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Violet No. 401; Salt: Na/ Lakes: Al.												
CI 61565	Green	1,4-bis(p-Tolylamino)anthraquinone	D&C Green No.6		128-80-3	204-909-5			X ^{188,189}	X ¹⁸⁸	X ¹⁸⁸	186,191
USA: Straight colour: D&C Green No.6; Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Green No. 202; Salt: -/ Lakes: -.												

²⁰² This numerical limit applies to cosmetic products, except for nail cosmetic products (see legislation of Canada, Annex I).

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ¹⁷⁹	Not to be used in eye products ¹⁸⁰	Not to be used in lip products ¹⁸¹	Not to be used in products applied on mucous membranes ¹⁸²	General notes
CI 61570	Green	Disodium 2,2'-(9,10-dioxoanthracene-1,4-diyl-diimino)bis(5-methylsulphonate)	D&C Green No.5		4403-90-1	224-546-6			X ¹⁸⁹			186,191,203
USA: Straight colour: D&C Green No.5 (Na salt); Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Green No. 201; Salt: Na/ Lakes: Al.												
CI 73360	Red	6-Chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-4-methylbenzo[b]thiophene-3(2H)-one	D&C Red No.30		2379-74-0	219-163-6			X ^{189,194}			186,191
USA: Straight colour: D&C Red No.30; Lakes ¹⁹⁰ : Na, K, Al, Ba, Ca, Sr, Zr. Japan: Red No. 226; Salt: -/ Lakes: -.												

²⁰³ The lakes of this colorant cannot be used in eye products (see legislation of the USA, Annex I).

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ¹⁷⁹	Not to be used in eye products ¹⁸⁰	Not to be used in lip products ¹⁸¹	Not to be used in products applied on mucous membranes ¹⁸²	General notes
CI 75120	Orange	Annatto	Annatto	E 160b	1393-63-1	215-735-4 / 289-561-2 / 230-248-7			X ¹⁸⁹			
CI 75130	Orange	β-Carotene (Natural Yellow 26; CI Food Orange 5)	β-Carotene	E 160a	7235-40-7	230-636-6			X ¹⁸⁹			
CI 75170	White	2-Amino-1,7-dihydro-6H-purin-6-one	Guanine		73-40-5	200-799-8			X ¹⁸⁹			
CI 75470	Red	Carmines	Carmine	E 120	1390-65-4 / 1343-78-8 / 1260-17-9 / 1328-60-5	215-724-4 / 215-680-6 / 215-023-3 / 215-527-3			X ¹⁸⁹			204
CI 75810	Green	Trisodium (2S-trans)-[18-carboxy-20-(carboxymethyl)-13-ethyl-2,3-dihydro-3,7,12,17-tetramethyl-8-vinyl-21H,23H-porphine-2-propionato(5-)-N21,N22,N23,N24] cuprate(3-) (Chlorophylls)	Chlorophyllin-copper complex	E 140 E 141	1406-65-1 / 479-61-8 / 519-62-0	215-800-7/ 207-536-6 / 208-272-4 / 287-483-3/ 239-830-5 / 246-020-5	0.1% ²⁰⁵		X ^{188,189}	X ¹⁸⁸	X ¹⁸⁸	206
CI 77000	White	Aluminium	Aluminum powder	E 173	7429-90-5	231-072-3				X ¹⁸⁸	X ²⁰⁷	
CI 77007	Blue	Lazurite	Ultramarines		1302-83-6	215-111-1				X ¹⁸⁸	X ²⁰⁷	

²⁰⁴ In South Korea, the following must be included on the labelling: a) products containing carmine: "People sensitive or allergic to carmine should use it with caution"; b) products containing cochineal extract: "People hypersensitive or allergic to the ingredients of cochineal extract should use it with caution".

²⁰⁵ According to the legislation of the USA and MERCOSUR (see Annex I).

²⁰⁶ Use only in dentifrices and in combination with certain substances (see legislation of the USA, Annex I).

²⁰⁷ According to the legislation of the USA (see Annex I). The prohibition of products applied on mucous membranes excludes products applied on the rim of the eyes.

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ¹⁷⁹	Not to be used in eye products ¹⁸⁰	Not to be used in lip products ¹⁸¹	Not to be used in products applied on mucous membranes ¹⁸²	General notes
CI 77163	White	Bismuth chloride oxide	Bismuth oxichloride		7787-59-9	232-122-7						
CI 77266	Black	Carbon black Carbon black (nano)	D&C Black No.2		1333-86-4/ 7440-44-0	215-609-9/ 231-153-3 / 931-328-0 / 931-334-3	10% (nano) ²⁰⁸					186,209,210, 211
CI 77267	Black	Charcoal, bone. A fine black powder obtained by burning animal bones in a closed container. It consists primarily of calcium phosphate and carbon	D&C Black No.3		8021-99-6	232-421-2						186,211,212
CI 77288	Green	Chromium(III) oxide	Chromium oxide greens		1308-38-9	215-160-9				X ¹⁸⁸	X ²⁰⁷	213
CI 77289	Green	Chromium(III) hydroxide	Chromium hydroxide green		12001-99-9	215-160-9				X ¹⁸⁸	X ²⁰⁷	213
CI 77400	Brown	Copper	Copper powder Bronze powder		7440-50-8	231-159-6						
CI 77489	Orange	Iron oxide	Iron oxides		1345-25-1	215-721-8						
CI 77491	Red	Iron Oxide Red	Iron oxides	E 172	1309-37-1	215-168-2						
CI 77492	Yellow	Iron Oxide Yellow	Iron oxides	E 172	51274-00-1	257-098-5						
CI 77499	Black	Iron Oxide Black	Iron oxides	E 172	12227-89-3	235-442-5						

²⁰⁸ This numerical limit applies for the "nano" form.

²⁰⁹ The "nano" form shall not be used in applications that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: primary particle size ≥ 20 nm; purity ≥ 97%.

²¹⁰ It is only permitted in products for make-up the eyes, lipsticks, blushes, make-up and nail polish (see legislation of the USA, Annex I).

²¹¹ In the event of marketing eye pencils in India, contact the Sustainability Department of Inditex.

²¹² It is only permitted in products for make-up the eyes and face powders (see legislation of the USA, Annex I).

²¹³ Free of chromate ion.

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ¹⁷⁹	Not to be used in eye products ¹⁸⁰	Not to be used in lip products ¹⁸¹	Not to be used in products applied on mucous membranes ¹⁸²	General notes
CI 77510	Blue	Ferric Ammonium Ferrocyanide Ferric Ferrocyanide	Ferric ammonium ferrocyanide Ferric ferrocyanide		25869-00-5 / 12240-15-2 / 14038-43-8	237-875-5				X ¹⁸⁸	X ²⁰⁷	214
CI 77742	Violet	Ammonium manganese(3+) diphosphate	Manganese violet		10101-66-3	233-257-4						
CI 77820	White	Silver	Silver	E 174	7440-22-4	231-131-3	1% ²¹⁵		X ¹⁸⁸	X ¹⁸⁸	X ¹⁸⁸	216
CI 77891	White	Titanium dioxide	Titanium dioxide	E 171	13463-67-7	236-675-5						217
CI 77947	White	Zinc oxide	Zinc oxide		1314-13-2	215-222-5						218
---	Brown	Caramel	Caramel	E 150a-d	8028-89-5	232-435-9			X ¹⁸⁹			

²¹⁴ Free of cyanide ion.

²¹⁵ According to the legislation of the USA (see Annex I). In Canada, MAC for mouthwashes is 0.04%.

²¹⁶ Use only in fingernail polishes (see legislation of the USA, Annex I). In Canada, the label must include: "This product contains silver and/or silver salts. Avoid contact with damaged or scraped skin".

²¹⁷ Titanium dioxide in powder form containing 1% or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$, to be used must meet the following requirements: a) Face products in loose, MAC: 25%, only in the pigmentary form; b) Hair aerosol spray products, MAC: 1.4% for general consumers and 1.1% for professional use, only in the pigmentary form; c) Other products, not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.

²¹⁸ Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.

Annex X. Summary Chart of Colorants

Regionalised Chart of Colorants²¹⁹

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 10006	Green	Sodium tris(1,2-naphthoquinone 1-oximato-O,O')ferrate (1-)			16143-80-9	240-299-7		X					USA, Japan, South Korea
CI 10020	Green	Trisodium tris[5,6-dihydro-5-(hydroxyimino)-6-oxonaphthalene-2-sulphonato(2-)-N5,O6]ferrate(3-)	Ext. D&C Green No.1		19381-50-1	243-010-2			X ^{225,226}	X ²²⁵	X	²²⁷	USA
Japan: Green No. 401; Salt: Fe/ Lakes: -.													
CI 11680	Yellow	2-[(4-Methyl-2-nitrophenyl)azo]-3-oxo-N-phenylbutyramide	Ext. D&C Yellow No.5		2512-29-0	219-730-8			X ^{225,226}	X ²²⁵	X	²²⁷	USA
Japan: Yellow No. 401; Salt: -/ Lakes: -.													

²¹⁹ Without prejudice to other provisions, a colorant shall include its salts and lakes and when a colorant is expressed as a specific salt, its other salts and lakes shall also be included (in the USA and Japan, only the salts and lakes specified in the table for each colorant shall be used). All colorants used must comply with the purity criteria established in the regulations included in this standard (see Annex I).

²²⁰ Leave-on product means a cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes.

²²¹ Eye product means a cosmetic product which is intended to be applied in the vicinity of the eyes.

²²² Lip product means a cosmetic product which is intended to be applied on the lips.

²²³ Product applied on mucous membranes means a cosmetic product which is intended to be applied on the mucous membranes of the oral cavity, on the rim of the eyes, or on the external genital organs.

²²⁴ These ingredients are not approved for use in cosmetic products in these markets.

²²⁵ According to the legislation of South Korea (see Annex I).

²²⁶ In India, the use of this colorant and its lakes in eye pencils is prohibited (see Annex I).

²²⁷ Barium, strontium and zirconium lakes of this colorant are prohibited (see legislation of South Korea, Annex I).

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 11710	Yellow	2-[[4-Chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide			6486-23-3	229-355-1			X ²²⁶		X		USA, Japan, South Korea
CI 11725	Orange	2-[[4-Methoxy-2-nitrophenyl)azo]-3-oxo-N-(o-tolyl)butyramide			6371-96-6	228-901-6		X			X ²²⁸	²²⁷	USA
Japan: Orange No. 401; Salt: -/ Lakes: -.													
CI 11920	Orange	4-(Phenylazo)resorcinol			2051-85-6	218-131-9			X ²²⁶				USA, Japan, South Korea
CI 12010	Red	4-[[4-Ethoxyphenyl)azo]naphthol			6535-42-8	229-439-8			X ²²⁶		X		USA, Japan, South Korea
CI 12120	Red	1-[[4-Methyl-2-nitrophenyl)azo]-2-naphthol	D&C Red No.35		2425-85-6	219-372-2		X				²²⁷	USA, Canada
Japan: Red No. 221; Salt: -/ Lakes: -.													
CI 12370	Red	3-Hydroxy-N-(o-tolyl)-4-[[2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide			6535-46-2	229-440-3		X					USA, Japan, South Korea
CI 12420	Red	N-(4-Chloro-2-methylphenyl)-4-[[4-chloro-2-methylphenyl)azo]-3-hydroxynaphthalene-2-carboxamide			6471-51-8	229-315-3		X					USA, Japan, South Korea
CI 12480	Brown	4-[[2,5-Dichlorophenyl)azo]-N-(2,5-dimethoxyphenyl)-3-hydroxynaphthalene-2-carboxamide			6410-40-8	229-106-7		X					USA, Japan, South Korea

²²⁸ According to the legislation of Japan and South Korea (see Annex I).

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 12490	Red	N-(5-Chloro-2,4-dimethoxyphenyl)-4-[[[5-[(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3-hydroxynaphthalene-2-carboxamide			6410-41-9	229-107-2					X ²²⁶	229	USA, Japan
CI 12700	Yellow	2,4-Dihydro-5-methyl-2-phenyl-4-(phenylazo)-3H-pyrazol-3-one			4314-14-1	224-330-1		X					USA, Japan, South Korea
CI 13015	Yellow	Disodium 2-amino-5-[(4-sulphonatophenyl)azo] benzenesulphonate			2706-28-7	220-293-0					X ²²⁶		USA, Japan, South Korea
CI 14270	Orange	Sodium 4-(2,4-dihydroxyphenylazo) benzenesulphonate			547-57-9	208-924-8					X ²²⁶		USA, Japan, South Korea
CI 14720	Red	Disodium 4-hydroxy-3-[(4-sulphonatonaphthyl)azo] naphthalenesulphonate		E 122	3567-69-9	222-657-4					X ²²⁶		USA, Japan, South Korea
CI 14815	Red	Disodium 6-[(2,4-dimethyl-6-sulphonatophenyl)azo]-5-hydroxynaphthalene-1-sulphonate			3257-28-1	221-856-3					X ²²⁶		USA, Japan, South Korea
CI 15525	Red	Calcium disodium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]-4-sulphonatobenzoate]			5850-80-6	227-456-5					X ²²⁶		USA, Japan, South Korea
CI 15580	Red	Barium bis[4-[(2-hydroxy-1-naphthyl)azo]-2-methylbenzenesulphonate]			5850-87-3	227-459-1					X ²²⁶		USA, Japan, South Korea

²²⁹ It is only permitted in soaps (see legislation of South Korea, Annex I).

