



# **i+COSMETICS**

Inditex Precautions and Limits for Users Safety  
for Cosmetics





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# INDEX



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# I. DEFINITION OF i+Cosmetics



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## I. DEFINITION OF *i+*Cosmetics

Inditex **P**recautions and **L**imits for **U**sers **S**afety for **C**osmetics (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.
- Regulates “Substances of Legally Limited Use” and that, if such substances are in the product above certain levels, this could affect human health.
- Also includes a section on the restrictions imposed on pH in cosmetic products and the respective labelling requirements associated with health and safety of products when they are in force; 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 products for consumption.
- 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.
- 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 those who are suppliers to Inditex.

*i+*Cosmetics is a general application standard that is mandatory for all cosmetic products<sup>1</sup> that are supplied to Inditex. This standard prioritized the control of 9 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 9 families of chemical substances 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 furnished 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 provided 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](http://www.inditex.com) or Inditex supplier Extranet.

The responsibility of the manufacturers and/or suppliers for guaranteeing compliance with the products supplied to Inditex with *i+*Cosmetics 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 XIV.

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.

<sup>1</sup> “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.



## I. DEFINITION OF i+Cosmetics

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 at Inditex to obtain further information on how to achieve conformity of your products with Inditex's requirements for cosmetics ([i+cosmetics@inditex.com](mailto:i+cosmetics@inditex.com)).

**Annex I** details all information concerning the legislation consulted.

# II. LEGAL REQUIREMENTS OF PRODUCTION (GMP)



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### II. LEGAL REQUIREMENTS OF PRODUCTION (GMP)

The manufacturing of cosmetic products takes place in compliance with good manufacturing practice (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 is a set of guidelines aimed at providing a guide of the Good Manufacturing Practice (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 removal, 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 GMPs is mandatory; Inditex reserves the right to conduct audits to check compliance with the GMPs.





# III. LEGAL REQUIREMENTS OF PRODUCT



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### III. LEGAL REQUIREMENTS OF PRODUCT

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

- A. COSMETIC PRODUCTS FOR BABIES-CHILDREN: shampoos, conditioners, lotions, oils, creams, talcs, other products for babies-children.
- B. COSMETIC PRODUCTS FOR THE AREA AROUND THE EYES: eye pencils, eyebrow pencils, eyeliner, eye shadows, eye make-up remover, mascaras, other products for the area around the eyes.
- C. COSMETIC PRODUCTS FOR THE LIPS: lipsticks, lip-gloss, lip protectors, lip liners, other products for the lips.
- D. COSMETIC PRODUCTS FOR THE FACE: make-up base (liquid, cream), blushes, face powders, face creams, face lotions, face masks, facial correctors, make-up remover, facial cleansing products, other products for the face.
- E. COSMETIC PRODUCTS FOR THE SKIN: body make-up base, body creams, hands creams, body lotions, body oils, body powders, other products for the skin.
- F. COSMETIC PRODUCTS FOR WASHING AND BODY HYGIENE: soaps, bath gels, bath foams, bath powders, bath oils, bath lotions, bath salts, bath shampoos, aromatic bath tablets, talcs, moisturizing towels and cloths, other products for washing and body hygiene.
- G. DEODORANT AND ANTI-PERSPIRANT PRODUCTS: deodorants, anti-perspirants, deodorants and anti-perspirants for intime hygiene, other deodorant and anti-perspirant products.
- H. COSMETIC PRODUCTS FOR THE NAILS: nail polish base, cuticle softener, nail cream, nail polish, nail polish remover, nails oil, nails gloss, other products for the nails.
- I. COSMETIC PERFUMERY PRODUCTS: eau de toilette, eau de cologne, eau de tender, eau de parfum, body mists, other perfumery products.
- J. SHAVE AND AFTER-SHAVE PRODUCTS: shave cream, shave lotion, shave foam, after-shave lotion, after-shave balsam, other shave and after-shave products.

In case of manufacturing cosmetic products not included in this list, please contact the Sustainability Department at 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 color code has been established on the basis of the degree or type of regulation covering the chemical substances considered. This color 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 summarizing 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 essences.

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

- i. **Nitromusks**, 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 six nitromusks that cannot form part of the composition of cosmetic products: **musk ambrette**, **musk moskene**, **musk tibetene**, **musk xylene**<sup>2</sup>, **musk alpha**<sup>3</sup> and **musk KS**<sup>3</sup>.

There is one nitromusk that can form part of the composition of cosmetic products subject to the restrictions that are listed below; the MACs<sup>4</sup> of this nitromusk in the finished cosmetic product are:

##### **musk ketone**<sup>5,6</sup>

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

2 According to the legislation of Gulf Cooperation Council (GCC) (see Annex I).

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

4 MAC = Maximum Authorized Concentration in the ready for use preparation.

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

6 Not to be used in oral products.



### III. LEGAL REQUIREMENTS OF PRODUCT

#### 2. Polycyclic musks

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

##### **tonalide**<sup>6</sup>

- 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. Macrocylic musks

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

#### **4. How are they analysed?<sup>7</sup>**

All the musks<sup>8</sup> 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 they supply do not contain the prohibited nitromusks or the polycyclic musk versalide, which is also prohibited; and that the nitromusk ketone and the polycyclic musks tonalide and phantolide comply with the limits established in Section 3 above. The musk ketone permitted but subject to restrictions must be gradually replaced by polycyclic musks that are permitted and/or by macrocylic musks.

**Annex II** details and extends all information concerning musks.

<sup>7</sup> See Annex XI to find out what the acronyms stand for each one of the analytical techniques.

<sup>8</sup> The quantification limit for the selected method will be less than or equivalent to 0.0001 % (1 ppm) for all musks considered.



#### b. ALLERGENIC FRAGRANCES

##### 1. What are they?

There are **26 substances associated with fragrances**, classified as potential causes of allergic reactions and known as **FAs** (Fragrance Allergens). Of the 26 chemical substances, 24 are volatile compounds and the other 2 are natural extracts from lichens that are not consistent with any defined chemical substance (*Evernia prunastri*, oakmoss and *Evernia furfuracea*, treemoss).

##### 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 essential oils and natural extracts. However, they can also appear as impurities of other synthetic ingredients.

##### 3. What are their acceptable limits?

Of the **26 allergenic fragrances**, only one cannot be part of the composition of cosmetic products because it is prohibited: **Lyral (Hydroxyisohexyl 3-cyclohexene carboxaldehyde)**.

The presence of any of the others **25 FAs** 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 cosmetics.

Of the **26 allergenic fragrances**, only three have maximum authorised concentration limits: **hydroxycitronellal** (1 %)<sup>9</sup>, **isoeugenol** (0.02 %)<sup>9</sup> and **methyl 2-octinoate** (0.01 %)<sup>9,10</sup>.

##### 4. How are they analysed?<sup>11</sup>

Potentially allergenic volatile substances<sup>12</sup> can be analysed by GC-MS or GC-MS-MS. As an alternative, there are analytical methods for allergenic fragrances 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 allergenic substances 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 allergenic fragrances with maximum authorized concentration limits, these comply with the restrictions described in Section 3.

Annex III details and extends all information concerning allergenic fragrances.

<sup>9</sup> These limits apply to all the products, with the exception of oral products.

<sup>10</sup> 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 %).

<sup>11</sup> See Annex XI to find out what the acronyms stand for each one of the analytical techniques.

<sup>12</sup> The quantification limit for the selected method shall be lower than or equivalent to 0.0005 % (5 ppm) for all the FAs 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 act as a nitrosating agent, generally under acidic conditions. Amines and their derivatives are mainly present 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 brackets:

**Dialkylamides** and **dialkanolamides of fatty acids**<sup>13</sup> (0.5 % as secondary amine).

**Monoalkylamines, monoalkanolamines and their salts**<sup>14</sup> (0.5 % as secondary amine).

**Trialkylamines, trialkanolamines and their salts**<sup>14</sup> (2.5 % in leave-on products and without limits in rinse-off products; 0.5 % as secondary amine).

13 1. Not to be used with nitrosant systems.  
2. Maximum content of secondary amine: 5.0 % (applied to raw materials).  
3. Maximum nitrosamine content: 50 µg/kg.  
4. Keep in nitrite-free containers.

14 1. Not to be used with nitrosant systems.  
2. Minimum purity 99 %.  
3. Maximum content of secondary amine: 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**<sup>15</sup>; **Amyl nitrite** and **isobutyl nitrite**.

**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 substances<sup>16</sup>, which have to be excluded 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 <sup>17</sup>	Amines and amino-derivatives	Nitrosating agents	Combinations
3-(N-Nitrosomethylamino)propionitrile	<b>Secondary alkyl- and alkanolamines and their salts</b> <sup>17</sup> ;	Inorganic nitrites	<b>To prevent the formation of nitrosamines in the final cosmetic product, any combination of any of the substances contained in this chart is prohibited</b> <sup>19</sup>
4-Nitrosodiphenylamine		Sodium nitrite	
4-(N-Nitrosomethylamino)-1-(3-pyridyl)-1-butanone Nitrosamide	Diethanolamine	Amyl nitrite <sup>18</sup>	
N-Nitrosodibutylamine	Diisopropanolamine	Isobutyl nitrite <sup>18</sup>	
N-Nitrosodiethanolamine	Dimethylamine		
N-Nitrosodiethylamine			
N-Nitrosodiisopropanolamine			
N-Nitrosodimethylamine	<b>Monoalkylamines, monoalkanolamines and their salts</b> <sup>20</sup> ;	Bronidox	
N-Nitrosodiphenylamine		Bronopol	
N-Nitrosodipropylamine			
N-Nitrosohexamethyleneimine	Ethanolamine		
N-Nitrosomethyl-N-butylamine			
N-Nitrosomethyl-N-decylamine			
N-Nitrosomethyl-N-dodecylamine			
N-Nitrosomethyl-N-heptylamine	<b>Trialkylamines, trialkanolamines and their salts</b> <sup>20</sup> ;		
N-Nitrosomethyl-N-hexylamine			
N-Nitrosomethyl-N-nonylamine			
N-Nitrosomethyl-N-octylamine			
N-Nitrosomethyl-N-pentylamine	Triethanolamine		
N-Nitrosomethyl-N-propylamine			
N-Nitrosomethyl-N-tetradecylamine	<b>Fatty acid dialkylamides and dialkanolamides</b> <sup>20</sup> ;		
N-Nitrosomethyl-N-undecylamine			
N-Nitroso-N-methylurea			
N-Nitroso-N-methylurethane			
N-Nitroso-N-methylvinylamine	DEA-Cocamide		
N-Nitrosomorpholine	DEA-Lauramide		
N-Nitrosornicotine	DEA-Oleamide		
N-Nitrosopiperidine			
N-Nitrosopyrrolidine			
N-Nitroso-para-amino benzoic acid esters			
N-Methyl-N-nitroso-ethanamine (etc.)			

15 Only allowed as corrosion 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.

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

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

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

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

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



### III. LEGAL REQUIREMENTS OF PRODUCT

#### 4. How are they analysed?<sup>21</sup>

The non-volatile NNAs<sup>22</sup> 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 prevented?

By obtaining from our suppliers the undertaking and the guarantee that the cosmetic products they supply 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.

21 See Annex XI to find out what the acronyms stand for each of the analytical techniques.

22 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 plasticizers (they make plastics like PVC - polyvinyl chloride- softer and more flexible); industrial solvents; additives in the textile industry and in pesticide formulations; as well as preservatives, and as alcohol denaturants (ethanol).

#### 2. Where can they be found?

In cosmetics, phthalates are used basically as plasticizers 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 essences in many other cosmetic products.

Where cosmetics are concerned, phthalates may be present in containers, lids/tops, and in the parts for sealing 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 into 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 products: **dimethyl phthalate (DMP)<sup>23</sup>, dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), dipentyl phthalate (DPP), diisopentyl phthalate (DIPP), pentyl-isopentyl phthalate (PIPP), dihexyl phthalate (DnHP), diisohexyl phthalate (DIHP), dicyclohexyl phthalate (DCHP), diethylhexyl phthalate (DEHP), dioctyl phthalate (DOP)<sup>24</sup>, diisodecyl phthalate (DIDP)<sup>25</sup>, diisononyl phthalate (DINP)<sup>25</sup>, benzyl butyl phthalate (BBP) and dimethoxyethyl 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?<sup>26</sup>

The analysis of phthalates<sup>27</sup> 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.

#### 5. How can they be prevented?

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.

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

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

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

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

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



## III. 4. METALS, METALLOIDS AND NON-METALS

### 1. What are they?

Metals, metalloids and non-metals are chemical elements whose use in cosmetics is regulated. This section also summarises the most important 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 appear as traces in cosmetic products due to the persistent nature of these substances and the fact that they occur naturally in the environment: in rock, soil and water. As a result, they could appear 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 generally, the deliberate use of heavy metals in cosmetics is now prohibited. Therefore, care and control are now concerned with the presence of these substances as traces.

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

Some cosmetics contain metal and non-metal additives, used, for example, in sunscreens, in the color of make-up, in nail varnish inks and lipsticks and lip gloss.

### 3. What are their acceptable limits?

Chemical elements (metals, metalloids and non-metals) and the substances of which they form part have widely differing regulation levels. For practical reference, this section provides a summary of the most relevant information affecting them.