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 15620	Red	Sodium 4-[(2-Hydroxy-1-naphthyl)azo] naphthalenesulphonate	Ext. D&C Red No.8		1658-56-6	216-760-3		X			X ²³⁰	227	USA
Japan: Red No. 506; Salt: Na/ Lakes: Al.													
CI 15630	Red	Sodium 2-[(2-hydroxynaphthyl)azo] naphthalenesulphonate	D&C Red No.10		1248-18-6	214-998-2	3%		X ^{225,226}	X ²²⁵		231	USA
Japan: Red No. 205; Salt: Na/ Lakes: - //Red No. 206; Salt: Ca/ Lakes: - //Red No. 207; Salt: Ba/ Lakes: -//Red No. 208; Salt: Sr/ Lakes: -.													
CI 15865	Red	Disodium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate			3564-21-4	222-642-2			X ^{225,226}	X ²²⁵	X ²³⁰	232	USA
Japan: Red No. 405; Salt: Ca/ Lakes: -.													
CI 15980	Orange	Disodium 6-hydroxy-5-[(3-sulphonatophenyl)azo] naphthalene-2-sulphonate			2347-72-0	219-073-7			X ²²⁶				USA, Japan, South Korea
CI 16035	Red	Disodium 6-hydroxy-5-[(2-methoxy-4-sulphonato-m-tolyl)azo]naphthalene-2-sulphonate	FD&C Red No.40	E 129	25956-17-6	247-368-0			X ²²⁶			186,233,234	Japan
USA: Straight colour: FD&C Red No.40 (Na salt); Lakes ^{190,192} : FD&C Red No.40: Al, Ca; D&C Red No.40: Na, K, Al, Ba, Ca, Sr, Zr.													
CI 16185	Red	Trisodium 3-hydroxy-4-[(4'-sulphonatonaphthyl)azo] naphthalene-2,7-disulphonate		E 123	915-67-3	213-022-2			X ²²⁶			235	USA

²³⁰ According to the legislation of Japan (see Annex I).

²³¹ This colorant includes the insoluble barium, strontium and zirconium lakes, salts and pigments; except in South Korea where barium, strontium and zirconium lakes of this colorant, are prohibited (see Annex I).

²³² This colorant includes the insoluble barium, strontium and zirconium lakes, salts and pigments.

²³³ The colorant must not be exposed to oxidising or reducing agents or any other conditions that may affect its integrity (see legislation of the USA, Annex I).

²³⁴ In eye products, only the colorant or its aluminium lake may be used (see legislation of the USA, Annex I).

²³⁵ It must not be used in products for children under 13 years of age (see legislation of South Korea, Annex I).

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
Japan: Red No. 2; Salt: Na/ Lakes: Al.													
CI 16230	Orange	Disodium 7-hydroxy-8-(phenylazo)naphthalene-1,3-disulphonate			1936-15-8	217-705-6			X ²²⁶		X		USA, Japan, South Korea
CI 16255	Red	Trisodium 1-(1-naphthylazo)-2-hydroxynaphthalene-4',6,8-trisulphonate		E 124	2611-82-7	220-036-2			X ²²⁶			232,235	USA
Japan: Red No. 102; Salt: Na/ Lakes: Al.													
CI 16290	Red	Tetrasodium 7-hydroxy-8-[(4-sulphonato-1-naphthyl)azo]naphthalene-1,3,6-trisulphonate			5850-44-2	227-454-4			X ²²⁶				USA, Japan, South Korea
CI 18050	Red	Disodium 5-acetylamino-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulphonate		E 128	3734-67-6	223-098-9		X ²³⁶	X ²²⁶		X		USA, Japan, South Korea
CI 18130	Red	2,7-Naphthalenedisulfonic acid, 3-((4-cyclohexyl-2-methylphenyl)azo)-4-hydroxy-5-(((4-methylphenyl)sulfonyl)amino)-, disodium salt			10236-37-0			X					USA, Japan, South Korea
CI 18690	Yellow	Hydrogen bis[2-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]benzoato(2-)]chromate(1-)			5601-29-6	227-022-5		X					USA, Japan, South Korea

²³⁶ According to the legislation of the United Mexican States (see Annex I).

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 18736	Red	Disodium hydrogen bis[5-chloro-3-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]-2-hydroxybenzenesulphonato(3-)]chromate(3-)			6408-26-0	229-051-9		X					USA, Japan, South Korea
CI 18820	Yellow	Sodium 4-(3-hydroxy-5-methyl-4-(phenylazo)pyrazol-2-yl) benzenesulphonate	Ext. D&C Yellow No.3		6359-82-6	228-808-0		X			X ²³⁰	²²⁷	USA
Japan: Yellow No. 407; Salt: Na/ Lakes: Al.													
CI 18965	Yellow	Disodium 2,5-dichloro-4-(5-hydroxy-3-methyl-4-(sulphophenyl)azo) pyrazol-1-yl) benzenesulphonate			6359-98-4	228-819-0			X ²²⁶				USA, Japan, South Korea
CI 20040	Yellow	N,N'-(3,3'-Dimethyl[1,1'-biphenyl]-4,4'-diyl)bis[2-[(2,4-dichlorophenyl)azo]-3-oxobutyramide]			5979-28-2	227-783-3		X					USA, Japan, South Korea
CI 20470	Black	Sodium 4-amino-5-hydroxy-3-((4-nitrophenyl)azo)-6-(phenylazo)naphthalene-2,7-disulphonate			1064-48-8	213-903-1		X			X ²³⁰	²²⁷	USA
Japan: Black No. 401; Salt: Na/ Lakes: Al.													
CI 21100	Yellow	2,2'-[(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxobutyramide]			5102-83-0	225-822-9		X					USA, Japan, South Korea

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 21108	Yellow	2,2'-[(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide]			5567-15-7	226-939-8		X					USA, Japan, South Korea
CI 21230	Yellow	2,2'-[Cyclohexylidenebis[(2-methyl-4,1-phenylene)azo]]bis [4-cyclohexylphenol]			6706-82-7	229-754-0			X ²²⁶		X		USA, Japan, South Korea
CI 24790	Red	Disodium 4,6-dihydroxy-3-[[4-[1-[4-[[1-hydroxy-7-[(phenylsulphonyl)oxy]-3-sulphonato-2-naphthyl]azo]phenyl]cyclohexyl]phenyl]azo]naphthalene-2-sulphonate			13421-53-9	236-531-1		X					USA, Japan, South Korea
CI 26100	Red	1-(4-(Phenylazo)phenylazo)-2-naphthol	D&C Red No.17		85-86-9	201-638-4			X ^{226,237}	X ²³⁷	X	227,238	China

USA: Straight colour: D&C Red No.17; Lakes:²³⁹ Na, K, Al, Ba, Ca, Sr, Zr.
 Japan: Red No. 225; Salt: -/ Lakes: -.

²³⁷ According to the legislation of the USA and South Korea (see Annex I).

²³⁸ This colorant must be batch certified by FDA if it is to be used in cosmetic products marketed in the USA.

²³⁹ The permitted lakes must comply with the provisions of 21 CFR 82.1051 (Lakes D&C). The lakes will be formed from a straight colour (or a derived salt) by depositing it onto the substrates listed below and using the radicals also indicated below. Substrate: alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, resin, aluminum benzoate, calcium carbonate, or any combination of two or more of these. Basic radical: sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 27755	Black	Tetrasodium 6-amino-4-hydroxy-3-[[[7-sulphonato-4-[(4-sulphonatophenyl)azo]-1-naphthyl]azo]naphthalene-2,7-disulphonate			2118-39-0	218-326-9			X ²²⁶				USA, Japan, South Korea
CI 28440	Black	Tetrasodium 1-acetamido-2-hydroxy-3-(4-((4-sulphonatophenylazo)-7-sulphonato-1-naphthylazo))naphthalene-4,6-disulphonate		E 151	2519-30-4	219-746-5			X ²²⁶				USA, Japan, South Korea
CI 40215	Orange	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-nitro-], disodium salt, reaction products with 4-[(4-aminophenyl)azo]benzenesulfonic acid, sodium salts			50814-31-8	256-783-6		X					USA, Japan, South Korea
CI 40820	Orange	8'-apo-beta-caroten-8'-al		E 160e	1962-15-8	214-171-6			X ²²⁶				USA, Japan, South Korea
CI 40825	Orange	Ethyl 8'-apo-beta-caroten-8'-oate		E 160f	1109-11-1	214-173-7			X ²²⁶				USA, Japan, South Korea
CI 40850	Orange	Canthaxanthin		E 161g	514-78-3	208-187-2			X ²²⁶				USA, Japan, South Korea
CI 42045	Blue	Ammonium, (4-(alpha-(p-(diethylamino)phenyl)-2,4-disulfobenzylidene)-2,5-cyclohexadien-1-ylidene)diethyl-, hydroxide, monosodium salt			129-17-9	204-934-1			X ²²⁶		X		USA, Japan, South Korea

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 42051	Blue	Ethanaminium, N-(4-((4-(diethylamino) phenyl)(5-hydroxy-2,4-disulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-N-ethyl-, hydroxide, inner salt, calcium salt (2:1)		E 131	3536-49-0	222-573-8					X ²²⁶	232	USA, Japan, South Korea
CI 42080	Blue	Hydrogen (benzyl)[4-[[4-[benzylethylamino] phenyl](2,4-disulphonatophenyl)methylene]cyclohexa-2,5-dien-1-ylidene](ethyl)ammonium, sodium salt			3486-30-4	222-476-0		X					USA, Japan, South Korea
CI 42100	Green	Hydrogen [4-[(2-chlorophenyl)[4-[ethyl(3-sulphonatobenzyl)amino] phenyl]methylene]cyclohexa-2,5-dien-1-ylidene](ethyl)(3-sulphonatobenzyl) ammonium, sodium salt			4857-81-2	225-458-0		X					USA, Japan, South Korea
CI 42170	Green	Hydrogen [4-[(2-chlorophenyl)[4-[ethyl(3-sulphonatobenzyl)amino]-o-tolyl]methylene]-3-methylcyclohexa-2,5-dien-1-ylidene](ethyl)(3-sulphonatobenzyl) ammonium, sodium salt			5863-51-4	227-513-4		X					USA, Japan, South Korea
CI 42510	Violet	(4-(4-Aminophenyl)(4-iminocyclohexa-2,5-dienylidene)methyl)-2-methylaniline hydrochloride			632-99-5	221-189-6					X ²²⁶		USA, Japan, South Korea, Taiwan

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 42520	Violet	4-[[4-Amino-m-tolyl](4-imino-3-methylcyclohexa-2,5-dien-1-ylidene)methyl]-o-toluidine monohydrochloride			3248-91-7	221-831-7	5 ppm	X					USA, Japan, South Korea
CI 42735	Blue	Hydrogen [4-[[4-(diethylamino)phenyl][4-ethyl[[3-sulphonatobenzyl)amino]-o-tolyl]methylene]-3-methylcyclohexa-2,5-dien-1-ylidene](ethyl)(3-sulphonatobenzyl) ammonium, sodium salt			6505-30-2	229-390-2			X ²²⁶		X		USA, Japan, South Korea
CI 44045	Blue	[4-[[4-Anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride			2580-56-5	219-943-6			X ²²⁶		X		USA, Japan, South Korea, Taiwan, Mexico
CI 44090	Green	Hydrogen [4-[4-(dimethylamino)-alpha-(2-hydroxy-3,6-disulphonato-1-naphthyl)benzylidene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium, monosodium salt		E 142	3087-16-9	221-409-2			X ²²⁶				USA, Japan, South Korea
CI 45100	Red	Hydrogen 3,6-bis(diethylamino)-9-(2,4-disulphonatophenyl) xanthylium, sodium salt			3520-42-1	222-529-8		X				²²⁷	USA

Japan: Red No. 106; Salt: Na/ Lakes: Al.

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 45190	Violet	Hydrogen 9-(2-carboxylatophenyl)-3-(2-methylanilino)-6-(2-methyl-4-sulphoanilino)xanthylium, monosodium salt	Ext. D&C Red No.3		6252-76-2	228-377-9		X			X ²³⁰		USA
Japan: Red No. 401; Salt: Na/ Lakes: Al.													
CI 45220	Red	Hydrogen 9-(2,4-disulphonatophenyl)-3,6-bis(ethylamino)-2,7-dimethylxanthylium, monosodium salt			5873-16-5	227-528-6		X					USA, Japan, South Korea
CI 45396	Orange	3',6'-Dihydroxy-4',5'-dinitrospiro [isobenzofuran-1(3H),9'-[9H]xanthene]-3-one			24545-86-6	246-308-0	1% ²⁴⁰		X ²²⁶				USA, Japan, South Korea
CI 45405	Red	Dipotassium 3,6-dichloro-2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxanthen-9-yl)benzoate			6441-77-6	229-225-4			X				USA, Japan, South Korea
CI 45430	Red	Disodium 2-(2,4,5,7-tetraido-6-oxido-3-oxoxanthen-9-yl)benzoate		E 127	16423-68-0	240-474-8			X ²²⁶			232	USA, South Korea
Japan: Red No. 3; Salt: Na/ Lakes: Al.													
CI 50325	Violet	Hydrogen 9-[(3-methoxyphenyl)amino]-7-phenyl-5-(phenylamino)-4,10-disulphonatobenzo[a]phenazinium, sodium salt			6837-46-3	229-951-1		X					USA, Japan, South Korea
CI 50420	Black	Sulfonated nigrosine color			2229-87-2				X ²²⁶		X		USA, Japan, South Korea

²⁴⁰ This numerical limit applies to lip cosmetics. When used in lip cosmetics, the colouring agent is allowed only in its free acid form.

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 51319	Violet	8,18-Dichloro-5,15-diethyl-5,15-dihydroindolo[3,2-b:3',2'-m]triphenodioxazine			6358-30-1	228-767-9		X				229	USA, Japan
CI 58000	Red	1,2-Dihydroxyanthraquinone			72-48-0	200-782-5			X ²²⁶				USA, Japan, South Korea
CI 60724	Violet	1-Anilino-4-hydroxyanthraquinone			19286-75-0	242-939-0		X					USA, Japan, South Korea
CI 61585	Blue	Sodium 3,3'-(9,10-dioxoanthracene-1,4-diylidimino)bis(2,4,6-trimethylbenzenesulphonate)			4474-24-2	224-748-4		X					USA, Japan, South Korea
CI 62045	Blue	Sodium 1-amino-4-(cyclohexylamino)-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate			4368-56-3	224-460-9		X					USA, Japan, South Korea
CI 69800	Blue	6,15-Dihydroanthrazine-5,9,14,18-tetrone			81-77-6	201-375-5			X ²²⁶				USA, Japan, South Korea
CI 69825	Blue	7,16-Dichloro-6,15-dihydroanthrazine-5,9,14,18-tetrone	D&C Blue No.9		130-20-1	204-980-2			X ²²⁶			227	USA
Japan: Blue No. 204; Salt: -/ Lakes: -.													
CI 71105	Orange	Bisbenzimidazo[2,1-b:2',1'-i]benzo[lmn][3,8]phenanthroline-8,17-dione			4424-06-0	224-597-4			X ²²⁶		X		USA, Japan, South Korea
CI 73000	Blue	2-(1,3-Dihydro-3-oxo-2H-indazol-2-ylidene)-1,2-dihydro-3H-indol-3-one	D&C Blue No.6		482-89-3	207-586-9			X ²²⁶			227	USA

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
Japan: Blue No. 201; Salt: -/ Lakes: -.													
CI 73015	Blue	Disodium 5,5'-(2-(1,3-dihydro-3-oxo-2H-indazol-2-ylidene)-1,2-dihydro-3H-indol-3-one)disulphonate	FD&C Blue No.2	E 132	860-22-0	212-728-8				X ²²⁶			USA
Japan: Blue No. 2; Salt: Na/ Lakes: Al.													
CI 73385	Violet	5-Chloro-2-(5-chloro-7-methyl-3-oxobenzothien-2(3H)-ylidene)-7-methylbenzo[b]thiophene-3(2H)-one			5462-29-3	226-750-0				X ²²⁶			USA, Japan, South Korea
CI 73900	Violet	5,12-Dihydroquino[2,3-b]acridine-7,14-dione			1047-16-1	213-879-2		X					USA, Japan, South Korea
CI 73915	Red	5,12-Dihydro-2,9-dimethylquino[2,3-b]acridine-7,14-dione			980-26-7	213-561-3		X					USA, Japan, South Korea
CI 74100	Blue	29H,31H-Phthalocyanine			574-93-6	209-378-3		X					USA, Japan, South Korea
CI 74160	Blue	29H,31H-Phthalocyaninato(2-)-N29,N30,N31,N32 copper			147-14-8	205-685-1			X ^{225,226}	X ²²⁵	X ²³⁰	²²⁷	USA
Japan: Blue No. 404; Salt: Cu/ Lakes: -.													
CI 74180	Blue	Disodium [29H,31H-phthalocyaninedisulphonato(4-)-N29,N30,N31,N32]cuprate(2-)			1330-38-7	215-537-8		X					USA, Japan, South Korea
CI 74260	Green	Polychloro copper phthalocyanine			1328-53-6	215-524-7			X			²²⁹	USA, Japan

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 75100	Yellow	8,8'-diapo-psi,psi-Carotenedioic acid			27876-94-4	248-708-0			X ²²⁶				USA, South Korea
CI 75125	Yellow	Lycopene		E 160d	502-65-8	207-949-1			X ²²⁶				USA
CI 75135	Yellow	(3R)-beta-4-Caroten-3-ol			3763-55-1				X ²²⁶				USA, South Korea
CI 75300	Yellow	Curcumins		E 100	458-37-7	207-280-5			X ²²⁶				USA
CI 77002	White	Aluminium hydroxide sulphate			1332-73-6	215-573-4							USA, South Korea
CI 77004	White	Natural hydrated aluminium silicate, Al ₂ O ₃ ·2SiO ₂ ·2H ₂ O, containing calcium, magnesium or iron carbonates, ferric hydroxide, quartz-sand, mica, etc. as impurities			1302-78-9 / 1327-36-2 / 1332-58-7	215-108-5 / 215-475-1 / 310-194-1							USA
CI 77015	Red	Aluminum silicate coloured with ferric oxide				310-127-6							USA, South Korea
CI 77120	White	Barium sulphate			7727-43-7 / 13462-86-7	2131-784-4							USA
CI 77220	White	Calcium carbonate		E 170	471-34-1 / 1317-65-3	207-439-9 / 215-279-6							USA
CI 77231	White	Calcium sulphate			7778-18-9	231-900-3							USA
CI 77268:1	Black	Coke black			1339-82-8	215-669-6						²⁴¹	USA
CI 77346	Green	Cobalt Aluminum Oxide			1345-16-0	310-193-6							USA
CI 77480	Brown	Gold		E 175	7440-57-5	231-165-9							USA
CI 77713	White	Magnesium carbonate			546-93-0	208-915-9							USA

²⁴¹ In the event of marketing eye pencils in India, contact the Sustainability Department of Inditex.

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
CI 77745	Red	Trimanganese bis(orthophosphate)			10236-39-2	237-997-9							USA, South Korea
---	Red	Sodium 4-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]-3-hydroxynaphthalene-1-sulphonate (Acid red 195)			12220-24-5				✗ ^{226,236}	✗ ²³⁶	✗		USA, Japan, South Korea
---	White	Aluminum stearate, Zinc stearate, Magnesium stearate, Calcium stearate			7047-84-9 / 557-05-1 / 557-04-0 / 1592-23-0	230-325-5 / 209-151-9 / 209-150-3 / 216-472-8			✗ ²²⁶			242	USA
---	Red	Anthocyanins		E 163	528-58-5 / 134-01-0 / 528-53-0 / 643-84-5 / 134-04-3 / 1429-30-7	208-438-6 / 205-125-6 / 211-403-8 / 208-437-0 / 205-127-7 / 215-849-4			✗ ²²⁶				USA
---	Red	Beetroot red		E 162	7659-95-2	231-628-5			✗ ²²⁶				USA
---	Green	Phenol, 4,4'-(3H-2,1-benzoxathiol-3-ylidene)bis[2,6-dibromo-3-methyl-,S,S-dioxide (Bromocresol Green)			76-60-8	200-972-8		✗					USA, Japan, South Korea
---	Blue	Phenol, 4,4'-(3H-2,1-benzoxathiol-3-ylidene)bis[2-bromo-3-methyl-6-(1-methylethyl)-, S,S-dioxide (Bromothymol Blue)			76-59-5	200-971-2	0.2% ²³⁶	✗					USA, Japan, South Korea

²⁴² In South Korea, for powder products containing Zinc stearate, the labelling must include "Be careful not to inhale it during use".

Colour Index Number	Colour	Chemical Name	FDA Name	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²²⁰	Not to be used in eye products ²²¹	Not to be used in lip products ²²²	Not to be used in products applied on mucous membranes ²²³	General notes	Restriction ²²⁴
---	Orange	(3R,3'S,5'R)-3,3'-dihydroxy-beta,kappa-caroten-6'-one (Capsanthin, Capsorubin, Paprika extract)		E 160c	465-42-9 / 470-38-2	207-364-1 / 207-425-2			X ²²⁶				USA
---	Yellow	Lactoflavin (Riboflavin)		E 101	83-88-5 / 130-40-5	201-507-1 / 204-988-6			X ²²⁶				USA

Annex X *bis*. Summary Chart of Impurities in ColorantsGlobal Chart of Metal Impurities in Colorants²⁴³

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁴
CI 10316	846-70-8		USA: 21 CFR 74.1707a (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 12085	2814-77-9		USA: 21 CFR 74.1336 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 14700	4548-53-2		USA: 21 CFR 74.1304 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 15510	633-96-5		USA: 21 CFR 74.1254 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.

²⁴³ For those impurities associated with colorants, whether or not they have specified limits, it must be ensured that the concentration of traces in the final cosmetic product does not exceed the limits stated (Annex VI); for the calculation, the percentage composition of the colorant shall be considered in the compositional formula of the cosmetic.

²⁴⁴ The colorants used in the formulation of cosmetic products must meet all purity requirements established in the referenced legislation.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁴
CI 15800	6371-76-2		USA: 21 CFR 74.1331 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 15850	5858-81-1	E 180	Regulation EU 231/2012 (E180). USA: D&C Red No. 6: 21 CFR 74.1306 (a)(1) and (b) / D&C Red No.7: 21 CFR 74.1307 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 15880	6417-83-0		USA: 21 CFR 74.1334 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 15985	2783-94-0	E 110	Regulation EU 231/2012 (E110). USA: 21 CFR 74.706 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 17200	3567-66-6		USA: 21 CFR 74.1333 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁴
CI 19140	1934-21-0	E 102	Regulation EU 231/2012 (E102). USA: 21 CFR 74.2705. JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 40800	7235-40-7	E 160a	Regulation EU 231/2012 (E160a). USA: 21 CFR 73.95 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 42053	2353-45-9		USA: 21 CFR 74.203 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 42090	3844-45-9	E 133	Regulation EU 231/2012 (E133). USA: FD&C Blue No. 1: 21 CFR 74.101 (b) / D&C Blue No.4: 21 CFR 74.1104 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 45350	2321-07-5 / 518-47-8		USA: D&C Yellow No. 7: 21 CFR 74.1707 (a) (1) and (b) / D&C Yellow No.8: 21 CFR 74.1708 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁴
CI 45370	596-03-2 / 4372-02-5		USA: 21 CFR 74.1255 (a) (1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 45380	17372-87-1		USA: D&C Red No. 21: 21 CFR 74.1321 (a) (1) and (b) / D&C Red No.22: 21 CFR 74.1322 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 45410	18472-87-2		USA: D&C Red No. 27: 21 CFR 74.1327 (a) (1) and (b) / D&C Red No.28: 21 CFR 74.1328 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 47000	8003-22-3		USA: 21 CFR 74.1711 (a) (1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 47005	95193-83-2 / 8004-92-0	E 104	Regulation EU 231/2012 (E104). USA: 21 CFR 74.1710 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁴
CI 59040	6358-69-6		USA: 21 CFR 74.1208 (a) (1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 60725	81-48-1		USA: 21 CFR 74.1602 (a) (1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 60730	4430-18-6		USA: 21 CFR 74.2602a. JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 61565	128-80-3		USA: 21 CFR 74.1206 (a) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 61570	4403-90-1		USA: 21 CFR 74.1205 (a) (1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁴
CI 73360	2379-74-0		USA: 21 CFR 74.1330 (a) (1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 75120	1393-63-1	E 160b	Regulation EU 231/2012 (E160b). USA: 21 CFR 73.30 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR ²⁴⁵ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 75130	7235-40-7	E 160a	Regulation EU 231/2012 (E160a). USA: 21 CFR 73.95 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR ²⁴⁵ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 75170	73-40-5		USA: 21 CFR 73.1329 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR ²⁴⁵ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 75470	1390-65-4 / 1343-78-8 / 1260-17-9 / 1328-60-5	E 120	Regulation EU 231/2012 (E120). USA: 21 CFR 73.100 (a)(2) and (b)(2). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR ²⁴⁵ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).