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

ELEMENT	Color	SALTS AND/OR COMPOUNDS	Underlining	Example
Prohibited	red	all prohibited	without underlining	<b>element</b>
		some prohibited	<u>red underlining</u>	<b>element</b>
		some restricted	<u>orange underlining</u>	<b>element</b>
Restricted	orange	some prohibited	<u>red underlining</u>	<b>element</b>
		some restricted	<u>orange underlining</u>	<b>element</b>
		Not restrictions	some prohibited	<u>red underlining</u>
	black	some restricted	<u>orange underlining</u>	<b>element</b>

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 detection<sup>28</sup>.

28 The value of nd ≈ < 0.0001 % ≈ < 1 ppm for all the elements considered, with the exceptions of Antimony and Lead (nd ≈ < 0.0005 % ≈ < 5 ppm) and Nickel (nd ≈ < 0.001 % ≈ < 10 ppm).



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 conditions<sup>29</sup>:

- 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 aluminium 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**<sup>30</sup> are prohibited as such, but **Zirconium** is prohibited.
- 2.4. The elements **Sulphur**<sup>31</sup>, **Bismuth**, **Tin**, **Iron**, **Manganese**, **Molybdenum**, **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 metal colorants: **Aluminium**, **Copper**, **Gold**<sup>32</sup>, **Silver** and **Titanium**<sup>33</sup>; 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-metal component of the salt”)<sup>34</sup>.

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 VIII *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?<sup>35</sup>

Metals<sup>36</sup> 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 substances indicated in Section 3 above; or, that the salts and compounds of the different elements contained 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 VIII bis (Global List of Metal Impurities and Regionalised List of Metal Impurities)** details and extends the metal limits as impurities in colorants.

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

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

31 MAC = 2 %; use only permitted in antidandruff and antiacne products (soaps, lotions, creams, gels and shampoos (see legislation of Taiwan, MERCOSUR and the United Mexican States, Annex I).

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

33 TiO<sub>2</sub> (CI 77891) is a compound that is allowed as a colorant (see Annex VIII of colorants).

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

35 See Annex XI 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 the limits proposed in this section and in Annexes VIII and VIII *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 characterized by their miscibility with water and with many other organic solvents. They have many industrial applications including use as solvents for varnishes, inks, dyes and as surfactants.

### 2. Where can they be found?

In cosmetics, they are basically found as solvents and agents to reduce the viscosity of products for the nails, face 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)**<sup>37</sup>, **tert-butoxy-2-propanol (PGBE)**<sup>38</sup>, **methyl and dimethyl ethers of diethylene glycol (DEGME, DEGDME)**, **dimethyl and diethyl ethers of ethylene glycol (EGDME, EGDEE)** and **dimethyl ethers of triethylene glycol (TEGDME)**. In addition, **diethylene glycol (DEG)** has been included in this section.

The glycol-ethers with restrictions are as follows: **monoethyl ether of diethylene glycol (DEGEE)**<sup>39</sup>, **monobutyl ether of diethylene glycol (DEGBE)**<sup>40</sup>, **1-methoxy-2-propanol (PGME)**<sup>41</sup> and its acetate **(PGMEA)**<sup>42</sup> and **polidocanol**<sup>43</sup>.

### 4. How are they analysed?<sup>44</sup>

These glycol-ethers<sup>45</sup> are analysed by HPLC-UV with prior derivatization or by GC-FID or GC-MS.

### 5. How can they be prevented?

By obtaining from our suppliers the undertaking and the guarantee that they are not used as solvents in their products. If it is necessary to use one of the restricted but not prohibited glycol-ethers, 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.

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

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

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

40 Use only as solvent of hair dyes (non aerosol dispensers) with MAC = 9 %.

41 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).

42 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).

43 MAC = 2 %.

44 See Annex XI 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 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 oxide. 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 contain them.

### 3. What are their acceptable limits?

The following substances cannot form part of the composition of cosmetic products: **1,4-dioxane** (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**<sup>46</sup>, **alkylphenol ethoxylates**<sup>47</sup>, **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?<sup>48</sup>

1,4-Dioxane, ethylene oxide and propylene oxide<sup>49</sup> can be analysed by GC-MS or GC-FID.

Formaldehyde<sup>50</sup> can be analysed by HPLC-DAD with post-column derivatization.

The alkylphenols and alkylphenol ethoxylates<sup>51</sup> can be analysed by liquid chromatography, not only coupled to conventional detectors (HPLC-DAD or HPLC-FLD) but also using mass spectrometry (LC-MS or LC-MS/MS); as an alternative, the GC-MS technique can be used.

### 5. How can they be prevented?

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.

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

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

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

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

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

51 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. COLORANTS

#### 1. What are they?

They are substances whose only or main purpose is to color the cosmetic product, or the whole body or parts thereof (skin, lips, eyes, etc.) by absorbing or reflecting visible light. Dyeing agents used for colouring hair are considered to be ingredients of different cosmetics and are known as “hair dyes”; they are not considered in this standard.

Colouring agents are classified into two major groups: colorants, 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 also be of natural origin (mineral, botanical or animal) or synthetic origin.

#### 2. Where can they be found?

Hydrosoluble colorants are used in lotions, perfums, 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.

In solid products such as make-up powders, eye pencils and shadows, lips and nails cosmetics and soaps and mascaras, inorganic pigments or insoluble organic pigments (lakes) are normally used. 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 color the product.

#### 3. What are their acceptable limits?

Use of Colorants: only the colorants specified in the Global List of Colorants<sup>52</sup> (Annex VIII) can be used, with the limits and restrictions mentioned in each case. There is also a Regionalised List of Colorants<sup>52</sup> (with their respective limits and restrictions) that can only be used in exceptional circumstances and with prior approval of Inditex.

Impurities: impurities associated with colorants can be found in Annex VIII *bis* (Global List of Metal Impurities and Regionalised List of Metal Impurities), which contains the maximum limits of metals and other elements that are allowed, for each one of the colorants included in the respective Global and Regionalised List of Colorants mentioned in the previous paragraph.

#### 4. How are they analysed?<sup>53</sup>

Organic colorants<sup>54</sup> 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 XRF or AAS.

52 In general terms, and for the purpose of the information contained in the lists of colorants, a colorant must include its salts and lakes, and, when it is expressed as a specific salt, its other salts and lakes must also be included.

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

54 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 42520 (0.0005 %), CI 75810 (0.1 %) 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 products supplied and used in the manufacture of articles sent to Inditex do not contain colorants or pigments that are not included in the Global List of Colorants (Annex VIII) referred to above.

Establishing a control system for raw materials and finished products that makes it possible to establish compliance with the aforementioned provision.

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

**Annex VIII bis (Global List of Metal Impurities and Regionalised List of Metal Impurities)** contains the maximum limits for impurities that are permitted, for each one of the colorants mentioned in the List concerned in **Annex VIII**.



## III. 8. 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 for the time it takes the consumer to finish it. However, the use of preservatives can also cause adverse 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 risk the stability of the preserving process of a cosmetic. That is why 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. In the final products, those with an aqueous base stand out, because those are where microbial growth is most likely, whereas 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 Preservatives<sup>55</sup> (Annex IX), can be used, with the limits and restrictions mentioned in each case. There is also a Regionalised List of Preservatives<sup>55</sup> (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 article, where 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?<sup>56</sup>

In general, preservatives<sup>57</sup> can be determined by GC or HPLC either coupled to conventional detector 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 products supplied and used in the manufacture of articles to be sent to Inditex do not contain preservatives that are not included in the Global List of Preservatives (Annex IX) referred to above.

Establishing a control system for raw materials and finished products that makes it possible to establish compliance with the aforementioned provision.

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

55 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.

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

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



## III. 9. UV FILTERS

### 1. What are they?

They are substances that have a high capacity to absorb UV radiation and are therefore generally used in sunscreen 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.

UV filters can be added to other cosmetic products, within the limits and conditions set in different legislations. They may be hydrosoluble or liposoluble, the most suitable one being used for each specific formulation; or, mixtures of both types.

### 2. Where can they be found?

In cosmetics, apart from in specific sun protection products, they are often used in lipsticks, in make-up products, moisturizing 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 X) can be used, with the limits and restrictions mentioned in each case. There is also a Regionalised List of UV Filters (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 article, where 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?<sup>58</sup>

In general, UV filters<sup>59</sup> to be controlled can be determined by HPLC-UV/VIS or LC-MS-MS.

### 5. How can they be controlled?

By obtaining from the suppliers of chemical substances the undertaking and the guarantee that the products supplied and used in the manufacture of articles to be sent to Inditex do not contain UV filters that are not included in the Global List of UV Filters (Annex X) referred to above.

Establishing a control system for raw materials and finished products that makes it possible to establish compliance with the aforementioned provision.

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

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

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



### III. 10. 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) and 14 (more alkaline).

It is controlled through the use of pH regulators, which are chemical substances considered to be essential to conserve 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, as long as this value is essential to enable the cosmetic product to suitably comply with its function (e.g.: soaps with a pH > 9 or exfoliant products whose effectiveness start showing at more acid pH). In these cases, please contact with the Sustainability Department at Inditex beforehand.

The pH values not only for the raw materials used in a specific formulation but also in the finished cosmetic product are requirements that have to be included 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  $\pm 0.1$  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 pH regulators 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. 11. MICROBIOLOGICAL CONTROL

### 1. Microbial contamination. What is it?

Cosmetic products must be properly conserved to prevent microbial contamination and spoilage, so a suitable preservative system must be used when formulating the product (see Section III.8 of preservatives). The different stages in the assessment of the design, manufacture, packaging and expected use of the cosmetic must take into account the potential sources of microbial contamination that could affect the end product, even after its commercialisation.

### 2. Microorganisms. Where can they be found?

All cosmetic products are exposed to microbiological contamination, but the degree of risk<sup>60</sup> depends on the ability of the product to sustain the growth of microorganisms and the likelihood that said microorganisms may cause harm to the user. Its source could come either from the cosmetic manufacturing process or its 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 summarized in the following table<sup>61</sup>:

	Limits in cosmetic products
Total n° of Aerobic Mesophilic Microorganisms <sup>62</sup> (Bacteria, yeast and moulds)	< 100 CFU en 1 g (ml) <sup>63</sup>
<b>Bacteria</b>	
<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> <sup>64</sup>	Absence in 25 g or 25 ml
<b>Yeast</b>	
<i>Candida albicans</i>	Absence in 1 g or 1 ml

60 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.

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

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

63 CFU: Colony Forming Unit.

64 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), whose following is required in this standard. For the correct microbiological risk assessment and microbiological control, please refer to Annex XII<sup>65</sup>.

Microbiological tests of cosmetic products also involve, as can be seen in the decision tree (Annex XII), the detection (presence/absence) and enumeration of microorganisms as well as the identification of specific and non-specific microorganisms<sup>66</sup>. 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 XII also contain a diagram that summarise how to apply the ISO norms of microbiology and the conclusions that can be drawn from them.

#### 5. How can they be prevented?

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.

Likewise, 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 XII (Microbiological Control)** contains the information concerning the standard test procedures for controlling microorganisms in cosmetic products.

65 The standards indicated below are essential for the application of all the standards explicitly mentioned in the text and/or the decision tree (Annex XII).  
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 12353:2013 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 29621:2017 Cosmetics. Microbiology. Guidelines for the risk assessment and identification of microbiologically low risk products.  
ISO 18415:2017 Cosmetics. Microbiology. Detection of specified and non-specified microorganisms.  
ISO 21149:2017 Cosmetics. Microbiology. Enumeration and detection of aerobic mesophilic bacteria.  
ISO 16212:2017 Cosmetics. Microbiology. Enumeration of yeast and moulds.

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

# **IV. LEGAL DOCUMENTATION REQUIREMENTS (PIF)**



**i+COSMETICS**

Inditex Precautions and Limits for Users Safety  
for Cosmetics







### IV. DOCUMENTAL REQUIREMENTS (PIF)

This section specifies the documentation that has to be enclosed with every cosmetic product (hereinafter, CP) in the commercialisation process. In the context of the European Union, the Regulation make it mandatory to prepare a Product Information File (*PIF*), the structure and content of which are explained in detail 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

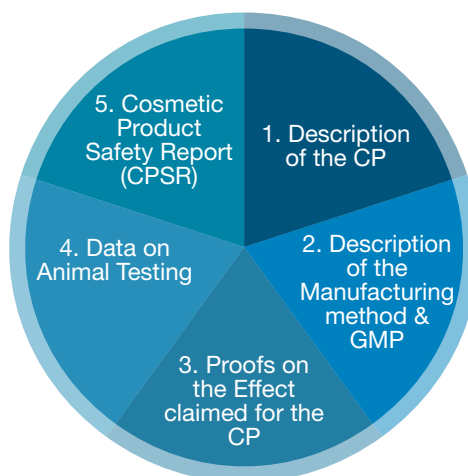
Cosmetic products made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use.

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 report<sup>67</sup> 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 2013<sup>68</sup>.

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 Practice (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



67 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.

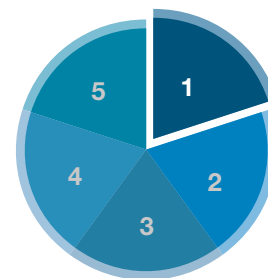
68 The Commission, in close cooperation with all the interested parties, will adopt a series of suitable guidelines that will enable the companies, especially the small and medium-sized ones, to comply with the requirements established in Annex I. Commission Implementing Decision dated 25th November 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)

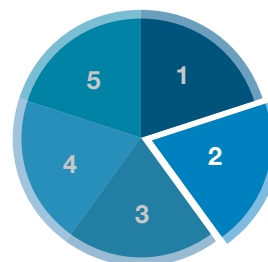
#### 1. Description of the Cosmetic Product

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 Directive 87/357/EEC<sup>69</sup> 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 might be enclosed in the PIF to show the presentation of the product and its intended use.



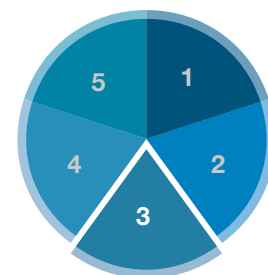
#### 2. Description of the Manufacturing Method and Good Manufacturing Practice (GMP)

To ensure their safety, cosmetic products placed on the market should be produced according to Good Manufacturing Practice (GMP) (Regulation (EC) N° 1223/2009 [See Section II. Legal Requirements of Production]). A description of the manufacturing method and the coding and lotification 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.

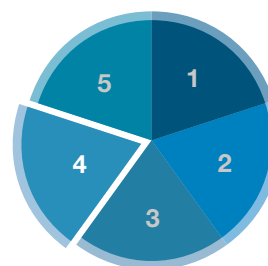


#### 4. Data on Animal Testing

Animal testing for the finished cosmetic products and for the cosmetic ingredients is prohibited<sup>70</sup>.

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.



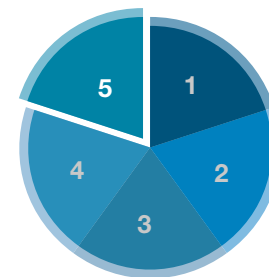
69 The products to which this Directive refers are those that, without being food products have a shape, and odour, a color, an appearance, a presentation, a labelling, a volumen or a size that are such that it is likely that the consumers, especially children, could mistake them for food products and put them in their mouths, lick them or swallow them, leading to a risk of asphyxia, intoxication, puncturing of or obstruction in the digestive tract. Their commercialisation, manufacture, import and export are prohibited.

70 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 include<sup>68</sup>:



### 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 flavor) compounds, their identifications are to include: the name, their code number, the identity of the supplier, the safety assessment, the IFRA certificate and the declaration of 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 justified<sup>71</sup>.
- 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

<sup>71</sup> Guidelines for the risk assessment and identification of microbiologically low risk products *ISO 29621:2017*.



## IV. LEGAL DOCUMENTATION REQUIREMENTS (PIF)

explanation must be given as to why it is not necessary to conduct this test. However, microbiological quality tests will be required<sup>72</sup>.

- 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 followed<sup>73</sup>.

### 4. Impurities, traces, 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 physico-chemical 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 product<sup>74</sup>, 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)<sup>75</sup>.
- 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

Quantify 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. 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.

### 7. Exposure to the substances

Determine 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. 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.

<sup>72</sup> Evaluation of the antimicrobial protection of a cosmetic product *ISO 11930:2019*.

<sup>73</sup> Detection of specified and non-specified microorganisms *ISO 18415:2017*.

<sup>74</sup> 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.

<sup>75</sup> ALARA: *As low as reasonably achievable*.



### 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 including the routes of exposure, the conditions of use of the product, the physico/chemical characteristics and the possible absorption of the substances.
- Ensure that the experimental data complies with the requirements concerning prohibition of animal testing<sup>76</sup>.
- Endpoints that may be relevant for the toxicological profile for each substance are the following<sup>77</sup>: 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; toxicokinetics; 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, where 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 information<sup>78</sup>, that is considered relevant in order to carry out the safety assessment of the product.

## PART B: COSMETIC PRODUCT SAFETY ASSESSMENT

Part B of the cosmetic product safety report consist of:

1. The **assessment conclusion**: 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. It should be explicitly mentioned the Regulation (EC) N° 1223/2009.
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**: clear and accurate explanation about how the safety assessor reaches his or her conclusions

<sup>76</sup> 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.

<sup>77</sup> For the required studied parameters, the most relevant concentrations or the No Observed Adverse Effect Level (NOAEL) must be identified, as well as the Lowest Observed Adverse Effect Levels (LOAEL) for using them in the process of risk characterisation. 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.

<sup>78</sup> Information not covered under the other headings of part A of Annex I of Regulation (EC) N° 1223/2009.



## IV. LEGAL DOCUMENTATION REQUIREMENTS (PIF)

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**: list the name and address for the safety assessor and to be dated and signed. The result of the safety assessment is to be signed stating the date of preparation.

**Annex XIII** contains “*checklists*” to facilitate the verification of the documentary content required in the PIF.

# V. OTHER MANDATORY LEGISLATIONS



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Inditex Precautions and Limits for Users Safety  
for Cosmetics







## V. OTHER MANDATORY LEGISLATIONS

### REACH

#### 1. What is it?

REACH is a European Union regulation 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 manufacture 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”<sup>79</sup> 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 Product Healthcare Team of Inditex.

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

### CLP

#### 1. What is it?

CLP is a European Union regulation concerning Classification, Labeling and Packaging of substances and mixtures (Regulation (EC) N° 1282/2008 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 SCCS<sup>80</sup> 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.

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.

<sup>79</sup> 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>).

<sup>80</sup> Scientific Committee on Consumer Safety (SCCS).



# VI. ANNEXES



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for Cosmetics





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

Markets	Legislation
<b>European Union</b>	1907/2006/EC 1272/2008/EC 1223/2009/EC 231/2012/EU and its amendments, adjustments and corrigendums
<b>Argentina</b>	Disposición 5930/1999 Disposición 5572/2005 Disposición 6544/2012 Disposición 7529/2013 Disposiciones 11276/2016 and 13832/2016 Disposición 249/2017 Disposición 7078/2019 and its amendments, adjustments and corrigendums
<b>Association of Southeast Asian Nations (ASEAN)</b> (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam)	ASEAN Cosmetic Directive ASEAN Guidelines on Limits of Contaminants for Cosmetics
<b>Brazil</b>	RDC Nº 15 (26-3-2013)
<b>Canada</b>	Cosmetic Ingredient Hotlist Guidance on Heavy Metal Impurities in Cosmetics
<b>China</b>	Technical Safety Standard for Cosmetics, 2015 Inventory of Existing Cosmetic Ingredients in China - IECIC
<b>Gulf Cooperation Council (GCC)</b> (United Arab Emirates, Bahrain, Saudi Arabia, Oman, Qatar, Kuwait and Yemen)	Cosmetic Products – Safety Requirements of Cosmetics and Personal Care Products GSO 1943/2018
<b>South Korea</b>	Cosmetic Act; Cosmetic Act Decree; Cosmetic Act Enforcement Rules; Regulations on safety standards for cosmetics Pigment type and specifications and test methods of cosmetic products
<b>Denmark</b>	Statutory Order No. 1217 of 11 October 2013
<b>Spain</b>	Real Decreto 85/2018
<b>United States of America</b>	<i>FEDERAL LAWS</i> 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 352 (Sunscreen Drug Products for Over-The-Counter Human Use) <i>STATE LAWS</i> California: Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)
<b>United Mexican States</b>	Reglamento de Control Sanitario de Productos y Servicios, DOF 12-2-2016 Secretaría de Salud, DOF 21-05-2010 Secretaría de Salud, DOF 11-03-2014 and its amendments NOM-141-SSA1/SCFI-2012 and its amendments

Continued on next page



Markets	Legislation
<b>Japan</b>	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
<b>Southern Common Market (MERCOSUR)</b> (Argentina, Brazil, Paraguay, Uruguay and Venezuela)	MERCOSUR/GMC/RES N° 51/98 MERCOSUR/GMC/RES N° 07/11 MERCOSUR/GMC/RES N° 24/11 MERCOSUR/GMC/RES N° 16/12 MERCOSUR/GMC/RES N° 62/14 MERCOSUR/GMC/RES N° 44/15
<b>Taiwan</b>	Cosmetic Hygiene and Safety Act
<b>Thailand</b>	Cosmetic Act B.E 2558
<b>Turkey</b>	Regulation on Cosmetics N° 25823 and its amendments
<b>Eurasian Customs Union</b> (Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia)	On Safety of Perfumes and Cosmetics, TP TC 009/2011 and its amendments



## ANNEX II. Summary Chart of Musk

Name of Common Ingredients Glossary	Chemical Name	CAS Number	EC Number	Limits <sup>81</sup>
<b>NITROMUSKS</b>				
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 xylene <sup>82</sup>	5- <i>tert</i> -Butyl-2,4,6-trinitro-m-xylene	81-15-2	201-329-4	nd
Musk alpha <sup>83</sup>	1,3-dibromo-4-methoxy-2-methyl-5-nitrobenzene	61827-59-6		nd
Musk KS <sup>83</sup>	1,3-dibromo-2-methoxy-4-methyl-5-nitrobenzene	62265-99-0	263-479-7	nd
Musk ketone <sup>84,85</sup>	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
<b>POLYCYCLIC MUSKS</b>				
Versalide	3'-Ethyl-5',6',7',8'-tetrahydro-5',5',8',8'-tetramethyl-2'-acetonephthone or 7-acetyl-6-ethyl-1,1,4,4-tetramethyl-1,2,3,4-tetrahydronaphthalen (AETT)	88-29-9	201-817-7	nd
Tonalide <sup>85</sup> ; 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	<b>leave-on products:</b> 0.1 % except:  hydroalcoholic products: 1.0 %  fine fragrance: 2.5 % fragrance cream: 0.5 %  <b>rinse-off products:</b> 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

81 nd ≈ < 0.0001 % ≈ < 1 ppm.

82 According to the legislation of Gulf Cooperation Council (GCC) (see Annex I)

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

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

85 Not to be used in oral products.

ANNEX III. Summary Chart of Allergenic Fragrances<sup>86</sup>

Name of Common Ingredients Glossary	Chemical Name	CAS Number	EC Number
alpha-Isomethyl ionone	3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1yl)-3-buten-2-one	127-51-5	204-846-3
Amyl cinnamal	2-Benzylideneheptanal	122-40-7	204-541-5
Amylcinnamyl alcohol	2-Pentyl-3-phenylprop-2-en-1-ol	101-85-9	202-982-8
Anise alcohol	4-Methoxybenzyl alcohol	105-13-5	203-273-6
Benzyl alcohol <sup>87</sup>	Benzyl alcohol	100-51-6	202-859-9
Benzyl benzoate	Benzyl benzoate	120-51-4	204-402-9
Benzyl cinnamate	2-Propenoic acid, 3-phenyl-, phenylmethyl ester	103-41-3	203-109-3
Benzyl salicylate	Benzyl salicylate	118-58-1	204-262-9
Butylphenyl methylpropional / Lilial <sup>88</sup>	2-(4-tert-Butylbenzyl)propionaldehyde; BMHCA	80-54-6	201-289-8
Cinnamal	2-Propenal, 3-phenyl-; Cinnamaldehyde	104-55-2	203-213-9
Cinnamyl alcohol	Cinnamyl alcohol	104-54-1	203-212-3
Citral	3,7-Dimethyl-2,6-octadienal	5392-40-5	226-394-6
Citronellol	(±)-3,7-Dimethyloct-6-en-1-ol	106-22-9 / 26489-01-0	203-375-0 / 247-737-6
Coumarin	2H-1-Benzopyran-2-one	91-64-5	202-086-7
Eugenol	Phenol, 2-methoxy-4-(2-propenyl)	97-53-0	202-589-1
Evernia furfuracea extract	Treemoss extract	90028-67-4	289-860-8
Evernia prunastri extract	Oakmoss extract	90028-68-5	289-861-3
Farnesol	2,6,10-Dodecatrien-1-ol, 3,7,11-trimethyl-	4602-84-0	225-004-1
Geraniol	2,6-Octadien-1-ol, 3,7-dimethyl-, (2E)-	106-24-1	203-377-1
Hexyl cinnamal	2-Benzylideneoctanal	101-86-0	202-983-3
Hydroxycitronella <sup>89</sup>	7-Hydroxycitronellal	107-75-5	203-518-7
Hydroxyisohexyl 3-cyclohexene carboxaldehyde / Lyrall	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 <sup>90</sup>	Phenol, 2-methoxy-4-(1-propenyl)	97-54-1 / 5932-68-3	202-590-7 / 227-678-2
Limonene <sup>91</sup>	d-Limonene(4R)-1-Methyl-4-(1-methylethenyl) cyclohexene	5989-27-5	227-813-5
Linalool	1,6-Octadien-3-ol, 3,7-dimethyl-	78-70-6	201-134-4
Methyl 2-octynoate <sup>92</sup>	Methyl oct-2-ynoate / Methyl heptine carbonate	111-12-6	203-836-6

86 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.

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

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

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

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

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

92 MAC = 0.01 % when it is used by itself. In combination with methyl octyl 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.