²⁴⁵ Verify the origin of the colorant. If the colorant is not of natural origin, it must meet the established purity requirements.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁴
CI 75810	1406-65-1 / 479-61-8 / 519-62-0	E 140 E 141	Regulation EU 231/2012 (E140 / E141). USA: 21 CFR 73.1125 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR ²⁴⁵ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 77000	7429-90-5	E 173	Regulation EU 231/2012 (E173). USA: 21 CFR 73.1645 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 77007	1302-83-6		USA: 21 CFR 73.2725 SOUTH KOREA: Types and standards of pigments in cosmetics.
CI 77163	7787-59-9		USA: 21 CFR 73.1162 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics.
CI 77266	1333-86-4/ 7440-44-0		Regulation CE 1223/2009 USA: 21 CFR 74.2052. SOUTH KOREA: Types and standards of pigments in cosmetics MERCOSUR ²⁴⁵ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 77267	8021-99-6		USA: 21 CFR 74.2053. MERCOSUR ²⁴⁵ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 77288	1308-38-9		USA: 21 CFR 73.1327 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics.
CI 77289	12001-99-9		USA: 21 CFR 73.1326 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics.
CI 77400	7440-50-8		USA: Copper powder: 21 CFR 73.1647 (a)(1) and (b) / Bronze powder: 21 CFR 73.1646 (a)(1) and (b).
CI 77489	1345-25-1		USA: 21 CFR 73.2250.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁴
CI 77491	1309-37-1	E 172	Regulation EU 231/2012 (E172). USA: 21 CFR 73.2250 SOUTH KOREA: Types and standards of pigments in cosmetics. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 77492	51274-00-1	E 172	Regulation EU 231/2012 (E172). USA: 21 CFR 73.2250 SOUTH KOREA: Types and standards of pigments in cosmetics. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 77499	12227-89-3	E 172	Regulation EU 231/2012 (E172). USA: 21 CFR 73.2250. SOUTH KOREA: Types and standards of pigments in cosmetics. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 77510	25869-00-5 / 12240-15-2 / 14038-43-8		USA: Ferric ammonium ferrocyanide: 21 CFR 73.1298 (a)(1) and (b) / Ferric ferrocyanide: 21 CFR 73.1299 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics.
CI 77742	10101-66-3		USA: 21 CFR 73.2775. SOUTH KOREA: Types and standards of pigments in cosmetics.
CI 77820	7440-22-4	E 174	Regulation EU 231/2012 (E174). USA: 21 CFR 73.2500.
CI 77891	13463-67-7	E 171	Regulation EU 231/2012 (E171). USA: 21 CFR 73.575 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 77947	1314-13-2		USA: 21 CFR 73.1991 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics.
Caramel	8028-89-5	E 150a-d	Regulation EU 231/2012 (E150a-d). USA: 21 CFR 73.85 (a)(1), (2), and (3) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR ²⁴⁵ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: IS 4707 (Part 1) ISRAEL: Pharmacists' Regulations (Cosmetics).

Annex X bis. Summary Chart of Impurities in Colorants

Regionalised Chart of Metal Impurities in Colorants²⁴⁶

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁷
CI 10006	16143-80-9		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 10020	19381-50-1		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 11680	2512-29-0		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 11710	6486-23-3		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 11725	6371-96-6		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 11920	2051-85-6		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 12010	6535-42-8		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.

²⁴⁶ For those impurities associated with colorants, whether or not they have specified limits, it must be ensured that the concentration of traces in the final cosmetic product does not exceed the limits stated (Annex VI); for the calculation, the percentage composition of the colorant shall be considered in the compositional formula of the cosmetic.

²⁴⁷ The colorants used in the formulation of cosmetic products must meet all purity requirements established in the referenced legislation.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁷
CI 12120	2425-85-6		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 12370	6535-46-2		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 12420	6471-51-8		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 12480	6410-40-8		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 12490	6410-41-9		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 12700	4314-14-1		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 13015	2706-28-7		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 14270	547-57-9		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 14720	3567-69-9	E 122	Regulation EU 231/2012 (E122). USA: 21 CFR 74.1710 (a)(1) and (b). MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 14815	3257-28-1		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁷
CI 15525	5850-80-6		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 15580	5850-87-3		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 15620	1658-56-6		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 15630	1248-18-6		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 15865	3564-21-4		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 15980	2347-72-0		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 16035	25956-17-6	E 129	Regulation EU 231/2012 (E129). USA: 21 CFR 74.340 (a)(1) and (b). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁷
CI 16185	915-67-3	E 123	Regulation EU 231/2012 (E123). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 16230	1936-15-8		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 16255	2611-82-7	E 124	Regulation EU 231/2012 (E124). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 16290	5850-44-2		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 18050	3734-67-6	E 128	Regulation EU 231/2012 (E128). MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 18130	10236-37-0		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 18690	5601-29-6		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 18736	6408-26-0		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁷
CI 18820	6359-82-6		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 18965	6359-98-4		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 20040	5979-28-2		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 20470	1064-48-8		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 21100	5102-83-0		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 21108	5567-15-7		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 21230	6706-82-7		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 24790	13421-53-9		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 26100	85-86-9		USA: 21 CFR 74.1317 (a)(1) and (b). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁷
CI 27755	2118-39-0		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 28440	2519-30-4	E 151	Regulation EU 231/2012 (E151). MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 40215	50814-31-8		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 40820	1962-15-8	E 160e	Regulation EU 231/2012 (E160e). MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 40825	1109-11-1	E 160f	Regulation EU 231/2012 (E160f). MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 40850	514-78-3	E 161g	Regulation EU 231/2012 (E161g). MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 42045	129-17-9		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 42051	3536-49-0	E 131	Regulation EU 231/2012 (E131). MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁷
CI 42080	3486-30-4		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 42100	4857-81-2		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 42170	5863-51-4		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 42510	632-99-5		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 42520	3248-91-7		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 42735	6505-30-2		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 44045	2580-56-5		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 44090	3087-16-9	E 142	Regulation EU 231/2012 (E142). MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 45100	3520-42-1		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 45190	6252-76-2		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁷
CI 45220	5873-16-5		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 45396	24545-86-6		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 45405	6441-77-6		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 45430	16423-68-0	E 127	Regulation EU 231/2012 (E127). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 50325	6837-46-3		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 50420	2229-87-2		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 51319	6358-30-1		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 58000	72-48-0		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 60724	19286-75-0		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 61585	4474-24-2		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 62045	4368-56-3		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁷
CI 69800	81-77-6		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 69825	130-20-1		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 71105	4424-06-0		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 73000	482-89-3		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 73015	860-22-0	E 132	Regulation EU 231/2012 (E132). JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 73385	5462-29-3		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 73900	1047-16-1		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 73915	980-26-7		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 74100	574-93-6		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁷
CI 74160	147-14-8		JAPAN: Ministerial Ordinance for the Designation of Tar Colours That May Be Used in Medical Drugs, etc. SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 74180	1330-38-7		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 74260	1328-53-6		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 75100	27876-94-4		MERCOSUR ²⁴⁸ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 75125	502-65-8	E 160d	Regulation EU 231/2012 (E160d). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR ²⁴⁸ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 75135	3763-55-1		MERCOSUR ²⁴⁸ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 75300	458-37-7	E 100	Regulation EU 231/2012 (E100). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR ²⁴⁸ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 77002	1332-73-6		
CI 77004	1302-78-9 / 1327-36-2 / 1332-58-7		SOUTH KOREA: Types and standards of pigments in cosmetics.

²⁴⁸ Verify the origin of the colorant. If the colorant is not of natural origin, it must meet the established purity requirements.

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁷
CI 77015			
CI 77120	7727-43-7 / 13462-86-7		SOUTH KOREA: Types and standards of pigments in cosmetics.
CI 77220	471-34-1 / 1317-65-3	E 170	Regulation EU 231/2012 (E170). SOUTH KOREA: Types and standards of pigments in cosmetics. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 77231	7778-18-9		SOUTH KOREA: Types and standards of pigments in cosmetics.
CI 77268:1	1339-82-8		MERCOSUR ²⁴⁸ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
CI 77346	1345-16-0		SOUTH KOREA: Types and standards of pigments in cosmetics.
CI 77480	7440-57-5	E 175	Regulation EU 231/2012 (E175). SOUTH KOREA: Types and standards of pigments in cosmetics. ISRAEL: Pharmacists' Regulations (Cosmetics).
CI 77713	546-93-0		SOUTH KOREA: Types and standards of pigments in cosmetics.
CI 77745	10236-39-2		
Acid Red 195	12220-24-5		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
Aluminum stearate, Zinc stearate, Magnesium stearate, Calcium stearate	7047-84-9 / 557-05-1 / 557-04-0 / 1592-23-0		SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
Anthocyanins	528-58-5 / 134-01-0 / 528-53-0 / 643-84-5 / 134-04-3 / 1429-30-7	E 163	Regulation EU 231/2012 (E163). MERCOSUR ²⁴⁸ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).

Colour Index Number	CAS Number	E (Food Additive Code)	Purity Requirements for Colorants ²⁴⁷
Beetroot red	7659-95-2	E 162	Regulation EU 231/2012 (E162). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR ²⁴⁸ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
Bromocresol Green	76-60-8		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
Bromothymol Blue	76-59-5		MERCOSUR: MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020.
Capsanthin, Capsorubin	465-42-9 / 470-38-2	E 160c	Regulation EU 231/2012 (E160c). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR ²⁴⁸ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).
Lactoflavin	83-88-5 / 130-40-5	E 101	Regulation EU 231/2012 (E101). SOUTH KOREA: Types and standards of pigments in cosmetics. MERCOSUR ²⁴⁸ : MERCOSUR Technical Regulation on the list of permitted colour substances for personal hygiene products, cosmetics, and perfumes. INDIA: Cosmetics Rules, 2020. ISRAEL: Pharmacists' Regulations (Cosmetics).

Annex XI. Summary Chart of Preservatives

Global Chart of Preservatives²⁴⁹

Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²⁵⁰	Not to be used in products applied on mucous membranes ²⁵¹	Not to be used in aerosol dispensers	Warnings	General notes
Benzalkonium chloride	63449-41-2 / 8001-54-5	264-151-6	0.1% / 0.05% (as benzalkonium chloride) ²⁵²			✗ ²⁵³	Avoid contact with eyes ²⁵⁴	
Benzethonium chloride	121-54-0	204-479-9	0.1%	✗ ²⁵⁵	✗ ²⁵⁶			257
Benzoates (salts and esters) other than sodium benzoate	Various	Various	0.5% (as acid)					
Benzoic acid; sodium benzoate	65-85-0 / 532-32-1	200-618-2 / 208-534-8	0.5% / 1.7% / 2.5% (as acid) ²⁵⁸					
Chlorhexidine	55-56-1	200-238-7	0.1% / 0.05% (as chlorhexidine) ²⁵²					259

²⁴⁹ For the purposes of this list, is taken to mean:

—Salts: salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines; salts of the anions chloride, bromide, sulphate and acetate.

—Esters: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl and phenyl.

²⁵⁰ Leave-on product means a cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes.

²⁵¹ Product applied on mucous membranes means a cosmetic product which is intended to be applied on the mucous membranes of the oral cavity, on the rim of the eyes, or of the external genital organs.

²⁵² The first limit applies to rinse-off cosmetics (non-mucous membranes). The second limit applies to leave-on cosmetics and to cosmetics that are used in mucous membranes.

²⁵³ According to the legislation of South Korea (see Annex I).

²⁵⁴ In South Korea, the labelling requirement is as follows: "Avoid contact with eyes and rinse immediately if contact occurs".

²⁵⁵ According to the legislation of the United Mexican States (see Annex I).

²⁵⁶ According to the legislation of Japan, Canada and South Korea (see Annex I).

²⁵⁷ Not to be used in oral products.

²⁵⁸ The first limit applies to leave-on products, the second limit applies to oral products, and the third limit applies to rinse-off products (except oral products). In China and the United Mexican States, MAC = 0.5%. In Japan, MAC for benzoic acid (in all products) = 0.2%, and MAC for sodium benzoate in rinse-off products = 1%.

²⁵⁹ Not to be used in oral products (see legislation of Thailand, Annex I).

Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²⁵⁰	Not to be used in products applied on mucous membranes ²⁵¹	Not to be used in aerosol dispensers	Warnings	General notes
Chlorhexidine dihydrochloride	3697-42-5	223-026-6	0.1% / 0.05% / 0.001% (as chlorhexidine) ²⁶⁰					259
Chlorhexidine digluconate	18472-51-0	242-354-0	0.1% / 0.05% (as chlorhexidine) ²⁵²					259
Chlorobutanol	57-15-8	200-317-6	0.1%			✗	Contains Chlorobutanol May cause an allergic reaction ²⁶¹	
Chloroxylenol	88-04-0 / 1321-23-9	201-793-8 / 215-316-6	0.3% / 0.2% ²⁵²					
Chlorphenesin	104-29-0	203-192-6	0.3%		✗ ²⁶²			
Dehydroacetic acid and its salts	Various	Various	0.5% (as acid)			✗		
Iodopropynyl butylcarbamate	55406-53-6	259-627-5	0.02% / 0.01% / 0.0075% ²⁶³			✗ ²⁶⁴	Not to be used for children under 3 years of age ²⁶⁵	266
Methylchloroisothiazolinone and methylisothiazolinone	55965-84-9 / 26172-55-4 / 2682-20-4 / 96118-96-6	247-500-7 / 220-239-6	0.0015% (MCI/MI= 3:1)	✗	✗ ²⁶²			267

²⁶⁰ The first limit applies to rinse-off cosmetics (non-mucous membranes); the second limit applies to leave-on cosmetics (non-mucous membranes); the third limit applies to cosmetics that are used in mucous membranes.

²⁶¹ The labelling requirement "May cause an allergic reaction" only applies in Thailand.

²⁶² According to the legislation of Japan (see Annex I).

²⁶³ The first limit applies to rinse-off cosmetics; the second limit applies to leave-on cosmetics; the third limit applies to deodorants and antiperspirants.

²⁶⁴ According to the legislation of Japan and South Korea (see Annex I).

²⁶⁵ The labelling requirements does not apply to bath products, shower gels and shampoos. In MERCOSUR, products intended for adults should include on the labelling "Not for use in children".