## ANNEX IV. Summary Chart of Nitrosamines and Nitrosating Agents<sup>93</sup>

Name of Common Ingredients Glossary	Chemical Name	Acronym	CAS Number	EC Number	Limits <sup>94</sup>
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		80-30-6	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

*Continued on next page*

93 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.

94 nd ≈ < 0.000001 % ≈ < 0.01 ppm.



Name of Common Ingredients Glossary	Chemical Name	Acronym	CAS Number	EC Number	Limits <sup>94</sup>
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
Ethanolamine <sup>95</sup>	2-Aminoethanol	MEA	141-43-5	205-483-3	0.5 % (as secondary amine)
Triethanolamine <sup>95</sup>	2,2',2''-Nitrilotriethanol	TEA	102-71-6	203-049-8	leave-on products: 2.5 % rinse-off products: no restrictions
DEA-Cocamide <sup>96</sup>	N,N-bis(Hydroxyethyl) cocoamide		68603-42-9	271-657-0	0.5 % (as secondary amine)
DEA-Lauramide <sup>96</sup>	N,N-bis(2-Hydroxyethyl) dodecanamide		120-40-1	204-393-1	0.5 % (as secondary amine)
DEA-Oleamide <sup>96</sup>	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 <sup>97</sup>			7632-00-0	231-555-9	0.2 % (only as rust inhibitor)
Amyl nitrite			110-46-3	203-770-8	nd
Isobutyl nitrite			542-56-3	208-819-7	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

95 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.

96 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.

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



## ANNEX V. Summary Chart of Phthalates

Name of Common Ingredients Glossary	Chemical Name	Acronym	CAS Number	CE Number	Limits <sup>98</sup>
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
Dihexyl phthalate		DnHP	84-75-3	201-559-5	nd
Diisobutyl phthalate		DIBP	84-69-5	201-553-2	nd
Diisodecyl phthalate <sup>99</sup>		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 <sup>99</sup>		DINP	28553-12-0	249-079-5	nd
Diisopentylphthalate		DIPP	605-50-5	210-088-4	nd
Dimethoxyethyl phthalate	bis(2-Methoxyethyl) phthalate	DMEP	117-82-8	204-212-6	nd
Dimethyl phthalate <sup>100</sup>		DMP	131-11-3	205-011-6	nd
Diocetyl phthalate <sup>101</sup>	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

98 nd ≈ < 0.0005 % ≈ < 5 ppm.

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

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

101 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	CE Number	Limits as traces in Final Cosmetic Product
Antimony	Sb	7440-36-0	231-146-5	Not detected <sup>102</sup>
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	CE Number	Comments on traces in Final Cosmetic Products
<u>Cobalt</u>	<u>Co</u>	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.
<u>Zirconium</u> <sup>103</sup>	<u>Zr</u>	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.

<sup>102</sup> The limit for these elements in the Final Cosmetic Product is not detection:  $nd \approx < 0.0001\% \approx < 1 \text{ ppm}$  for all the elements considered prohibited, with the exception of Antimony and Lead ( $nd \approx < 0.0005\% \approx < 5 \text{ ppm}$ ) and Nickel ( $nd \approx < 0.001\% \approx < 10 \text{ ppm}$ ). 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.

<sup>103</sup> 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 <sup>104</sup>		Prohibited	Restricted <sup>105</sup>
<b>Chromium</b>	CI 77289	Chromium(III) hydroxide	Chromic acid	
	CI 77288	Chromium(III) oxide	Chromic acid salts	
	CI 18690 <sup>106</sup>	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 <sup>106</sup>	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		
<b>Cobalt</b>	CI 77346 <sup>106</sup>	Cobalt aluminium oxide	Cobalt dichloride	
			Cobalt sulphate	
			Cobalt benzenesulphonate	
			Cobalt di(acetate)	
			Cobalt dinitrate	
			Cobalt carbonate	
<b>Barium</b>	CI 77120 <sup>106</sup>	Barium sulphate	Barium salts	
	Lakes, salts and pigments of colorants <sup>107</sup>		Barium sulphide	
<b>Strontium</b> <sup>108</sup>	Lakes, salts and pigments of colorants <sup>107</sup>		Strontium compounds <sup>109</sup>	Strontium salts <sup>110</sup>
			Strontium lactate	Strontium acetate
			Strontium nitrate	Strontium chloride
			Strontium nitrite	Strontium hydroxyde
			Strontium polycarboxylate	Strontium peroxide
<b>Zirconium</b>	Lakes, salts and pigments of colorants <sup>107</sup>		Zirconium compounds	Aluminium zirconium salts <sup>111</sup>
				Aluminium zirconium chloride hydroxide complexes $Al_xZr(OH)_yCl_z$
				Aluminium zirconium chloride hydroxide glycine complexes

Continued on next page

- 104 For the specifications of the colorants, refer to section III.7 of colorants and to the corresponding annexes (Annex VIII and Annex VIII *bis*).
- 105 For any doubt about the restricted substances that appear in this column, contact the Sustainability Department at Inditex.
- 106 For the specifications of these colorants, refer to Regionalised Chart of Colorants (section III.7 and to the corresponding Annexes VIII and VIII *bis*).
- 107 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 VIII); 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 VIII).
- 108 MAC = 2.1 %; prohibited in aerosol cosmetic products (see legislation of Canada, Annex I).
- 109 According to the legislation of Japan, Taiwan and South Korea (see Annex I).
- 110 According to the legislation of Canada (see Annex I).
- 111 According to the legislation of Taiwan (see Annex I).



Elements	Colorants <sup>104</sup>		Prohibited	Restricted <sup>105</sup>
<b>Sulfur</b> <sup>112</sup>			Alkali sulphides	Inorganic sulfites
			Alkali earth sulphides	Hydrogen-sulphites
<b>Bismuth</b>	CI 77163	Bismuth chloride oxide	Bismuth compounds <sup>113</sup>	Bismuth subnitrate <sup>111</sup>
<b>Tin</b>			Dibutyltin dichloride	Tin difluoride
			Dimethyltin dichloride	
			Dibutyltin hydrogen borate	
			Tributyl compounds	
			Triphenyltin acetate	
			Triphenyltin hydroxide	
			Trichloromethylstannane	
			2-Ethylhexyl 10-ethyl-4-((2-((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	
		Tricyclohexylhydroxytin <sup>111</sup>		
		Bis(tri-n-butyltin)oxide <sup>111</sup>		
<b>Iron</b>	CI 10006 <sup>106</sup>	Sodium tris(1,2-naphthoquinone-1-oximato-O,O')ferrate(1-)	Alkali pentacyanonitrosylferrate(2-)	
	CI 10020 <sup>106</sup>	Trisodium tris[5,6-dihydro-5-(hydroxyimino)-6-oxonaphthalene-2-sulphonato(2-)-N5,O6]ferrate(3-)		
	CI 77004 <sup>106</sup>	Natural hydrated aluminium silicate, Al <sub>2</sub> O <sub>3</sub> ·2SiO <sub>2</sub> ·2H <sub>2</sub> O, containing calcium, magnesium or iron carbonates, ferric hydroxide, quartz-sand, mica, etc. as impurities		
	CI 77015 <sup>106</sup>	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		

Continued on next page

112 MAC = 2 %; use only permitted in antidandruff and antiacne products (soaps, lotions, creams, gels and shampoos (see legislation of Taiwan, MERCOSUR and the United Mexican States, Annex I). The list of sulphur compounds and/or its salts, restricted and banned, is not exhaustive.

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



Elements	Colorants <sup>104</sup>		Prohibited	Restricted <sup>105</sup>
<b>Manganese</b>	CI 77742	Ammonium manganese(3+) diphosphate	Manganese ethylenebis (dithiocarbamate) (polymeric)	
	CI 77745 <sup>106</sup>	Trimanganese bis(orthophosphate)	Manganese ethylenebis (dithiocarbamate) (polymeric) complex with zinc salt	
<b>Molybdenum</b>			Molybdenum trioxide	
<b>Vanadium</b>			Divanadium pentoxide	
<b>Zinc</b>	-----	Zinc stearate <sup>106</sup>	Zinc Dimethyldithio carbamate	Water-soluble zinc salts Zinc pyrithione <sup>114</sup>
	CI 77947	Zinc oxide	Managnese ethylenebis(dithiocarbamate) (polymeric) complex with zinc salt	Zinc oxide (as UV Filter) <sup>115</sup> Ammonium Silver Zinc Aluminum Silicate <sup>111</sup>
<b>Aluminium</b>	CI 77000	Aluminium		Aluminium sulphate buffered <sup>116</sup>
	CI 77002 <sup>106</sup>	Aluminium hydroxide sulphate		Aluminium potassium bis(sulfate) <sup>111</sup>
	CI 77004 <sup>106</sup>	Natural hydrated aluminium silicate, Al <sub>2</sub> O <sub>3</sub> ·2SiO <sub>2</sub> ·2H <sub>2</sub> O containing calcium, magnesium or iron carbonates, ferric hydroxide, quartz-sand, mica, etc. as impurities		Aluminium chloride
				Aluminium chlorhydrate, its salts and its associated complexes
	CI 77015 <sup>106</sup>	Aluminium silicate coloured with ferric oxide		Ammonium Silver Zinc Aluminum Silicate <sup>111</sup> Aluminium chlorhydroxy allantoinate <sup>109</sup>
	CI 77346 <sup>106</sup>	Cobalt aluminium oxide		Aluminium zirconium salts <sup>111</sup>
	-----	Aluminium stearate <sup>106</sup>		Aluminium zirconium chloride hydroxide complexes Al <sub>x</sub> Zr(OH) <sub>y</sub> Cl <sub>z</sub> Aluminium zirconium chloride hydroxide glycine complexes

Continued on next page

114 For the specifications of preservatives, refer to the section III.8 of preservatives and to the corresponding Annex IX.

115 For the specifications of UV filters, refer to section III.9 of UV filters and to the corresponding Annex X.

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



Elements	Colorants <sup>104</sup>		Prohibited	Restricted <sup>105</sup>
<b>Copper</b>	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 <sup>106</sup>	(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 <sup>106</sup>	Disodium [29H,31H-phthalocyaninedisulphonato(4-)-N29,N30,N31,N32] cuprate(2-)	Slimes and sludges, copper electrolyte refining, decopperised	
	CI 74260 <sup>106</sup>	Polychloro copper phthalocyanine		
<b>Gold</b>	CI 77480 <sup>106</sup>	Gold	Gold salts	
<b>Silver</b>	CI 77820	Silver		Silver nitrate
				Silver chloride deposited on titanium dioxide <sup>114</sup>
				Citric acid (and) silver citrate (as Preservative) <sup>114</sup>
				Ammonium Silver Zinc Aluminum Silicate <sup>111</sup>
<b>Titanium</b>	CI 77891	Titanium dioxide	Bis(Cyclopentadienyl)-bis(2,6-difluoro-3-(pyrrol-1-yl)-phenyl)titanium	Titanium dioxide (as UV Filter) <sup>115</sup>
			Potassium titanium oxide	





## ANNEX VII. Summary Chart of Glycol-Ethers

Name of Common Ingredients Glossary	Chemical Name	Acronym	CAS Number	EC Number	Limits <sup>117</sup>
Diethylene glycol	2,2'-Oxydiethanol	DEG	111-46-6	203-872-2	nd
Diethylene glycol dimethyl ether	bis(2-Methoxyethyl) ether	DEGDME	111-96-6	203-924-4	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 <sup>118</sup>	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 <sup>119</sup>	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
	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	120
Propylene glycol monomethyl ether acetate	1-Methoxy-2-propyl acetate	PGMEA	108-65-6 / 84540-57-8	203-603-9	121
Diethylene glycol monobutyl ether	2-(2-Butoxyethoxy)ethanol	DEGBE	112-34-5	203-961-6	9 % <sup>122</sup>
Diethylene glycol monoethyl ether	2-(2-Ethoxyethoxy)ethanol	DEGEE	111-90-0	203-919-7	2.6-10 % <sup>123</sup>
Nonaethylene glycol monododecyl ether	Polidocanol		3055-99-0	221-284-4	2 %

117 nd ≈ < 0.0001 % ≈ < 1 ppm.

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

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

120 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).

121 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).

122 Use only as solvent of hair dyes (no aerosol dispensers).

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



## ANNEX VIII. Summary Chart of Colorants

GLOBAL Chart of Colorants<sup>124,125</sup>

Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>126</sup>	Not to be used in eye products <sup>127</sup>	Not to be used in lip products <sup>128</sup>	Not to be used in pro-ducts applied on mucous membranes <sup>129</sup>	General notes
CI 10316	Yellow	Sodium 5,7-dinitro-8-oxidonaphthalene-2-sulphonate	Ext. D&C Yellow No.7		846-70-8	212-690-2			x	x <sup>130</sup>	x	131, 132
CI 12085	Red	1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol	D&C Red No.36		2814-77-9	220-562-2	3 %		x <sup>133</sup>		x <sup>133</sup>	131, 132
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 <sup>130</sup>	x <sup>130</sup>	x <sup>134</sup>	132, 135
CI 15510	Orange	Sodium 4-[(2-hydroxy-1-naphthyl)azo] benzenesulphonate	D&C Orange No.4		633-96-5	211-199-0			x	x <sup>133</sup>	x <sup>133</sup>	131, 132
CI 15800	Red	Calcium bis[3-hydroxy-4-(phenylazo)-2-naphthoate]	D&C Red No.31		6371-76-2	228-899-7			x <sup>130</sup>	x <sup>130</sup>	x	132, 135, 136

*Continued on next page*

124 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.

125 In the United Mexican States, the lake of a synthetic colorant must be declared on the label with word "lake" after the common name of the colorant.

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

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

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

129 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.

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

131 This colorant includes the insoluble Barium, Strontium and Zirconium lakes, salts and pigments.

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

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

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

135 Barium, Strontium and Zirconium lakes of this colorant are prohibited (see legislation of South Korea, Annex I).

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



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>126</sup>	Not to be used in eye products <sup>127</sup>	Not to be used in lip products <sup>128</sup>	Not to be used in pro-ducts applied on mucous membranes <sup>129</sup>	General notes
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 <sup>133</sup>			131, 132
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 <sup>133</sup>	x <sup>133</sup>		132, 135
CI 15985	Yellow	Disodium 6-hydroxy-5-[(4-sulphonatophenyl)azojnaphthalene-2-sulphonate	FD&C Yellow No.6	E 110	2783-94-0	220-491-7			x <sup>133</sup>			131, 132
CI 16035	Red	Disodium 6-hydroxy-5-[(2-methoxy-4-sulphonato-m-tolyl)azojnaphthalene-2-sulphonate	FD&C Red No.40	E 129	25956-17-6	247-368-0						132, 137, 138
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 % <sup>139</sup>		x <sup>133</sup>			132, 140, 141
CI 19140	Yellow	Trisodium 5-hydroxy-1-(4-sulphophenyl)-4-[(4-sulphophenyl)azo]pyrazole-3-carboxylate	FD&C Yellow No.5 & its Aluminium Lake	E 102	1934-21-0	217-699-5						131, 132, 138

*Continued on next page*

137 The colorant must not be exposed to oxidant or reductant agents or to any other conditions that could affect its integrity (see legislation of the USA, Annex I).

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

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

140 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).

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



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>126</sup>	Not to be used in eye products <sup>127</sup>	Not to be used in lip products <sup>128</sup>	Not to be used in pro-ducts applied on mucous membranes <sup>129</sup>	General notes
CI 42053	Green	Benzene-methanaminium, N-ethyl-N-(4-((4-(ethyl((3-sulphophenyl)methyl)amino)phenyl)(4-hydroxy-2-sulphophenyl)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 <sup>133</sup>				132
CI 42090	Blue	Benzene-methanaminium, N-ethyl-N-(4-((4-(ethyl((3-sulphophenyl)methyl)amino)phenyl)(2-sulphophenyl)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 <sup>142</sup>	x <sup>133</sup>	x <sup>133</sup>	132, 135, 143
CI 45350	Yellow	Disodium 2-(3-oxo-6-oxidoxanthin-9-yl)benzoate	D&C Yellow No.7 D&C Yellow No.8		2821-07-5 / 518-47-8	219-031-8 / 208-253-0	6 %		x <sup>130</sup>	x <sup>130</sup>	x <sup>133</sup>	132, 135
CI 45370	Orange	4',5'-Dibromo-3',6'-dihydroxyspiro-[isobenzofuran-1(3H),9'-[9H]xanthen e]-3-one	D&C Orange No.5		596-03-2 / 4372-02-5	209-876-0 / 224-468-2	5 % <sup>144</sup>		x <sup>130</sup>			131, 132, 141

*Continued on next page*

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

143 It can only be used the sodium salt (including its aluminium lake) and the ammonium salt of this colorant. The ammonium salt of this colorant cannot be used in eye product, nor lip products and nor products applied on mucous membranes (see legislation of the USA and Taiwan, Annex I).

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



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>126</sup>	Not to be used in eye products <sup>127</sup>	Not to be used in lip products <sup>128</sup>	Not to be used in pro-ducts applied on mucous membranes <sup>129</sup>	General notes
CI 45380	Red	Sodium 2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxanthin-9-yl) benzoate	D&C Red No.21 D&C Red No.22		17372-87-1	241-409-6			x <sup>130</sup>			131, 132
CI 45410	Red	3,4,5,6-Tetrachloro-2-(1,4,5,8-tetrabromo-6-hydroxy-3-oxoxanthin-9-yl) benzoic acid	D&C Red No.27 D&C Red No.28		18472-87-2	242-355-6			x <sup>130</sup>			131, 132
CI 47000	Yellow	1,3-Isobenzofuran-dione, reaction products with methylquinoline and quinoline	D&C Yellow No.11		8003-22-3	232-318-2			x <sup>130</sup>	x <sup>130</sup>	x	132, 135,136
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 <sup>130</sup>			132
CI 59040	Green	Trisodium 8-hydroxy-pyrene-1,3,6-trisulphonate	D&C Green No.8		6358-69-6	228-783-6	0.01 % <sup>130</sup>		x <sup>130</sup>	x <sup>130</sup>	x	132, 135
CI 60725	Violet	1-Hydroxy-4-(p-toluidino) anthraquinone	D&C Violet No.2		81-48-1	201-353-5			x <sup>133</sup>	x <sup>133</sup>	x <sup>133</sup>	132, 135
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 <sup>130</sup>	x <sup>130</sup>	x	132, 135

Continued on next page



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>126</sup>	Not to be used in eye products <sup>127</sup>	Not to be used in lip products <sup>128</sup>	Not to be used in pro-ducts applied on mucous membranes <sup>129</sup>	General notes
CI 61565	Green	1,4-bis(p-Tolylamino) anthraquinone	D&C Green No.6		128-80-3	204-909-5			x <sup>133</sup>	x <sup>133</sup>	x <sup>133</sup>	132, 135
CI 61570	Green	Sodium 2,2'-(9,10-ioxoanthracene-1,4-diyldiimino) bis(5-methylsulphonate)	D&C Green No.5		4403-90-1	224-546-6						132, 135, 145
CI 73360	Red	6-Chloro-2-(6-chloro-4-methyl-3-oxo-benzo[b]thien-2(3H)-ylidene)-4-methylbenzo[b]thiophene-3(2H)-one	D&C Red No.30		2379-74-0	219-163-6			x <sup>133</sup>			132, 135
CI 75120	Orange	Annatto		E 160b	1393-63-1	215-735-4/ 289-561-2/ 230-248-7						
CI 75130	Orange	$\beta$ -Carotene (Natural Yellow 26; CI Food Orange 5)		E 160a	7235-40-7	230-636-6						
CI 75170	White	2-Amino-1,7-dihydro-6H-purin-6-one (Guanine)			73-40-5	200-799-8						
CI 75470	Red	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						

Continued on next page

145 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 Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>126</sup>	Not to be used in eye products <sup>127</sup>	Not to be used in lip products <sup>128</sup>	Not to be used in pro-ducts applied on mucous membranes <sup>129</sup>	General notes
CI 75810	Green	Trisodium (2S-trans)-[18-carboxy-20-(carboxymethyl)-13-ethyl-2,3-dihydro-3,7,12,17-tetramethyl-8-vinyl-21H,23Hporphine-2-propionato(5-)-N21,N22,N23,N24]cuprate(3-) (Chlorophyllis)		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 % <sup>146</sup>		x <sup>133</sup>	x <sup>133</sup>	x <sup>133</sup>	147
CI 77000	White	Aluminium		E 173	7429-90-5	231-072-3				x <sup>133</sup>	x <sup>133</sup>	
CI 77007	Blue	Lazurite			1302-83-6	215-111-1				x <sup>133</sup>	x <sup>133</sup>	
CI 77163	White	Bismuth chloride oxide			7787-59-9	232-122-7						
CI 77266	Black	Carbon black Carbon black (nano)	D&C Black No.2	E 153	1333-86-4 / 7440-44-0	215-609-9 / 231-153-3 / 931-328-0 / 931-334-3	10 % <sup>148</sup> (nano)					132, 149, 150
CI 77288	Green	Chromium(III) oxide			1308-38-9	215-160-9				x <sup>133</sup>	x <sup>133</sup>	151
CI 77289	Green	Chromium(III) hydroxide			12001-99-9	215-160-9				x <sup>133</sup>	x <sup>133</sup>	151
CI 77400	Brown	Copper			7440-50-8	231-159-6						
CI 77489	Orange	Iron oxide			1345-25-1	215-721-8						

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<sup>146</sup> According to the legislation of the USA and MERCOSUR (see Annex I).

<sup>147</sup> Use only in dentifrices and in combination with certain substances (see legislation of the USA, Annex I).

<sup>148</sup> This numerical limit applies for the "nano" form.

<sup>149</sup> The "nano" form shall 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: primary particle size  $\geq 20$  nm; purity  $\geq 97$  %.

<sup>150</sup> It is only permitted in products for make-up the eyes, lipsticks, blushes, make-ups and nail polish (see legislation of the USA, Annex I).

<sup>151</sup> Free of chromate ion.



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>126</sup>	Not to be used in eye products <sup>127</sup>	Not to be used in lip products <sup>128</sup>	Not to be used in pro-ducts applied on mucous membranes <sup>129</sup>	General notes
CI 77491	Red	Iron Oxide Red		E 172	1309-37-1	215-168-2						
CI 77492	Yellow	Iron Oxide Yellow		E 172	51274-00-1	257-098-5						
CI 77499	Black	Iron Oxide Black		E 172	12227-89-3	235-442-5						
CI 77510	Blue	Ferric Ammonium Ferrocyanide			14038-43-8	237-875-5				x <sup>133</sup>	x <sup>133</sup>	152
CI 77742	Violet	Ammonium manganese(3+) diphosphate			10101-66-3	233-257-4						
CI 77820	White	Silver		E 174	7440-22-4	231-131-3	1 % <sup>133</sup>		x <sup>133</sup>	x <sup>133</sup>	x <sup>133</sup>	153
CI 77891	White	Titanium dioxide		E 171	13463-67-7	236-675-5						
CI 77947	White	Zinc oxide			1314-13-2	215-222-5						154
---	Brown	Caramel		E 150a-d	8028-89-5	232-435-9						

152 Free of cyanide ion.

153 Use only in fingernail polishes (see legislation of the USA, Annex I).

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





## ANNEX VIII. Summary Chart of Colorants

### REGIONALISED Chart of Colorants<sup>155, 156</sup>

Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
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, Taiwan
CI 10020	Green	Trisodium tris[5,6-dihydro-5-(hydroxyimino)-6-oxo-naphthalene-2-sulphonato(2-)-N5,O6]ferrate(3-)	Ext. D&C Green No.1		19381-50-1	243-010-2			x <sup>162</sup>	x <sup>162</sup>	x	163	USA
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 <sup>162</sup>	x <sup>162</sup>	x	163	USA
CI 11710	Yellow	2-[(4-Chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide			6486-23-3	229-355-1					x		USA, Japan, South Korea, Taiwan

Continued on next page

<sup>155</sup> 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.

<sup>156</sup> In the United Mexican States, the lake of a synthetic colorant must be declared on the label with the word "lake" after the common name of the colorant.

<sup>157</sup> Leave-on product means a cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes.

<sup>158</sup> Eye product means a cosmetic product which is intended to be applied in the vicinity of the eyes.

<sup>159</sup> Lip product means a cosmetic product which is intended to be applied on the lips.

<sup>160</sup> 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.

<sup>161</sup> These ingredients are not approved for use in cosmetic products in these markets.

<sup>162</sup> According to the legislation of South Korea (see Annex I).

<sup>163</sup> Barium, Strontium and Zirconium lakes of this colorant are prohibited (see legislation of South Korea, Annex I).



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
CI 11725	Orange	2-[[4-Methoxy-2-nitrophenyl]azo]-3-oxo-N-(o-tolyl)butyramide			6371-96-6	228-901-6		x			x <sup>164</sup>	163	USA
CI 11920	Orange	4-(Phenylazo)resorcinol			2051-85-6	218-131-9							USA, Japan, South Korea, Taiwan
CI 12010	Red	4-[[4-Ethoxyphenyl]azo]naphthol			6535-42-8	229-439-8					x		USA, Japan, South Korea, Taiwan
CI 12120	Red	1-(4-Methyl-2-nitrophenylazo)-2-naphthol	D&C Red No.35		2425-85-6	219-372-2		x				163	USA, Canada
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, Taiwan
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, Taiwan
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, Taiwan

*Continued on next page*

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



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
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						165	USA, Japan, Taiwan
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, Taiwan
CI 13015	Yellow	Disodium 2-amino-5-[[4-sulphonatophenyl]azo]benzenesulphonate			2706-28-7	220-293-0							USA, Japan, South Korea
CI 14270	Orange	Sodium 4-(2,4-dihydroxyphenylazo)benzenesulphonate			547-57-9	208-924-8							USA, Japan, South Korea, Taiwan
CI 14720	Red	Disodium 4-hydroxy-3-[[4-sulphonatophenyl]azo]naphthalene-sulphonate		E 122	3567-69-9	222-657-4							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							USA, Japan, South Korea, Taiwan

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



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
CI 15525	Red	Calcium disodium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]-4-sulphonatobenzoate]			5850-80-6	227-456-5							USA, Japan, South Korea, Taiwan
CI 15580	Red	Barium bis[4-[(2-hydroxy-1-naphthyl)azo]-2-methylbenzenesulphonate]			5850-87-3	227-459-1							USA, Japan, South Korea, Taiwan
CI 15620	Red	Sodium 4-(2-hydroxy-1-naphthyl)azobenzene-2-sulphonate	Ext. D&C Red No.8		1658-56-6	216-760-3		x			x <sup>166</sup>	163	USA
CI 15630	Red	Sodium 2-[(2-hydroxynaphthyl)azo]naphthalenesulphonate	D&C Red No.10		1248-18-6	214-998-2	3 %		x <sup>162</sup>	x <sup>162</sup>		167	USA
CI 15865	Red	Disodium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate			3564-21-4	222-642-2			x <sup>162</sup>	x <sup>162</sup>	x <sup>166</sup>	168	USA
CI 15980	Orange	Disodium 6-hydroxy-5-[(3-sulphonatophenyl)azo]naphthalene-2-sulphonate			2347-72-0	219-073-7							USA, Japan, South Korea, Taiwan

*Continued on next page*

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

167 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).