²⁶⁶ Not to be used in lip products, oral products, body lotions and body creams aimed to be applied on a large part of the body. Not to be used in products for children under 3 years of age, except for bath, shower gel and shampoo products; this last ban applies to children under 13 years of age in South Korea.

²⁶⁷ The use of methylchloroisothiazolinone is only permitted in combination with methylisothiazolinone in ratio MCI/MI = 3:1; furthermore, the methylisothiazolinone is regulated alone. The two entries are mutually exclusive: the use of the mixture of methylchloroisothiazolinone (and) methylisothiazolinone is incompatible with the use of methylisothiazolinone alone in the same product.

Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²⁵⁰	Not to be used in products applied on mucous membranes ²⁵¹	Not to be used in aerosol dispensers	Warnings	General notes
Methylisothiazolinone	2682-20-4	220-239-6	0.0015%	✘	✘ ²⁶²			268
Methyl 4-hydroxybenzoate and its salts; Ethyl 4-hydroxybenzoate and its salts	99-76-3 / 120-47-8	202-758-7 / 204-399-4	0.4% / 0.8% (as acid) ²⁶⁹					270
o-Cymen-5-ol	3228-02-2	221-761-7	0.1%					
Propyl-4-hydroxybenzoate and its salts; Butyl 4-hydroxybenzoate and its salts	94-13-3 / 94-26-8	202-307-7 / 202-318-7	0.14% / 0.8% (as acid) ²⁷¹					272
p-Chloro-m-cresol	59-50-7	200-431-6	0.04%		✘		Do not use in the eye, mouth, or nose area ²⁷³	
Phenoxyethanol	122-99-6	204-589-7	1.0%					
Piroctone olamine	68890-66-4	272-574-2	0.05%		✘ ²⁶²		Contains Piroctone olamine If irritation occurs, stop using the products and consult with a physician or pharmacist ²⁷⁴	

²⁶⁸ Methylisothiazolinone is also regulated in a mixture with methylchloroisothiazolinone. The two entries are mutually exclusive: the use of the mixture of methylchloroisothiazolinone (and) methylisothiazolinone is incompatible with the use of methylisothiazolinone alone in the same product.

²⁶⁹ The first limit refers to the maximum concentration for one single ester; the second limit refers to the maximum concentration for the mixture of esters.

²⁷⁰ In Japan, only the ester and the corresponding sodium salt are permitted.

²⁷¹ The first limit refers to the sum of the individual concentrations; the second limit refers to the maximum concentration for the mixture of methyl, ethyl, butyl and propyl esters of 4-hydroxybenzoic acid, provided that the sum of the concentration of the esters of butyl and propyl does not exceed 0.14%.

²⁷² Not to be used in products intended for children under 3 years of age. In Japan, only the ester and the corresponding sodium salt are permitted.

²⁷³ The labelling requirement applies only in Canada.

²⁷⁴ The labelling requirements are for hair and facial hair products (eyebrows, moustaches, beards, except eyelashes) (see legislation of Thailand, Annex I).

Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²⁵⁰	Not to be used in products applied on mucous membranes ²⁵¹	Not to be used in aerosol dispensers	Warnings	General notes
Polyaminopropyl biguanide	Various	Various	0.05%			✘		275
Salicylic acid	69-72-7	200-712-3	0.2% / 0.5% (as acid) ²⁷⁶			✘	Not to be used for children under 3 years of age ²⁷⁷ Contains salicylic acid ²⁷⁸	279
Salts of salicylic acid	Various	Various	0.2% / 0.5% (as acid) ²⁷⁶				Not to be used for children under 3 years of age ²⁷⁷ Contains salicylic acid ²⁷⁸	280
Sorbic acid and its salts	Various	Various	0.5% (as acid)					

²⁷⁵ Not to be used in applications that may lead to exposure of the end user's lungs by inhalation.

²⁷⁶ The first limit applies to salicylic acid; the second limit applies to the sum of the acid and its salts.

²⁷⁷ In MERCOSUR, products intended for adults should include on the labelling "Not for use in children".


²⁷⁸ The labelling requirement "Contains salicylic acid" only applies in China.

²⁷⁹ Not to be used in oral products or in applications that may lead to exposure of the end-users' lungs by inhalation or in products for children under 3 years of age; the latter ban applies to children under 13 years of age in South Korea.

²⁸⁰ No to be used in products for children under 3 years of age (except for shampoos); this ban applies to children under 13 years of age in South Korea.

Annex XI. Summary Chart of Preservatives

Regionalised Chart of Preservatives²⁸¹

Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²⁸²	Not to be used in products applied on mucous membranes ²⁸³	Not to be used in aerosol dispensers	Warnings	General notes	Restrictions ²⁸⁴
4-Hydroxybenzoic acid and its salts	Various	Various	0.4%						Japan
Alkyl (C12-22) trimethyl ammonium bromide and chloride	Various	Various	0.1%					²⁸⁵	Japan
Benzalkonium bromide and saccharinate	91080-29-4 / 68989-01-5	293-522-5/ 273-545-7	0.1% / 0.05% (as benzalkonium chloride) ²⁸⁶			 ²⁸⁷	Avoid contact with eyes ²⁸⁸		Japan
Benzyl alcohol	100-51-6	202-859-9	1.0%						Japan
Bromochlorophene	15435-29-7	239-446-8	0.1%						Japan
Chlorhexidine diacetate	56-95-1	200-302-4	0.1% / 0.05% (as chlorhexidine) ²⁸⁹					²⁹⁰	Japan
Citric acid (and) Silver citrate		460-890-5	0.2%, corresponding to 0.0024% of silver					²⁹¹	China, Japan, South Korea

²⁸¹ For the purposes of this list, is taken to mean:

—Salts: salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines; salts of the anions chloride, bromide, sulphate and acetate.

—Esters: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl and phenyl.

²⁸² Leave-on product means a cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes.

²⁸³ Product applied on mucous membranes means a cosmetic product which is intended to be applied on the mucous membranes of the oral cavity, on the rim of the eyes, or of the external genital organs.

²⁸⁴ These ingredients are not approved for use in cosmetic products in these markets.

²⁸⁵ Do not use in hair products (see legislation of South Korea, Annex I).

²⁸⁶ The first limit applies to rinse-off cosmetics. The second limit applies to leave-on cosmetics.

²⁸⁷ According to the legislation of South Korea (see Annex I).

²⁸⁸ In South Korea, the labelling requirement is as follows: "Avoid contact with eyes and rinse immediately if contact occurs".

²⁸⁹ The first limit applies to rinse-off cosmetics (non-mucous membranes). The second limit applies to leave-on cosmetics and cosmetics used on mucous membranes.

²⁹⁰ Not to be used in oral products (see legislation of Thailand, Annex I).

²⁹¹ Do not use in oral products or eye products. Use is only permitted in skin care products (see legislation of the United Mexican States, Annex I).

Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²⁸²	Not to be used in products applied on mucous membranes ²⁸³	Not to be used in aerosol dispensers	Warnings	General notes	Restrictions ²⁸⁴
Climbazole	38083-17-9	253-775-4	0.2% / 0.5% ²⁹²				Contains climbazole Avoid contact with eyes If irritation occurs after using the product, stop using and consult a doctor or pharmacist ²⁹³	²⁹⁴	Japan
Dibromohexamidine and its salts (including isethionate)	Various	Various	0.1%						Japan
Dichlorobenzyl alcohol	1777-82-8	217-210-5	0.15%						Japan
Ethyl Lauroyl Arginate HCl	60372-77-2	434-630-6	0.4%		×	×	Not to be used for children under 10 years of age Avoid contact with eyes ²⁹⁵	²⁹⁶	Japan, Mexico
Formic acid; sodium formate	64-18-6 / 141-53-7	200-579-1/ 205-488-0	0.5% (as acid)						Japan
Glutaral	111-30-8	203-856-5	0.1%			×	Contains glutaral May cause an allergic reaction IRRITANT. Avoid contact with eyes ²⁹⁷		Japan
Hexamidine and its salts (including isethionate and p-hydroxybenzoate)	Various	Various	0.1%						Japan

²⁹² The first limit applies to hair lotions and face creams. The second limit applies to rinse-off shampoos.

²⁹³ The labelling requirement applies only in Thailand.

²⁹⁴ Use only permitted in hair lotions, face creams and rinse-off shampoos (except in South Korea where its use is allowed only in hair products (see legislation of South Korea, Annex I)).

²⁹⁵ The labelling requirement "Avoid contact with eyes" only applies in China.

²⁹⁶ Not to be used in oral products and in lip products.

²⁹⁷ The labelling requirement is only necessary when the concentration of glutaral in the finished product exceeds 0.05%. The labelling requirement "May cause an allergic reaction" applies only in Thailand. The labelling requirement "IRRITANT. Avoid contact with eyes" applies only in Australia.

Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products ²⁸²	Not to be used in products applied on mucous membranes ²⁸³	Not to be used in aerosol dispensers	Warnings	General notes	Restrictions ²⁸⁴
Hexetidine	141-94-6	205-513-5	0.1%	✗ ²⁸⁷					Japan
Hydroxyethoxyphenyl butanone	569646-79-3	933-435-8	0.7%						China, South Korea, Mexico, Japan, Taiwan, India
Inorganic sulphites and hydrogen-sulphites	Various	Various	0.2% (as free SO ₂)						Japan
o-Phenylphenol	90-43-7	201-993-5	0.15% (as phenol)				Avoid contact with eyes		California
Phenoxyisopropanol	770-35-4	212-222-7	1.0%	✗					Japan
Piroctone	50650-76-5		1% / 0.5% ²⁸⁶						Japan
Propionic acid and its salts	Various	Various	0.9% (as acid)						Japan
Silver chloride deposited on titanium dioxide	7783-90-6	232-033-3	0.004% (as AgCl)				This product contains silver and/or silver salts. Avoid contact with damaged or scraped skin ²⁹⁸	²⁹⁹	Japan, South Korea
Undecylenic acid and its salts	Various	Various	0.2% (as acid)	✗ ²⁸⁷					Japan

²⁹⁸ The labelling requirement applies only in Canada.

²⁹⁹ 20% AgCl (w/w) on TiO₂. Not to be used in products for children under 3 years of age. Not to be used in oral products, lip products or eye products.

Annex XII. Summary Chart of UV Filters

Global Chart of UV Filters³⁰⁰

Name of Common Ingredients Glossary	Other names	Acronym	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in products applied on mucous membranes ³⁰¹	General notes ³⁰²
Benzophenone-4	Sulisobenzone	BP4	4065-45-6	223-772-2	5% ³⁰³ (as acid)		
Butyl methoxydibenzoylmethane	Avobenzone	BMBM	70356-09-1	274-581-6	5% ³⁰⁴		
Ethylhexyl dimethyl PABA	Padimate O	EHDP	21245-02-3	244-289-3	8% ³⁰⁵		
Ethylhexyl salicylate	Octisalate	EHS	118-60-5	204-263-4	5%		
Homosalate	Homosalate	HMS	118-56-9	204-260-8	7.34%	✗	306
Phenylbenzimidazole sulfonic acid	Ensulizole	PBSA	27503-81-7	248-502-0	8% ³⁰⁷	✗ ³⁰⁸	
Titanium dioxide; Titanium dioxide (nano)		TiO ₂	13463-67-7/ 1317-70-0/ 1317-80-2	236-675-5/ 205-280-1/215-28 2-2	25%		309
Zinc oxide; Zinc oxide (nano)		ZnO	1314-13-2	215-222-5	25%		310

³⁰⁰ When these substances are used to protect the product formulation, the MAC = 0.5% (see legislation of South Korea, Annex I).

³⁰¹ Product applied on mucous membranes means a cosmetic product which is intended to be applied on the mucous membranes of the oral cavity, on the rim of the eyes, or of the external genital organs.

³⁰² In USA, if UV filter combinations are intended to be used in sunscreen formulations, it is important to note that not all UV filter combinations are permitted. Consult Title 21 CFR, Part 352 (Sunscreen Drug Products for Over-The-Counter Human Use) (see Annex I).

³⁰³ MAC = 5%, except in Japan where the MAC is 0.1% for products applied on the mucous membranes.

³⁰⁴ MAC = 5% except in Canada and USA where the MAC is 3%.

³⁰⁵ MAC = 8% except in Japan where the MAC is 7% for products applied on the mucous membranes.

³⁰⁶ Use exclusively permitted in face products with the exception of propellant spray products.

³⁰⁷ MAC = 8% except in Australia, Canada, South Korea and USA where the MAC is 4% and in Japan where the MAC is 3%.

³⁰⁸ According to the legislation of Japan (see Annex I).

³⁰⁹ Titanium dioxide in powder form containing 1% or more of particles with aerodynamic diameter $\leq 10 \mu\text{m}$, to be used must meet the following requirements: a) Face products in loose, MAC = 25%, only in the pigmentary form; b) Hair aerosol spray products, MAC = 1.4% for general consumers and 1.1% for professional use, only in the pigmentary form; c) Other products, MAC = 25%, not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.