168 This colorant includes the insoluble Barium, Strontium and Zirconium lakes, salts and pigments.



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
CI 16185	Red	Trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-diol-sulphonate		E 123	915-67-3	213-022-2						169	USA, Taiwan
CI 16230	Orange	Disodium 7-hydroxy-8-phenylazonaphthalene-1,3-disulphonate			1936-15-8	217-705-6					x		USA, Japan, South Korea, Taiwan
CI 16255	Red	Trisodium 1-(1-naphthylazo)-2-hydroxynaphthalene-4',6,8-trisulphonate		E 124	2611-82-7	220-036-2						168, 169	USA
CI 16290	Red	Tetrasodium 7-hydroxy-8-[[4-sulphonato-1-naphthyl]azo]naphthalene-1,3,6-trisulphonate			5850-44-2	227-454-4							USA, Japan, South Korea, Taiwan
CI 18050	Red	Disodium 5-acetylamino-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulphonate			3734-67-6	223-098-9		x <sup>170</sup>			x		USA, Japan, South Korea
CI 18130	Red	2,7-Naphthalenedisulfonic acid, 3-((4-cyclohexyl-2-methyl-phenyl)azo)-4-hydroxy-5-(((4-methylphenyl)sulfonyl)amino)-, disodium salt			10236-37-0								USA, Japan, South Korea, Taiwan

*Continued on next page*

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

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



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
CI 18690	Yellow	Hydrogen bis[2-(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]benzoate(2-)]chromate(1-)			5601-29-6	227-022-5		x					USA, Japan, South Korea, Taiwan
CI 18736	Red	Sodium hydrogen bis[5-chloro-3-(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]2-hydroxybenzenesulphonate(3-)]chromate(3-)			6408-26-0	229-051-9		x					USA, Japan, South Korea, Taiwan
CI 18820	Yellow	Sodium 4-(3-hydroxy-5-methyl-4-phenylazopyrazol-2-yl)benzenesulphonate	Ext. D&C Yellow No.3		6359-82-6	228-808-0		x			x <sup>166</sup>	163	USA
CI 18965	Yellow	Sodium 2,5-dichloro-4-(5-hydroxy-3-methyl-4-(sulphophenyl)azo)pyrazol-1-yl)benzenesulphonate			6359-98-4	228-819-0							USA, Japan, South Korea, Taiwan
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, Taiwan

Continued on next page



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
CI 20470	Black	Sodium 4-amino-5-hydroxy-3-(4-nitrophenylazo)-6-(phenylazo)naphthalene-2,7-disulphonate			1064-48-8	213-903-1		x			x <sup>166</sup>	163	USA
CI 21100	Yellow	2,2'-(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)bis[N-(2,4-dimethylphenyl)-3-oxo-butyramide]			5102-83-0	225-822-9		x					USA, Japan, South Korea, Taiwan
CI 21108	Yellow	2,2'-(3,3'-Dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo-butyramide]			5567-15-7	226-939-8		x					USA, Japan, South Korea, Taiwan
CI 21230	Yellow	2,2'-(Cyclohexylidenebis[(2-methyl-4,1-phenylene)azo])bis [4-cyclohexylphenol]			6706-82-7	229-754-0					x		USA, Japan, South Korea, Taiwan
CI 24790	Red	Disodium 4,6-dihydroxy-3-[[4-[1-[4-[1-hydroxy-7-(phenylsulphonyloxy)-3-sulphonato-2-naphthyl]azo]phenyl] cyclohexyl] naphthalene-2-sulphonate			13421-53-9	236-531-1		x					USA, Japan, South Korea, Taiwan

Continued on next page



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>171</sup>	Not to be used in eye products <sup>168</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
CI 26100	Red	1-(4-(Phenylazo)phenylazo)-2-naphthol	D&C Red No. 17		85-86-9	201-638-4			x <sup>171</sup>	x <sup>171</sup>	x	163, 172	China
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							USA, Japan, South Korea, Taiwan
CI 28440	Black	Tetrasodium 1-acetamido-2-hydroxy-3-(4-[(4-sulphonatophenylazo)-7-sulphonato-1-naphthyl]azo)naphthalene-4,6-disulphonate		E 151	2519-30-4	219-746-5							USA, Japan, South Korea, Taiwan
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, Taiwan
CI 40800	Orange	$\beta$ -carotene (Synthetic; Food Orange 5)		E 160a	7235-40-7	230-636-6							South Korea

*Continued on next page*

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

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





Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
CI 40820	Orange	8'-apo-beta-caroten-8'-al		E 160e	1962-15-8	214-171-6							USA, Japan, South Korea, Taiwan
CI 40825	Orange	Ethyl 8'-apo-beta-caroten-8'-oate			1109-11-1	214-173-7							USA, Japan, South Korea, Taiwan
CI 40850	Orange	Canthaxanthin		E 161g	514-78-3	208-187-2							USA, Japan, South Korea, Taiwan
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		USA, Japan, South Korea, Taiwan
CI 42051	Blue	Ethaniminium, 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						168	USA, Japan, South Korea, Taiwan

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Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
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, Taiwan
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, Taiwan
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, Taiwan
CI 42510	Violet	(4-(4-Aminophenyl) (4-iminocyclohexa-2,5-dienylidene) methyl)aniline hydrochloride			632-99-5	221-189-6					x		USA, Japan, South Korea, Taiwan

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Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
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, Taiwan
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		USA, Japan, South Korea, Taiwan
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		USA, Japan, South Korea, Taiwan
CI 44090	Green	Hydrogen [4-[[4-(dimethylamino)-alpha-(2-hydroxy-3,6-disulphonato-1-naphthyl)benzylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium, mono-sodium salt		E 142	3087-16-9	221-409-2							USA, Japan, South Korea, Taiwan

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Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
CI 45100	Red	Hydrogen 3,6-bis(diethylamino)-9-(2,4-disulphonatophenyl)xanthylum, sodium salt			3520-42-1	222-529-8		x				163	USA
CI 45190	Violet	Hydrogen 9-(2-carboxylatophenyl)-3-(2-methylamino)-6-(2-methyl-4-sulphoanilino)xanthylum, monosodium salt	Ext. D&C Red No.3		6252-76-2	228-377-9		x			x <sup>166</sup>		USA
CI 45220	Red	Hydrogen 9-(2,4-dihydroxy-5-sulphonatophenyl)-3,6-bis(ethylamino)-2,7-dimethylxanthylum, monosodium salt			5873-16-5	227-528-6		x					USA, Japan, South Korea, Taiwan
CI 45396	Orange	3',6'-Dihydroxy-4',5'-dinitrospiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one			24545-86-6	246-308-0	1 % <sup>173</sup>						USA, Japan, South Korea, Taiwan
CI 45405	Red	Dipotassium 3,6-dichloro-2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxanthan-9-yl)benzoate			6441-77-6	229-225-4			x				USA, Japan, South Korea, Taiwan
CI 45430	Red	Disodium 2-(2,4,5,7-tetraiodo-6-oxido-3-oxoxanthan-9-yl)benzoate		E 127	16423-68-0	240-474-8						168	USA, South Korea

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173 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 Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
CI 50325	Violet	Hydrogen 9-[(3-methoxyphenyl)amino]-7-phenyl-5-(phenylamino)-4,10-disulphonatobenzotriphenylmethane sodium salt			6837-46-3	229-951-1		x					USA, Japan, South Korea, Taiwan
CI 50420	Black	Sulfonated nigrosine color			2229-87-2						x		USA, Japan, South Korea, Taiwan
CI 51319	Violet	8,18-Dichloro-5,15-dimethyl-5,15-dihydroindolo[3,2-b:3',2'-m]triphenodioxazine			6358-30-1	228-767-9		x					USA, Japan, South Korea, Taiwan
CI 58000	Red	1,2-Dihydroxyanthraquinone			72-48-0	200-782-5							USA, Japan, South Korea, Taiwan
CI 60724	Violet	1-Anilino-4-hydroxyanthraquinone			19286-75-0	242-939-0		x					USA, Japan, South Korea, Taiwan
CI 61585	Blue	Sodium 3,3'-(9,10-dioxanthracene-1,4-diyldiimino)bis(2,4,6-trimethylbenzenesulphonate)			4474-24-2	224-748-4		x					USA, Japan, South Korea, Taiwan

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Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
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, Taiwan
CI 69800	Blue	6,15-Dihydroanthrazine-5,9,14,18-tetrone			81-77-6	201-375-5							USA, Japan, South Korea, Taiwan
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						163	USA
CI 71105	Orange	Bisbenzimidazol[2,1-b:2',1'-i]benzo[lmn][3,8]phenanthroline-8,17-dione			4424-06-0	224-597-4					x		USA, Japan, South Korea, Taiwan
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						163	USA
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							USA
CI 73385	Violet	5-Chloro-2-(5-chloro-7-methyl-3-oxobenzo[ <i>l</i> ]thien-2(3H)-ylidene)-7-methylbenzo[ <i>b</i> ]thiophene-3(2H)-one			5462-29-3	226-750-0							USA, Japan, South Korea, Taiwan

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Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
CI 73900	Violet	5,12-Dihydro-quinol[2,3-b]acridine-7,14-dione			1047-16-1	213-879-2		x					USA, Japan, South Korea, Taiwan
CI 73915	Red	5,12-Dihydro-2,9-dimethylquinol[2,3-b]acridine-7,14-dione			980-26-7	213-561-3		x					USA, Japan, South Korea, Taiwan
CI 74100	Blue	29H,31H-Phthalocyanine			574-93-6	209-378-3		x					USA, Japan, Taiwan
CI 74160	Blue	[29H,31H-Phthalocyaninato(2-)-N29,N30,N31,N32]copper			147-14-8	205-685-1			x <sup>162</sup>	x <sup>162</sup>	x <sup>166</sup>	163	USA
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, Taiwan
CI 74260	Green	Polychloro copper phthalocyanine			1328-53-6	215-524-7			x				USA, Japan, South Korea
CI 75100	Yellow	8,8'-diapo-psi,psi-Carotenedioic acid			27876-94-4	248-708-0							USA, Japan, South Korea
CI 75125	Yellow	Psi, psi-carotene (Lycopene)		E 160d	502-65-8	207-949-1							USA, Japan, Taiwan

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Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
CI 75135	Yellow	(3R)-beta-4-Caroten-3-ol			3763-55-1								USA, Japan, South Korea, Taiwan
CI 75300	Yellow	Curcumins		E 100	458-37-7	207-280-5							USA, Japan, Taiwan
CI 77002	White	Aluminium hydroxide sulphate			1332-73-6	215-573-4							USA, Japan, South Korea
CI 77004	White	Natural hydrated aluminium silicate, Al <sub>2</sub> O <sub>3</sub> .2SiO <sub>2</sub> .2H <sub>2</sub> 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, Japan
CI 77015	Red	Aluminium silicate coloured with ferric oxide				310-127-6							USA, Japan, South Korea, Taiwan
CI 77120	White	Barium sulphate			7727-43-7 / 13462-86-7	2131-784-4							USA, Japan
CI 77220	White	Calcium carbonate		E 170	471-34-1 / 1317-65-3	207-439-9 / 215-279-6							USA, Japan
CI 77231	White	Calcium sulphate			7778-18-9	231-900-3							USA, Japan

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Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>177</sup>	Not to be used in eye products <sup>188</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
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						172, 174	Japan, Taiwan
CI 77268:1	Black	Coke black			1339-82-8	215-669-6							USA, Japan, Taiwan
CI 77346	Green	Cobalt Aluminium Oxide			1345-16-0	310-193-6							USA, Japan
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, Japan
CI 77745	Red	Trimanganese bis(orthophosphate)			10236-39-2	237-997-9							USA, Japan, South Korea, Taiwan
---	Red	Sodium 4-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]-3-hydroxy-naphthalene-1-sulphonate (Acid red 195)			12220-24-5				x <sup>170</sup>	x <sup>170</sup>	x		USA, Japan, South Korea, Taiwan
---	White	Aluminum stearate, Zinc stearate, Magnesium stearate, Calcium stearate			7047-84-9 / 557-05-1 / 557-04-0 / 216-472-8	230-325-5 / 209-151-9 / 209-150-3 / 216-472-8							USA, Japan, Taiwan