Nano form: Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: purity $\geq 99\%$; median particle size based on number size distribution $\geq 30 \text{ nm}$; with the coatings permitted in the European Union; photocatalytic activity ≤ 10 and nanoparticles are photostable in the final formulation; in addition to other restrictions on its chemical and physical form and appearance. In case of combined use of titanium dioxide and titanium dioxide (nano), the sum shall not exceed the limit of maximum concentration given. Face products containing Titanium dioxide(nano) coated with the combination Alumina and Manganese dioxide, must carry the warning: "Not to be used on the lips".

³¹⁰ Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: purity $\geq 96\%$; D50 $> 30 \text{ nm}$ and D1 $> 20 \text{ nm}$; water solubility $< 50 \text{ mg/L}$; uncoated or with the coatings permitted in the European Union. In case of combined use of zinc oxide and zinc oxide (nano), the sum shall not exceed the limit of maximum concentration given.

Annex XII. Summary Chart of UV Filters

Regionalised Chart of UV Filters³¹¹

Name of Common Ingredients Glossary	Other names	Acronym	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in products applied on mucous membranes ³¹²	General notes	Restrictions ³¹³
Benzophenone-3	Oxybenzone	BP3	131-57-7	205-031-5	6% / 2.2% / 0.5% ³¹⁴		³¹⁵	In sunscreens, prohibited in: USA, Aruba, Bonaire
Benzophenone-5		BP5	6628-37-1		5% ³¹⁶ (as acid)			USA, South Korea, Canada
Benzylidene camphor sulfonic acid and its salts		BCS	56039-58-8		6% (as acid)			USA, Japan, South Korea, Canada
Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine Bis-(Diethylaminohydroxybenzoyl Benzoyl) Piperazine (nano)		HAA299 HAA299 (nano)	919803-06-8	485-100-6	10%		³¹⁷	Australia, Canada, China, South Korea, USA, Mexico, India, Japan, MERCOSUR, Taiwan, Eurasian Customs Union, Saudi Arabia
Bis-ethylhexyloxyphenol methoxyphenyl triazine	Bemotrizinol	BEMT	187393-00-6		10% ³¹⁸	✗ ³¹⁹		USA, Canada ³²⁰
Camphor benzalkonium methosulfate		CBM	52793-97-2	258-190-8	6%			USA, Japan, South Korea, Canada
Diethylamino hydroxybenzoyl hexyl benzoate		DHHB	302776-68-7	443-860-6	10%	✗ ³¹⁹		USA, Canada

³¹¹ When these substances are used to protect the product formulation, the MAC is 0.5% (see legislation of South Korea, Annex I).

³¹² Product applied on mucous membranes means a cosmetic product which is intended to be applied on the mucous membranes of the oral cavity, on the rim of the eyes, or of the external genital organs.

³¹³ These ingredients are not approved for use in cosmetic products in these markets.

³¹⁴ The first limit applies to face products, hand products, and lip products, excluding propellant and pump spray products (in Japan and South Korea, this MAC is 5%). The second limit applies to body products, including propellant and pump spray products. The third limit applies to other products. When used to protect the product formulation, the MAC is 0.5%. The sum of the concentrations of benzophenone-3 used as a UV filter and as a UV absorber must not exceed the established MAC limits.

³¹⁵ Warning: "Contains benzophenone-3".

³¹⁶ MAC = 5% except in Japan where the MAC is 1% for products applied to mucous membranes.

³¹⁷ Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation (for nano form). Only nanomaterials having the following characteristics are allowed: purity ≥ 97%; median particle size D50 (50% of the number below this diameter): ≥ 50 nm of number size distribution. In case of combined use of HAA299 and its nano forms, the sum shall not exceed the limit of maximum concentration given.

³¹⁸ MAC = 10% except in Canada where the MAC is 6% and in Japan where the MAC is 3%.

³¹⁹ According to the legislation of Japan (see Annex I).

³²⁰ In Canada, this UV filter is not permitted in secondary sunscreens; it is only allowed for use in primary sunscreens.

Name of Common Ingredients Glossary	Other names	Acronym	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in products applied on mucous membranes ³¹²	General notes	Restrictions ³¹³
Diethylhexyl butamido triazone	Iscotrizinol	DBT	154702-15-5		10%			USA, Japan, Canada, Australia
Disodium phenyl dibenzimidazole tetrasulfonate	Bisdisulizole disodium	DPDT	180898-37-7	429-750-0	10% (as acid)			USA, Japan, Canada
Drometrizole trisiloxane		DTS	155633-54-8		15% ³²¹	✗ ³¹⁹		USA
Ethylhexyl methoxycinnamate	Octinoxate	EHMC	5466-77-3	226-775-7	10% ³²²			In sunscreens, prohibited in: USA, Aruba, Bonaire
Ethylhexyl triazone		EHT	88122-99-0	402-070-1	5%	✗ ³¹⁹		USA, Canada
Isoamyl p-methoxycinnamate	Amiloxate	IMC	71617-10-2	275-702-5	10%			USA, Japan, Canada
Methylene bis-benzotriazolyl tetramethylbutylphenol; Methylene bis-benzotriazolyl tetramethylbutylphenol (nano)	Bisoctrizole	MBBT; MBBT (nano)	103597-45-1	403-800-1	10%	✗ ³¹⁹	³²³	USA, Canada ³²⁴
Methoxypropylamino Cyclohexenylidene Ethoxyethylcyanoacete			1419401-88-9	700-860-3	3%		³²⁵	Australia, Canada, China, USA, Mexico, Japan, Taiwan
Octocrylene	Octocrylene	OCR	6197-30-4	228-250-8	9% / 10% ³²⁶			In sunscreens, prohibited in: USA, Aruba, Bonaire
PEG-25 PABA		P25	116242-27-4		10%			USA, Japan, South Korea, Canada

³²¹ MAC = 15% except in Australia where the MAC is 10%.

³²² MAC = 10% except in Canada, USA (not sunscreens) and South Korea where the MAC is 7.5% and in Japan where the MAC is 8% for products applied on the mucous membranes.

³²³ Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation (for nano form). Only nanomaterials having the following characteristics are allowed: purity $\geq 98.5\%$, with 2,2'-Methylene-bis-(6(2H-benzotriazol-2-yl)-4-(isooctyl)phenol) isomer fraction not exceeding 1.5%; Solubility < 5 ng/L in water at 25°C; Partition coefficient (Log Pow): 12.7 at 25°C; Uncoated; Median particle size D50 (50% of the number below this diameter): ≥ 120 nm of mass distribution and/or ≥ 60 nm of number size distribution. In case of combined use of MBBT and MBBT (nano), the sum shall not exceed the limit of maximum concentration given.

³²⁴ In Canada, this UV filter is not permitted in secondary sunscreens; it is only allowed for use in primary sunscreens with MAC = 5%.

³²⁵ Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Do not use with nitrosating agents. Maximum nitrosamine content: 50 $\mu\text{g}/\text{kg}$. Keep in nitrite-free containers.

³²⁶ The first limit applies to propellant spray products; the second limit applies to other products. Benzophenone, as an impurity and/or as a degradation product of octocrylene, must be kept at trace levels.

Name of Common Ingredients Glossary	Other names	Acronym	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in products applied on mucous membranes ³¹²	General notes	Restrictions ³¹³
Phenylene Bis-Diphenyltriazine			55514-22-2	700-823-1	5%		327	China, South Korea, USA, Mexico, Japan, Taiwan, Canada, Australia
Polyacrylamidomethyl benzylidene camphor		PBC	113783-61-2		6%			USA, Japan, South Korea, Canada, Australia
Polysilicone-15		PS15	207574-74-1	426-000-4	10%			USA, Canada
Potassium, sodium and triethanolamine salts of Phenylbenzimidazole sulfonic acid					8% (as acid)			USA, Japan, South Korea, Canada, Australia
Salts of Terephthalydene dicamphor sulfonic acid					10% (as acid)			USA, Japan, Canada, Australia
Terephthalydene dicamphor sulfonic acid	Ecamsule	TDSA	92761-26-7 / 90457-82-2	410-960-6	10% (as acid)	✗ ³¹⁹		USA
Tris-biphenyl triazine; tris-biphenyl triazine (nano)		TBPT; TBPT (nano)	31274-51-8		10%		328	USA, South Korea, China, Canada, Mexico

³²⁷ Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. The concentration of the impurities of methyl-pyrrolidone and hydrazine must be kept at trace levels (see legislation of MERCOSUR, Annex I).

³²⁸ Not to be used in sprays. Only nanomaterials having the following characteristics are allowed: median primary particle size > 80 nm; purity ≥ 98%; uncoated.

Annex XIII. Summary Chart of Instrumental Techniques Proposed for Analysing the Substances Selected in this Standard

DETECTORS	INSTRUMENTAL TECHNIQUES																
	HPLC						GC						IC	CE	SPECTROMETRY		
	UV/DAD	EQ	FLD	TEA	MS	MS/MS	TEA	MS	MS/MS	FID	ECD	AED			ICP/MS	AAS/AES	XRFS
COMPOUNDS																	
Nitromusks								X	X		X	X					
Polycyclic and Macrocyclic musks								X	X					X ^a			
Fragrance allergens	X					X		X	X								
Nitrosamines	X			X	X	X	X	X	X								
Amines and aminoderivatives													X				
Nitrosating agents	X	X						X	X		X		X ^b		X		
Phthalates	X							X	X	X							
Metals/Metalloids/Nonmetals														X	X	X	
Glycol-ethers	X ^c							X		X							
Residues from Surfactants	X ^c		X ^d					X		X							
Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)						X		X	X								
Colorants	X				X	X								X		X	X
Preservatives	X ^c				X	X		X	X					X			
UV Filters	X				X	X											

^a The electrophoretic variant NA-MEKC may also be used.

^b Only nitrites.

^c With derivatisation.

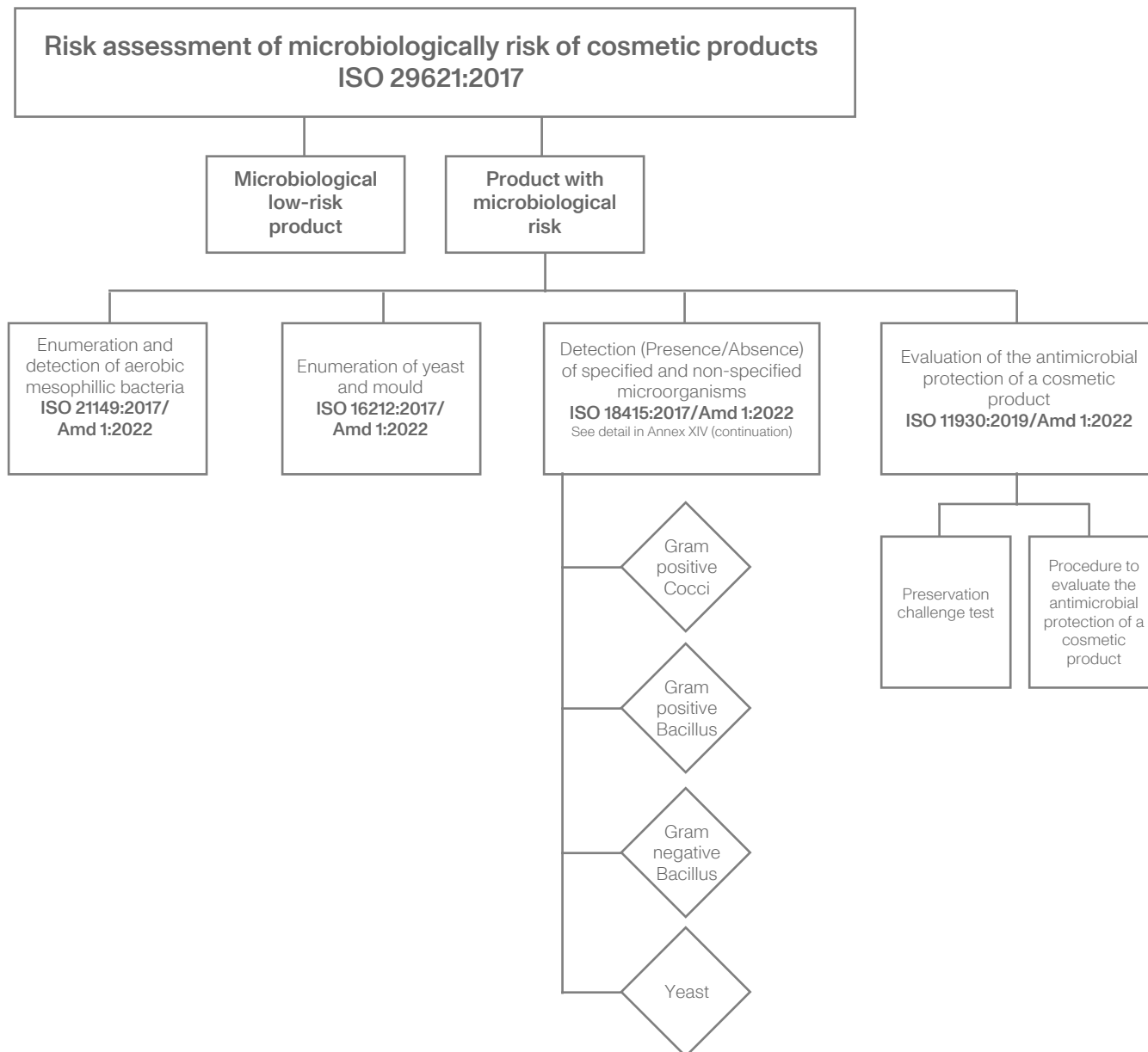
^d Only alkylphenols (APs) and alkylphenol ethoxylates (APEOs).

ACRONYMS:

HPLC (High Performance Liquid Chromatography); **LC** (Liquid Chromatography); **GC** (Gas Chromatography); **IC** (Ionic Chromatography); **CE** (Capillary Electrophoresis); **NA-MEKC** (Non-Aqueous Micellar Electrokinetic Chromatography); **UV** (Ultra-Violet Detector); **DAD** (Diode Array UV-Vis Detector); **EQ** (Electrochemical Detector); **FLD** (Fluorescence Detector); **TEA** (Thermal Energy Analyzer); **MS** (Mass Spectrometry); **MS²** (Tandem Mass Spectrometry); **FID** (Flame Ionisation Detector); **ECD** (Electron Capture Detector); **AED** (Atomic Emission Detector); **ICP-MS** (Inductively Coupled Plasma-Mass Spectrometer); **AAS** (Atomic Absorption Spectroscopy); **AES** (Atomic Emission Spectroscopy); **XRFS** (X-Ray Fluorescence Spectroscopy).

Annex XIV. Microbiological Control

The following decision tree summarises the most frequent stages in carrying out the microbiological control analyses and their respective ISO Standards^{329,330}:



³²⁹ The standards indicated below are essential for the application of all the standards explicitly mentioned in the text and/or the decision tree (Annex XIV):

ISO 22716:2007 Cosmetic products. Good Manufacturing Practice (GMP). Guide to Good Manufacturing Practice.

ISO/TR 19838:2016 Guidelines for the application of ISO standards on Cosmetic Microbiology.

ISO 21148:2017 Cosmetics. Microbiology. General Instructions for the microbiological examination.

EN 12353:2021 Chemical disinfectants and antiseptics. Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity.

³³⁰ The ISO 29621:2017 Standard defines “microbiologically low-risk products” such as products whose environment denies the physical and chemical requirements for growth and/or survival of microorganisms; with the following specifications:

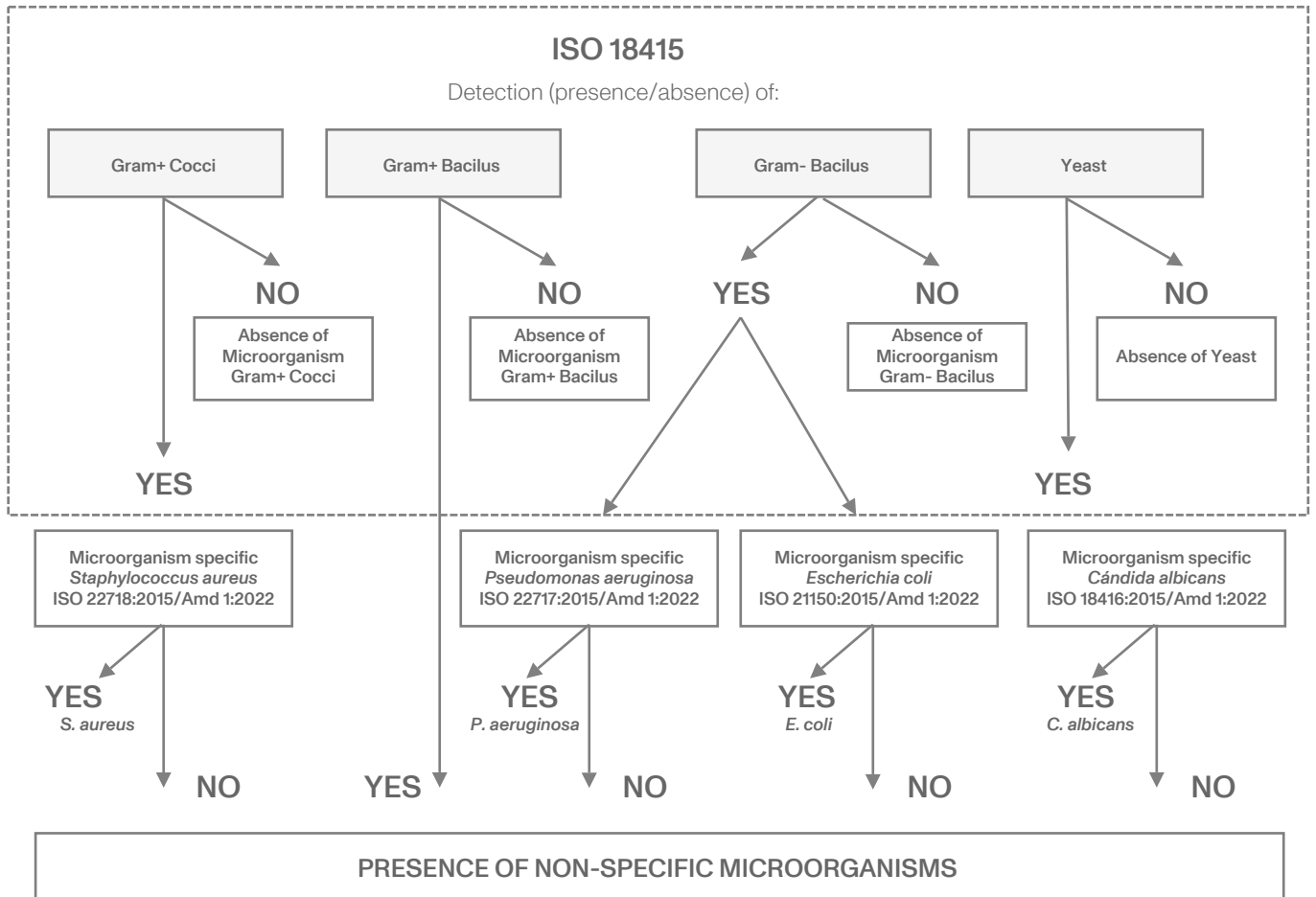
Note 1. This category of low-risk products applies to microbiological contamination which may occur during manufacturing and/or intended use by the consumer.

Note 2. A product whose packaging prevents the ingress of microorganisms is considered a microbiological low-risk product during its use.

Note 3. The inclusion of preservatives or other antimicrobial compounds in a formulation by itself would not necessarily constitute a low-risk product.

Annex XIV. Microbiological control (continuation)

The following diagram summarises the path to apply the Standard ISO 18415:2017/Amd 1:2022 and the conclusions that may be drawn from it³³¹:



³³¹ The identification of non-specific microorganisms may be useful in locating the source of contamination.

Annex XV. Checklists

1. Checklist of Product Information File (PIF). General data of the cosmetic product (CP)

		✓/✗/NA
1. DESCRIPTION OF CP		
Presentation	CP Name	
	CPNP notification certificate	
	Conformity with Regulation EU 2023/988	
	CP Presentation (single item, set/kit, tester)	
	CP Category See section 1.1 CP Categories	
Labelling	Name of the Responsible Person for the CP	
	Address of the Responsible Person for the CP	
	Country of Origin	
	Reference for identifying the CP or batch number	
	Function	
	Nominal content (at the time of packaging)	
	Period-after-opening (PAO)/Date of minimum durability	
	List of ingredients (INCI) preceded by the term "ingredients" <ul style="list-style-type: none"> • Parfum or Aroma + the mention of other substances (annex III) when required • Colorants by CI (if range: "may contain" or "+/-") 	
	Precautions for use, those listed in annexes III to VI and particulars	
2. DESCRIPTION OF THE METHOD OF MANUFACTURING & GMP		
	Description of the method of manufacturing	
	Declaration of compliance with GMP	
3. PROOF OF THE EFFECT CLAIMED FOR THE CP		
4. DATA ON ANIMAL TESTING		
5. CP SAFETY REPORT (CPSR)		
CPSR PART A	See section 1.2 Checklist of Cosmetic Product Safety Report (CPSR Part A)	
CPSR PART B	Assessment conclusion (Safe, safe with restrictions or unsafe)	
	Labelled warnings and instructions of use	
	Reasoning for assessment conclusion	
	Assessor's credentials and approval	

1.1. Cosmetic product categories

CP Categories	CP Type
A. Cosmetic products for the area around the eyes	1.- Eye pencil, eyebrow pencil
	2.- Eyeliner
	3.- Eye shadow
	4.- Eye make-up remover
	5.- Mascara
	6.- Other products for the area around the eyes
B. Cosmetic products for the lips	1.- Lipstick
	2.- Lip gloss
	3.- Lip protector
	4.- Lip liner
	5.- Other products for the lips
C. Cosmetic products for the face	1.- Make-up base (liquid, cream)
	2.- Blush
	3.- Face powders
	4.- Face cream
	5.- Face lotion
	6.- Face mask
	7.- Facial corrector
	8.- Make-up remover
	9.- Facial cleansing product
	10.- Other products for the face
D. Cosmetic products for the skin	1.- Body make-up base
	2.- Body cream
	3.- Hands cream
	4.- Body lotion
	5.- Body oil
	6.- Body powders
	7.- Other products for the skin
E. Cosmetic products for washing and body hygiene	1.- Soap
	2.- Bath gel
	3.- Bath foam
	4.- Bath powders
	5.- Bath oil
	6.- Bath lotion
	7.- Bath salts
	8.- Aromatic bath tablet
	9.- Talcum powders
	10.- Moisturising towels and cloths
	11.- Other products for washing and body hygiene
F. Deodorant and antiperspirant products	1.- Deodorant
	2.- Antiperspirant

CP Categories	CP Type
G. Cosmetic products for the nails	1.- Nail polish base
	2.- Cuticle softener
	3.- Nail cream
	4.- Nail polish
	5.- Nail polish remover
	6.- Nail oil
	7.- Nail gloss
	8.- Other products for the nails
H. Cosmetic perfumery products	1.- Eau de toilette
	2.- Eau de cologne
	3.- Eau de tender
	4.- Eau de parfum
	5.- Body mist
	6.- Other cosmetic perfumery products
I. Shave and after-shave products	1.- Shave foam
	2.- Shave lotion
	3.- Shave cream
	4.- After-shave lotion
	5.- After-shave balm
	6.- Other shave and after-shave products
J. Hair products	1.- Shampoo
	2.- Conditioner
	3.- Fixative
	4.- Hair mask
	5.- Hair straightening product
	6.- Hair curling product
	7.- Hair dye (non-oxidative)
	8.- Other hair products
K. Cosmetic products for mouth and dental hygiene	1.- Toothpaste
	2.- Mouthwash
	3.- Oral rinse
	4.- Other oral and dental hygiene products
L. Sun protection and self-tanning products	1.- Pre- and post- sun product
	2.- Sun protection product
	3.- Self-tanning product
	4.- Other sun protection and self-tanning products
M. Depilatory products	Refer to Inditex Sustainability Department
N. Skin whitening products	
O. Other products: Refill, oxidative dyes, temporary tattoos	

1.2. Checklist of Cosmetic Product Safety Report (CPSR Part A)

		✓/✗/NA
1. Quantitative and qualitative composition of the CP		
The complete product composition: name, identity (incl. INCI, CAS, EINECS/ELINCS...) and the amount of each raw material (% in weight)		
Compliance with i+Cosmetics		
Suppliers of the raw materials		
Intended function of each substance		
Quantity, molecular formula and analytical specifications of chemically well-defined substances		
Definition, nature and quantity of complex ingredients (incl. purity criteria and test methods)		
Fragrance (or flavour)		
Flavour name		
Code number		
Manufacturer or supplier		
Declaration of fragrance allergens ³³²		
IFRA Declaration ³³³		
Safety assessment of fragrance		
2. Physical/chemical characteristics and stability of the CP		
Physical and chemical specifications of raw materials (pH, odour, density, viscosity...)		
Physical and chemical specifications of CP (pH, odour, density, viscosity...)		
Stability of the cosmetic product		
• Stability test		
• Minimum durability or period-after-opening (PAO)		
3. Microbiological quality³³⁴		
Microbiological quality of the raw materials		
Microbiological quality of the CP		
Risk assessment and identification of microbiologically low-risk products (ISO 29621:2017)		
Microbiological quality test		
• Enumeration and detection of aerobic mesophilic bacteria (ISO 21149:2017/Amd 1:2022)		
• Enumeration of yeast and mould (ISO 16212:2017/Amd 1:2022)		
• Detection of specified and non-specified microorganisms (ISO 18415:2017/Amd 1:2022)		
Evaluation of the antimicrobial protection of a CP (ISO 11930:2019/Amd 1:2022)		
• Preservation efficacy test (Preservative challenge test)		
• Evaluation of the overall antimicrobial protection of a CP		

³³² A model of Declaration of fragrance allergens is available at the end of this section (see section 1.2.1 Declaration of fragrance allergens).

³³³ IFRA Declaration of the year of the cosmetic product launch and subsequent revisions if any.

³³⁴ Additional information is provided on Guidelines for the application of ISO standards on Cosmetic Microbiology (ISO/TR 19838:2016). It is recommended to follow the General instructions for the microbiological examination included in the ISO 21148:2017.