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



Colour Index Number	Colour	Chemical Name	FDA Code	E (Food Additive Code)	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>157</sup>	Not to be used in eye products <sup>158</sup>	Not to be used in lip products <sup>159</sup>	Not to be used in products applied on mucous membranes <sup>160</sup>	General notes	Restrictions <sup>161</sup>
---	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							USA, Japan, Taiwan
---	Red	Beetroot red		E 162	7659-95-2	231-628-5							USA, Japan, Taiwan
---	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		x					USA, Japan, South Korea, Taiwan
---	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 % <sup>170</sup>	x					USA, Japan, South Korea, Taiwan
---	Orange	(3R,3',5',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							USA, Japan, Taiwan
---	Yellow	Lactoflavin (Riboflavin)		E 101	83-88-5 / 130-40-5	201-507-1 / 204-988-6							USA, Japan, Taiwan



## ANNEX VIII bis. Summary Chart of Impurities in Colorants

### GLOBAL Chart of Metal Impurities in Colorants<sup>175</sup>

Limits are in ppm (mg/kg) unless otherwise specified

Colour Index Number	Colour	CAS Number	E (Food Additive Code)	As	Ba	Cd	Cr	Cu	Fe	Hg	Mn	Ni	Sb	Pb	Zn	Other heavy metals <sup>176</sup>
CI 10316	Yellow	846-70-8		3	500					1				20		100
CI 12085	Red	2814-77-9		3	500					1				20		100
CI 14700	Red	4548-53-2		3	500					1				10		100
CI 15510	Orange	633-96-5		3	500					1				20		100
CI 15800	Red	6371-76-2		3	500					1				20		100
CI 15850	Red	5858-81-1	E 180	3	500	1				1				2		100
CI 15880	Red	6417-83-0		3	500					1				20		100
CI 15985	Yellow	2783-94-0	E 110	3	500	1				1				2		100
CI 16035	Red	25956-17-6	E 129	3	500	1				1				2		100
CI 17200	Red	3567-66-6		3	500					1				20		100
CI 19140	Yellow	1934-21-0	E 102	3	500	1				1				2		100
CI 42053	Green	2353-45-9		3	500		50 <sup>177</sup>			1				10		100
CI 42090	Blue	3844-45-9	E 133	3	500	1	50 <sup>177</sup>			1	100			2		100
CI 45350	Yellow	2321-07-5 / 518-47-8		3	500					1				20		100
CI 45370	Orange	596-03-2 / 4372-02-5		3	500					1				20		100
CI 45380	Red	17372-87-1		3	500					1				20		100
CI 45410	Red	18472-87-2		3	500					1				20		100

*Continued on next page*

<sup>175</sup> 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.

<sup>176</sup> This limit corresponds to the total sum of heavy metals other than Arsenic and Lead.

<sup>177</sup> No detection for Cr(VI).



Colour Index Number	Colour	CAS Number	E (Food Additive Code)	As	Ba	Cd	Cr	Cu	Fe	Hg	Mn	Ni	Sb	Pb	Zn	Other heavy metals <sup>176</sup>
CI 47000	Red	8003-22-3		3	500					1				20		100
CI 47005	Yellow	95193-83-2 / 8004-92-0	E 104	3	500	1				1				2		100
CI 59040	Green	6358-69-6		3	500					1				20		100
CI 60725	Violet	81-48-1		3	500									20		100
CI 60730	Violet	4430-18-6		3	500					1				20		100
CI 61565	Green	128-80-3		3	500					1				20		100
CI 61570	Green	4403-90-1		3	500					1				20		100
CI 73360	Red	2379-74-0		3	500					1				20		100
CI 75120	Orange	1393-63-1	E 160b	3		1				1				2		
CI 75130	Orange	7235-40-7	E 160a	3										2		
CI 75170	White	73-40-5		3						1				20		
CI 75470	Red	1390-65-4 / 1343-78-8 / 1260-17-9 / 1328-60-5	E 120	1		1				1				5		
CI 75810	Green	1406-65-1 / 479-61-8 / 519-62-0	E 140 E 141	3		1		200 8 % <sup>178</sup>	0.5 %	1				2		
CI 77000	White	7429-90-5	E 173	3		1				1				10		
CI 77007	Blue	1302-83-6		3						1				20		
CI 77163	White	7787-59-9		3						1				20		
CI 77266	Black	1333-86-4 / 7440-44-0	E 153	3		1				1				2		
CI 77288	Green	1308-38-9		3			0.075 % <sup>177,179</sup>			1				20		

Continued on next page

178 The colorant CI 75810, when it is the additive E 141 (cupric complexes of chlorophylls and chlorophyllins) must not have more than 200 ppm of copper ions or more than 6 % of total Copper (out of the total cupric pheophytins).

179 The concentration of Chromium in the extract (2 % NaOH) must not be greater than 0.075 % as Cr<sub>2</sub>O<sub>3</sub> (% in weight).



Colour Index Number	Colour	CAS Number	E (Food Additive Code)	As	Ba	Cd	Cr	Cu	Fe	Hg	Mn	Ni	Sb	Pb	Zn	Other heavy metals <sup>176</sup>
CI 77289	Green	12001-99-9		3			0.1 % / 2.5% <sup>177,180</sup>			1				20		
CI 77400	Brown	7440-50-8		3		15				1				20		
CI 77489	Orange	1345-25-1		3		1	100 <sup>177</sup>	50		1		200		10	100	
CI 77491	Red	1309-37-1	E 172	3		1	100 <sup>177</sup>	50		1		200		10	100	
CI 77492	Yellow	51274-00-1	E 172	3		1	100 <sup>177</sup>	50		1		200		10	100	
CI 77499	Black	12227-89-3	E 172	3		1	100 <sup>177</sup>	50		1		200		10	100	
CI 77510	Blue	14038-43-8		3						1		200		20		200 (Co)
CI 77742	Violet	10101-66-3		3						1				20		
CI 77820	White	7440-22-4	E 174	5						1				10		
CI 77891	White	13463-67-7	E 171	1		1				1			2	10		
CI 77947	White	1314-13-2		3		15				1				20		
Caramel	Brown	8028-89-5	E 150a-d	1		1				1				2		

180 The concentration of Chromium in the extract (2 % NaOH) must not be greater than 0.1 % as Cr<sub>2</sub>O<sub>3</sub> (% in weight) and in aqueous extract it must not be greater than 2.5 %.

## ANNEX VIII bis. Summary Chart of Impurities in Colorants

### REGIONALISED Chart of Metal Impurities in Colorants<sup>181</sup>

Limits are in ppm (mg/kg) unless otherwise specified

Colour Index Number	Colour	CAS Number	E (Food Additive Code)	As	Ba	Cd	Cr	Cu	Fe	Hg	Mn	Ni	Sb	Pb	Zn	Other heavy metals <sup>182</sup>
CI 10006	Green	16143-80-9		3	500									20		100
CI 10020	Green	19381-50-1		3	500									20		100
CI 11680	Yellow	2512-29-0		3	500									20		100
CI 11710	Yellow	6486-23-3		3	500									20		100
CI 11725	Orange	6371-96-6		3	500									20		100
CI 11920	Orange	2051-85-6		3	500									20		100
CI 12010	Red	6535-42-8		3	500									20		100
CI 12120	Red	2425-85-6		3	500									20		100
CI 12370	Red	6535-46-2		3	500									20		100
CI 12420	Red	6471-51-8		3	500									20		100
CI 12480	Brown	6410-40-8		3	500									20		100
CI 12490	Red	6410-41-9		3	500									20		100
CI 12700	Yellow	4314-14-1		3	500									20		100
CI 13015	Yellow	2706-28-7		3	100									20		100
CI 14270	Orange	547-57-9		3	100									20		100
CI 14720	Red	3567-69-9	E 122	3	500	1				1				2		100
CI 14815	Red	3257-28-1		3	100									20		100

*Continued on next page*

<sup>181</sup> 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 V); for the calculation, the percentage composition of the colorant shall be considered in the compositional formula of the cosmetic.

<sup>182</sup> This limit corresponds to the total sum of heavy metals other than Arsenic and Lead.



Colour Index Number	Colour	CAS Number	E (Food Additive Code)	As	Ba	Cd	Cr	Cu	Fe	Hg	Mn	Ni	Sb	Pb	Zn	Other heavy metals <sup>182</sup>
CI 15525	Red	5850-80-6		3	500									20		100
CI 15580	Red	5850-87-3		3	500									20		100
CI 15620	Red	1658-56-6		3	500									20		100
CI 15630	Red	1248-18-6		3	500									20		100
CI 15865	Red	3564-21-4		3	500									20		100
CI 15980	Orange	2347-72-0		3	100									20		100
CI 16185	Red	915-67-3	E 123	3	500	1				1				2		100
CI 16230	Orange	1936-15-8		3	500									20		100
CI 16255	Red	2611-82-7	E 124	3	500	1				1				2		100
CI 16290	Red	5850-44-2		3	100									20		100
CI 18050	Red	3734-67-6		3	500	1				1				10		40 <sup>183</sup>
CI 18130	Red	10236-37-0		3	500									20		100
CI 18690	Yellow	5601-29-6		3	500									20		100
CI 18736	Red	6408-26-0		3	500									20		100
CI 18820	Yellow	6359-82-6		3	500									20		100
CI 18965	Yellow	6359-98-4		3	500									20		100
CI 20040	Yellow	5979-28-2		3	500									20		100
CI 20470	Black	1064-48-8		3	500									20		100
CI 21100	Yellow	5102-83-0		3	500									20		100
CI 21108	Yellow	5567-15-7		3	500									20		100
CI 21230	Yellow	6706-82-7		3	500									20		100
CI 24790	Red	13421-53-9		3	500									20		100
CI 26100	Red	85-86-9		3	500					1				20		100

*Continued on next page*

183 In this case, the limit corresponds to the total sum of heavy metals other than Arsenic, Lead, Mercury and Cadmium.



Colour Index Number	Colour	CAS Number	E (Food Additive Code)	As	Ba	Cd	Cr	Cu	Fe	Hg	Mn	Ni	Sb	Pb	Zn	Other heavy metals <sup>162</sup>
CI 27755	Black	2118-39-0		2	100									10		100
CI 28440	Black	2519-30-4	E 151	3	500	1				1				2		100
CI 40215	Orange	50814-31-8		3	500									20		100
CI 40800	Orange	7235-40-7	E 160a	3	500									2		100
CI 40820	Orange	1962-15-8	E 160e	3	500	1				1				2		100
CI 40825	Orange	1109-11-1		3	500	1				1				10		40 <sup>163</sup>
CI 40850	Orange	514-78-3	E 161g	3	500	1				1				2		100
CI 42045	Blue	129-17-9		3	500									20		100
CI 42051	Blue	3536-49-0	E 131	3	500	1				1				2		100
CI 42080	Blue	3486-30-4		3	500									20		100
CI 42100	Green	4857-81-2		3	500									20		100
CI 42170	Green	5863-51-4		3	500									20		100
CI 42510	Violet	632-99-5		3	500									20		100
CI 42520	Violet	3248-91-7		3	500									20		100
CI 42735	Blue	6505-30-2		3	500									20		100
CI 44045	Blue	2580-56-5		3	500									20		100
CI 44090	Green	3087-16-9	E 142	3	500	1				1				2		100
CI 45100	Red	3520-42-1		3	500									20		100
CI 45190	Violet	6252-76-2		3	500									20		100
CI 45220	Red	5873-16-5		3	500									20		100
CI 45396	Orange	24545-86-6		3	500									20		100
CI 45405	Red	6441-77-6		3	500									20		100
CI 45430	Red	16423-68-0	E 127	3	500	1				1				2		100
CI 50325	Violet	6837-46-3		3	500									20		100

Continued on next page





Colour Index Number	Colour	CAS Number	E (Food Additive Code)	As	Ba	Cd	Cr	Cu	Fe	Hg	Mn	Ni	Sb	Pb	Zn	Other heavy metals <sup>182</sup>
CI 50420	Black	2229-87-2		3	500									20		100
CI 51319	Violet	6358-30-1		3	500									20		100
CI 58000	Red	72-48-0		3	500									20		100
CI 60724	Violet	19286-75-0		3	500									20		100
CI 61585	Blue	4474-24-2		3	500									20		100
CI 62045	Blue	4368-56-3		3	500									20		100
CI 69800	Blue	81-77-6		3	100									20		100
CI 69825	Blue	130-20-1		3	500									20		100
CI 71105	Orange	4424-06-0		3	500									20		100
CI 73000	Blue	482-89-3		3	500									20		100
CI 73015	Blue	860-22-0	E 132	3	500	1				1				2		100
CI 73385	Violet	5462-29-3		3	500									20		100
CI 73900	Violet	1047-16-1		3	500									20		100
CI 73915	Red	980-26-7		3	500									20		100
CI 74100	Blue	574-93-6		3	500									20		100
CI 74160	Blue	147-14-8		3	500									20		100
CI 74180	Blue	1330-38-7		3	500									20		100
CI 74260	Green	1328-53-6		3	500									20		100
CI 75100	Yellow	27876-94-4														
CI 75125	Yellow	502-65-8	E 160d	3		1				1				1		
CI 75135	Yellow	3763-55-1		5	100 <sup>184</sup>		100 <sup>184,185</sup>	100 <sup>184</sup>					100 <sup>184</sup>	20	100 <sup>184</sup>	
CI 75300	Yellow	458-37-7	E 100	3		1				1				10		
CI 77002	White	1332-73-6														

*Continued on next page*

<sup>184</sup> This colorant may not contain more than 100 ppm of the following matter, taken separately: Antimony, Copper, Chromium, Zinc and Barium; or more than 200 ppm of those products as a whole.  
<sup>185</sup> No detection for Cr(VI).