	✓/✘/NA
4. Impurities, traces and information about the packaging material	
Purity of raw materials (specifications/technical data/physicochemical analysis)	
Evidence of the technical unavoidability of traces of prohibited substances	
The relevant characteristics of the packaging material (or primary packaging) (specifications/technical data/potential migration to the CP) <ul style="list-style-type: none"> • Reference to EC/1935/2004 	
5. Normal and reasonably foreseeable use	
Communication of the intended use to the consumer	
Consistency of the intended use with the labelling	
6. Exposure to the CP	
Product type (rinse-off or leave-on products)	
Area of application	
Amount per application (normal and reasonably foreseeable use)	
Duration and frequency	
Possible (foreseeable) routes of exposure	
Target group for use (< 3 years, adults)	
Impact of particle size on exposure	
7. Exposure to the substances	
Amount of each substance coming into contact with the external parts of the human body or the teeth and the mucous membranes of the oral cavity	
8. Toxicological profile of the substances	
Toxicological profile of substances (NOAEL/LOAEL)	
Significant routes of absorption (SED)	
Consideration of systemic effects and calculation of the margin of the safety (MoS)	
9. Undesirable effects and serious undesirable effects	
Management scheme of the undesirable effects and serious undesirable effects	
Inclusion of the relationship between undesirable effects and serious undesirable effects and the CP in the CP safety report	
10. Additional CP information	
Skin compatibility test	
Inclusion of any additional information not previously provided	

1.2.1. Declaration of Fragrance Allergens

Labelling name ³³⁵	CAS Number	Concentration (%) ³³⁶	Labelling ³³⁷
3-Propylideneophthalide	17369-59-4		
6-Methylcoumarin	92-48-8		
Acetyl Cedrene	32388-55-9		
Rose Ketones	43052-87-5 / 23726-94-5 / 24720-09-0 / 23696-85-7 / 57378-68-4 / 71048-82-3 / 23726-92-3 / 23726-91-2		
Alpha-Isomethyl ionone	127-51-5		
Alpha-Terpinene	99-86-5		
Amyl cinnamal	122-40-7		
Amylcinnamyl alcohol	101-85-9		
Amyl Salicylate	2050-08-0		
Anethole	104-46-1 / 4180-23-8		
Anise alcohol	105-13-5		
Benzaldehyde	100-52-7		
Benzyl alcohol	100-51-6		
Benzyl benzoate	120-51-4		
Benzyl cinnamate	103-41-3		
Benzyl salicylate	118-58-1		
Beta-Caryophyllene	87-44-5		
Camphor	76-22-2 / 21368-68-3 / 464-49-3 / 464-48-2		
Cananga Odorata Oil/Extract	83863-30-3 / 8006-81-3 / 68606-83-7 / 93686-30-7		
Carvone	99-49-0 / 6485-40-1 / 2244-16-8		
Cedrus Atlantica Oil/ Extract	92201-55-3 / 8023-85-6		
Cinnamal	104-55-2		
Cinnamomum Cassia Leaf Oil	8007-80-5 / 84961-46-6		
Cinnamomum Zeylanicum Bark Oil	8015-91-6 / 84649-98-9		
Cinnamyl alcohol	104-54-1		
Citral	5392-40-5 / 141-27-5 / 106-26-3		
Citronellol	106-22-9 / 26489-01-0 / 1117-61-9 / 7540-51-4		
Citrus Aurantium Flower Oil	72968-50-4 / 8028-48-6 / 8016-38-4		
Citrus Aurantium Peel Oil	68916-04-1 / 72968-50-4 / 97766-30-8 / 8028-48-6 / 8008-57-9		
Citrus Aurantium Bergamia Peel Oil	8007-75-8 / 89957-91-5 / 68648-33-9 / 85049-52-1		
Citrus Limon Peel Oil	84929-31-7 / 8008-56-8		
Coumarin	91-64-5		
Lemongrass Oil	8007-02-1 / 89998-16-3 / 91844-92-7		
Dimethyl Phenethyl Acetate	151-05-3		
Eucalyptus Globulus Oil	97926-40-4 / 8000-48-4		
Eugenia Caryophyllus Oil	8000-34-8 / 8015-97-2 / 84961-50-2		
Eugenol	97-53-0		
Eugenyl Acetate	93-28-7		
Evernia furfuracea extract	90028-67-4		
Evernia prunastri extract	90028-68-5		
Farnesol	4602-84-0		

³³⁵ The name for labelling provided corresponds to the one established by the European Union Regulation.

³³⁶ In final cosmetic product.

³³⁷ The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on products and 0.01% in rinse-off products.

Labelling name ³³⁵	CAS Number	Concentration (%) ³³⁶	Labelling ³³⁷
Geraniol	106-24-1		
Geranyl Acetate	105-87-3		
Hexadecanolactone	109-29-5		
Hexamethylindanopyran	1222-05-5		
Hexyl cinnamal	101-86-0		
Hydroxycitronellal	107-75-5		
Isoeugenol	97-54-1/ 5932-68-3 / 5912-86-7		
Isoeugenyl Acetate	93-29-8		
Jasmine Oil/Extract	84776-64-7 / 90045-94-6 / 8022-96-6 / 8024-43-9		
Juniperus Virginiana Oil	8000-27-9 / 85085-41-2		
Laurus Nobilis Leaf Oil	8002-41-3 / 8007-48-5 / 84603-73-6		
Lavandula Oil/ Extract	91722-69-9 / 8022-15-9 / 93455-96-0 / 93455-97-1 / 92623-76-2 / 84776-65-8 / 8000-28-0 / 90063-37-9		
Limonene	138-86-3 / 7705-14-8 / 5989-27-5 / 5989-54-8		
Linalool	78-70-6		
Linalyl Acetate	115-95-7		
Lippia citriodora absolute	8024-12-2 / 85116-63-8		
Mentha Piperita Oil	8006-90-4 / 84082-70-2		
Mentha Viridis Leaf Oil	8008-79-5 / 84696-51-5		
Menthol	89-78-1 / 1490-04-6 / 2216-51-5 / 15356-60-2		
Methyl 2-octynoate	111-12-6		
Methyl Salicylate	119-36-8		
Myroxylon Pereirae Oil/ Extract	8007-00-9		
Narcissus Extract	90064-26-9 / 68917-12-4 / 90064-27-0 / 90064-25-8		
Pelargonium Graveolens Flower Oil	90082-51-2 / 8000-46-2		
Pinene	80-56-8 / 7785-70-8 / 127-91-3 / 18172-67-3		
Pinus Mugo	90082-72-7		
Pinus Pumila	97676-05-6		
Pogostemon Cablin Oil	8014-09-3 / 84238-39-1		
Rose Flower Oil/Extract	8007-01-0 / 90106-38-0 / 93334-48-6 / 84696-47-9 / 84604-12-6 / 84604-13-7 / 92347-25-6		
Salicylaldehyde	90-02-8		
Santalol	11031-45-1 / 115-71-9 / 77-42-9		
Santalum Album Oil	8006-87-9 / 84787-70-2		
Sclareol	515-03-7		
Terpineol	8000-41-7 / 98-55-5 / 138-87-4 / 586-81-2		
Terpinolene	586-62-9		
Tetramethyl acetyloctahydronaphthalenes	54464-57-2 / 54464-59-4 / 68155-66-8 / 68155-67-9		
Trimethylbenzenepropanol	103694-68-4		
Trimethylcyclopentenyl Methylisopentenol	67801-20-1		
Turpentine	9005-90-7 / 8006-64-2 / 8052-14-0		
Vanillin	121-33-5		

Annex XVI. Commitment to comply with Inditex Group's i+Cosmetics standard

I hereby confirm that:

- 1) We have received the Inditex Precautions and Limits for Users Safety for Cosmetics (hereinafter, i+Cosmetics), we have read it and thoroughly understand its implications.
- 2) We acknowledge that compliance with i+Cosmetics is a contractual obligation and undertake, accordingly, to meet the i+Cosmetics requirements in all orders involving production, marketing or distribution placed by any of the formats of the Inditex Group.
- 3) We undertake to disclose and formally demand i+Cosmetics implications to the whole production line.
- 4) The Inditex Group:
 - Reserves the right to check: i) compliance with i+Cosmetics regarding any goods supplied, by any method, at any time, and/or at any stage of the production, marketing or distribution processes, and ii) the appropriate disclosure of i+Cosmetics.
 - Reserves the right to cancel any order for any goods where a non-compliance with i+Cosmetics regarding any test and/or inspection has been established.
 - Reserves the right to return any orders already delivered where a non-compliance with i+Cosmetics regarding any test and/or inspection has been established.
 - Reserves the right to adopt any measure deemed to be necessary in relation with the goods subject to the cancelled order, subject to the fact that the cancellation of the relevant order shall entail the non existence of the obligation to pay any sum whatsoever for the goods failing to comply with i+Cosmetics.
 - Holds the Supplier as solely responsible for any and all damages caused by goods failing to comply with i+Cosmetics;

and finally,

- 5) We acknowledge that approval of a "sample" and any subsequent "repetition" of goods by the INDITEX Group do not release us from our liability, for the entire production, marketing and distribution processes.

THE SUPPLIER IS RESPONSIBLE FOR ALWAYS REFERRING TO THE LATEST UPDATED VERSION OF THIS DOCUMENT, AVAILABLE AT www.inditex.com

The information contained in this Standard is subject to changes. The latest version of this Standard will always prevail. Refer to www.inditex.com

Annex XVII. Change log for i+Cosmetics version 2025³³⁸

CHAPTER	MODIFICATION
I. Definition of i+Cosmetics	<ul style="list-style-type: none"> • Added mention of GMP. • Added mention of the new sun protection parameter. • Added reference to compliance with the French decree on endocrine disruptors and the Australian Poisons Standard. • Added 2 new families of chemical substances (PFAS and VOCs)
III. Legal Requirements of Product	<ul style="list-style-type: none"> • Removed the specific category for baby and children's products. • Modified some product examples within existing categories. • Added the categories: hair products, oral and dental hygiene products, and sun protection and self-tanning products.
III.1. Fragrances a) Musk / Annex II b) Fragrance allergens / Annex III	<ul style="list-style-type: none"> • Renamed chapter b) to "Fragrance allergens". • Updated the regulatory status of certain substances. • Included new fragrance allergens; previously 26, now 83. • Included a column in the annex with the labelling terms for fragrance allergens.
III.2. Nitrosamines and nitrosating agents / Annex IV	<ul style="list-style-type: none"> • Added prohibited nitrites.
III.3. Phthalates / Annex V	<ul style="list-style-type: none"> • Added prohibited phthalates. • Added prohibition of all phthalic acid esters in certain US states.
III.4. Metals, metalloids and non-metals / Annex VI / Annex VI bis	<ul style="list-style-type: none"> • Added Platinum. • Added salts and compounds of certain elements and updated the regulatory status of some existing ones.
III.5. Glycol-ethers / Annex VII	<ul style="list-style-type: none"> • Updated the regulatory status of certain substances. • Added trace limit for DEG.
III.6. Residual products from surfactants	<ul style="list-style-type: none"> • Added non-detection limit for 1,4-dioxane and modified the quantification limit. • Modified the quantification limit for formaldehyde.
III.7. Volatile organic compounds / Annex VIII / Annex VIII bis	<ul style="list-style-type: none"> • New chapter. • New annex (Annex VIII) including limits by product type. • New annex (Annex VIII bis) including substances excluded from VOC calculation.
III.8. Perfluoroalkyl and polyfluoroalkyl substances (PFAS) / Annex IX	<ul style="list-style-type: none"> • New chapter. • New annex (Annex IX) listing, non-exhaustively, certain PFAS.
III.9. Colorants / Annex X / Annex X bis	<ul style="list-style-type: none"> • Updated the regulatory status of certain colorants. • Included reference to salts and lakes used in the USA and Japan. • Annex X bis: format change.
III.10. Preservatives / Annex XI	<ul style="list-style-type: none"> • Updated the regulatory status of certain preservatives.
III.11. UV Filters and sun protection / Annex XII	<ul style="list-style-type: none"> • Renamed chapter to "UV Filters and sun protection". • Updated the regulatory status of certain UV filters. • Included mention of sun protection and UV absorbers.
III.13. Microbiological control / Annex XIV	<ul style="list-style-type: none"> • Updated the dates of applicable ISO standards. • Added requirement for the absence of <i>Clostridium spp</i> in certain products. • Included mention of ISO 21322 standard for wipes and masks analysis. • Changed the format of the decision tree.
IV. Legal Documentation Requirements (PIF)	<ul style="list-style-type: none"> • Updated the legislative reference regarding misleading product appearance.
V. Other Mandatory Legislations	<ul style="list-style-type: none"> • Included reference to compliance with the French decree on endocrine disruptors and the Australian Poisons Standard.
Annex I. List of the Documents Consulted to Prepare the Global Strategy for Comparing Legislations	<ul style="list-style-type: none"> • Updated with the latest version of legislation and added new applicable legislation. • Included legislation for the following new markets: Australia, Andean Community, Egypt, Hong Kong, India, Israel and the United Kingdom.

³³⁸ The most significant changes are included.

CHAPTER	MODIFICATION
Annex XIII. Summary Chart of Instrumental Techniques Proposed for Analysing the Substances Selected in this Standard	• Added analytical techniques for PFAS.
Annex XVII. Change log for i+Cosmetics version 2025	• New annex including the most relevant changes of i+Cosmetics 2025.

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