Colour Index Number	Colour	CAS Number	E (Food Additive Code)	As	Ba	Cd	Cr	Cu	Fe	Hg	Mn	Ni	Sb	Pb	Zn	Other heavy metals <sup>182</sup>
CI 77004	White	1302-78-9 / 1327-36-2 / 1332-58-7														
CI 77015	Red															
CI 77120	White	7727-43-7 / 13462-86-7														
CI 77220	White	471-34-1 / 1317-65-3	E 170	3	100 <sup>186</sup>	1	100 <sup>185,186</sup>	100 <sup>186</sup>					100 <sup>186</sup>	3	100 <sup>186</sup>	
CI 77231	White	7778-18-9														
CI 77267	Black	8021-99-6		3										10		
CI 77268:1	Black	1339-82-8		3		1				1				2		
CI 77346	Green	1345-16-0														
CI 77480	Brown	7440-57-5	E 175					4 %								7 % (Ag)
CI 77713	White	546-93-0														
CI 77745	Red	10236-39-2														
Acid Red 195	Red	12220-24-5		3	500									20		100
Aluminum stearate, Zinc stearate, Magnesium stearate, Calcium stearate	White	7047-84-9 / 557-05-1 / 557-04-0 / 216-472-8		3	500									20		100
Anthocyanins	Red	528-58-5 / 134-01-0 / 528-53-0 / 643-84-5 / 134-04-3 / 1429-30-7	E 163	3		1				1				2		

Continued on next page

186 100 ppm of Antimony, Copper, Chromium, Zinc and Barium, single or in combination.



Colour Index Number	Colour	CAS Number	E (Food Additive Code)	As	Ba	Cd	Cr	Cu	Fe	Hg	Mn	Ni	Sb	Pb	Zn	Other heavy metals <sup>102</sup>
Beetroot red	Red	7659-95-2	E 162	3		1				1				2		
Bromocresol Green	Green	76-60-8		3	500									20		100
Bromothymol Blue	Blue	76-59-5		3	500									20		100
Capsanthin, Capsorubin	Orange	465-42-9 / 470-38-2	E 160c	3		1				1				2		
Lactoflavin	Yellow	83-88-5 / 130-40-5	E 101	3		1				1				2		



## ANNEX IX. Summary Chart of Preservatives

GLOBAL Chart of Preservatives<sup>187</sup>

Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in preparation ready for use	Not to be used in leave-on products <sup>188</sup>	Not to be used in products applied on mucous membranes <sup>189</sup>	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) <sup>190</sup>				Avoid contact with eyes	
Benzethonium chloride	121-54-0	204-479-9	0.1 %	x <sup>191</sup>	x <sup>192</sup>			193
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	0.2 % / 0.5 % (as acid) <sup>194</sup>					
Chlorhexidine	55-56-1	200-238-7	0.1 % / 0.05 % (as chlorhexidine) <sup>190</sup>					195
Chlorhexidine digluconate	18472-51-0	242-354-0	0.1 % / 0.05 % (as chlorhexidine) <sup>190</sup>				Avoid contact with eyes <sup>196</sup>	195
Chlorhexidine dihydrochloride	56-95-1	200-302-4	0.1 % / 0.05 % / 0.001 % (as chlorhexidine) <sup>197</sup>					195

*Continued on next page*

187 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.

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

189 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.

190 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.

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

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

193 Not to be used in oral products.

194 The first limit applies to benzoic acid; the second limit applies to the sum of benzoic acid and sodium benzoate.

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

196 The labelling requirements only apply in Taiwan.

197 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 (see legislation of Japan, South Korea and Taiwan, 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 <sup>188</sup>	Not to be used in products applied on mucous membranes <sup>189</sup>	Not to be used in aerosol dispensers	Warnings	General notes
Chlorobutanol	57-15-8	200-317-6	0.1 %			x	Contains Chlorobutanol May cause an allergic reaction <sup>196</sup>	
Chloroxylenol	88-04-0 / 1321-23-9	201-793-8 / 215-316-6	0.3 % / 0.2 % <sup>190</sup>					
Chlorphenesin	104-29-0	203-192-6	0.3 %		x <sup>199</sup>			
Dehydroacetic acid and its salts	Various	Various	0.5 % (as acid)			x		
Iodopropynyl butylcarbamate	55406-53-6	259-627-5	0.02 % / 0.01 % / 0.0075 % <sup>200</sup>			x <sup>201</sup>	Not to be used for children under 3 years of age <sup>202</sup>	203
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)	x	x <sup>199</sup>			204
Methylisothiazolinone	2682-20-4	220-239-6	0.0015 %	x	x <sup>199</sup>			205
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) <sup>206</sup>					

*Continued on next page*

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

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

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

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

202 The labelling requirements does not apply to bath products, shower gels and shampoos.

203 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 ban applies to children under 13 years of age in South Korea.

204 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.

205 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.

206 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.



Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>188</sup>	Not to be used in products applied on mucous membranes <sup>189</sup>	Not to be used in aerosol dispensers	Warnings	General notes
Propyl-4-hydroxybenzoate and its salts; Butyl 4-hydroxybenzoate and its salts;	94-13-3 / 94-26-8	202-307-7 / 224-208-8	0.14 % / 0.8 % (as acid) <sup>207</sup>					208
p-Chloro-m-cresol	59-50-7	200-431-6	0.04 %		x			
Phenoxyethanol	122-99-6	204-589-7	1.0 %					
Piroctone olamine	68890-66-4	272-574-2	0.05 %		x <sup>199</sup>		Contains Piroctone olamine If irritation occurs, stop using the products and consult with a physician or pharmacist <sup>209</sup>	
Polyaminopropyl biguanide	Various	Various	0.05 %			x		210
Salicylic acid	69-72-7	200-712-3	0.2 % / 0.5 % (as acid) <sup>211</sup>			x	Not to be used for children under 3 years of age Contains salicylic acid <sup>212</sup>	213
Salts of salicylic acid	Various	Various	0.2 % / 0.5 % (as acid) <sup>211</sup>				Not to be used for children under 3 years of age <sup>214</sup> Contains salicylic acid <sup>212</sup>	215
Sorbic acid and its salts	Various	Various	0.5 % (as acid)					

*Continued on next page*

207 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, when the sum of the concentration of the esters of butyl and propyl does not exceed 0.14 %.

208 Not to be used in products intended for children under 3 years of age.

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

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

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

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

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

214 The labelling requirement is only for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin.

215 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.



Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>188</sup>	Not to be used in products applied on mucous membranes <sup>189</sup>	Not to be used in aerosol dispensers	Warnings	General notes
Triclocarban	101-20-2	202-924-1	0.2 %		x <sup>199</sup>			216, 217
Triclosan	3380-34-5	222-182-2	0.1 %			x		218
Zinc pyrithione	13463-41-7	236-671-3	0.01 %	x			Contains Zinc pyrithione Avoid contact with eyes If contact occurs flush the eyes with clean water immediately If irritation occurs, stop using the product and consult with a physician or pharmacist <sup>209</sup>	193

216 Purity criteria: 3,3',4,4'-tetrachloroazobenzene < 1ppm and 3,3',4,4'-tetrachloroazoxybenzene < 1 ppm.

217 Use only in deodorants aimed at users older than 3 years of age (see legislation of the United Mexican States, USA and Argentina, Annex I).

218 Use only permitted in: deodorants, face powders, corrector creams and products for cleaning the nails of the hands and feet before applying artificial nail systems (its frequency of use cannot be higher than once per 2 weeks).



## ANNEX IX. Summary Chart of Preservatives

REGIONALISED Chart of Preservatives<sup>219</sup>

Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>220</sup>	Not to be used in products applied on mucous membranes <sup>221</sup>	Not to be used in aerosol dispensers	Warnings	General notes	Restrictions <sup>222</sup>
4-Hydroxybenzoic acid and its salts	Various	Various	0.4 %						Japan
Alkyl (C12-22) trimethyl ammonium bromide and chloride	Various	Various	0.1 %						Japan
Benzalkonium bromide and saccharinate	91080-29-4 / 68989-01-5	293-522-5 / 273-545-7	0.1 % / 0.05 % (as benzalkonium chloride) <sup>223</sup>				Avoid contact with eyes		Japan
Benzyl alcohol	100-51-6	202-859-9	1.0 %						Japan
Bromochlorophene	15435-29-7	239-446-8	0.1 %						Japan
Chlorhexidine diacetate	3697-42-5	223-026-6	0.1 % / 0.05 % (as chlorhexidine) <sup>223</sup>					<sup>224</sup>	Japan
Citric acid (and) Silver citrate		460-890-5	0.2 %, corresponding to 0.0024 % of silver					<sup>225</sup>	China, Japan, South Korea, Mexico

Continued on next page

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

- Salts: salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanalamines; salts of the anions chloride, bromide, sulphate and acetate.
- Esters: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl and phenyl.

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 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.

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

223 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.

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

225 Not to be used in oral products and in eye products.





Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>220</sup>	Not to be used in products applied on mucous membranes <sup>221</sup>	Not to be used in aerosol dispensers	Warnings	General notes	Restrictions <sup>222</sup>
<b>Climbazole</b>	38083-17-9	253-775-4	0.2 % / 0.5 % <sup>226</sup>				Not to be used for children under 6 years of age Contains Climbazole Avoid contact with eyes If irritation occurs, stop using the product and consult with a physician or pharmacist <sup>227</sup>	<sup>228</sup>	Japan
Dibromohexamidine and its salts (including isethionate)	Various	Various	0.1 %						Japan
Dichlorobenzyl alcohol	1777-82-8	217-210-5	0.15 %						Japan
Dimethyl oxazolidine	51200-87-4	257-048-2	0.05 %					<sup>229</sup>	Japan
Ethyl Lauroyl Arginate HCl	60372-77-2	434-630-6	0.4 %		x	x	Not to be used for children under 10 years of age	<sup>230</sup>	China, Japan, Mexico
Formic acid; sodium formate	64-18-6 / 141-53-7	200-579-1 / 205-488-0	0.5 % (as acid)						Japan
<b>Glutaral</b>	111-30-8	203-856-5	0.1 %			x	Contains glutaral May cause an allergic reaction; when the concentration of glutaral in the finished product exceeds 0.05 % <sup>231</sup>		Japan
Hexamidine and its salts (including isethionate and p-hydroxybenzoate)	Various	Various	0.1 %						Japan

*Continued on next page*

<sup>226</sup> The first limit applies to hair lotions, face creams and foot care products; the second limit applies to rinse-off shampoos.

<sup>227</sup> The labelling requirements are for scalp hair and facial hair products (eyebrows, mustaches, beards, except eyelashes) (see legislation of Thailand, Annex I).

<sup>228</sup> Use only permitted in hair lotions, face creams, foot care products and rinse-off shampoos (except in South Korea where its use is allowed only in hair products (see legislation of South Korea, Annex II)).

<sup>229</sup> The pH for the finished product must not be less than 6.

<sup>230</sup> Not to be used in oral products and in lip products.

<sup>231</sup> The labelling requirement "May cause an allergic reaction" only applies in Thailand.



Name of Common Ingredients Glossary	CAS Number	EC Number	Maximum concentration in ready for use preparation	Not to be used in leave-on products <sup>220</sup>	Not to be used in products applied on mucous membranes <sup>221</sup>	Not to be used in aerosol dispensers	Warnings	General notes	Restrictions <sup>222</sup>
Hexetidine	141-94-6	205-513-5	0.1 %	x <sup>232</sup>					Japan
Hydroxyethoxyphenyl butanone	569646-79-3	933-435-8	0.7 %		x <sup>233</sup>	x <sup>233</sup>			ASEAN, China, South Korea, Mexico, Japan, Taiwan, Eurasian Customs Union
Inorganic sulfites and hydrogen-sulphites	Various	Various	0.2 % (as free SO <sub>2</sub> )						Japan
o-Cymen-5-ol	3228-02-2	221-761-7	0.1 %						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 %	x					Japan
Piroctone	50650-76-5		1.0 % / 0.5 % <sup>234</sup>						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)					<sup>235</sup>	Japan, South Korea
Undecylenic acid and its salts	Various	Various	0.2 % (as acid)						Japan, South Korea

<sup>232</sup> According to the legislation of South Korea (see Annex I).

<sup>233</sup> According to the legislation of MERCOSUR (see Annex I).

<sup>234</sup> The first limit applies to rinse-off cosmetics; the second limit applies to leave-on cosmetics.

<sup>235</sup> 20 % AgCl (w/w) on TiO<sub>2</sub>. Not to be used in products for children under 3 years of age. Not to be used in oral products, lip products and eye products.



## ANNEX X. Summary Chart of UV Filters

### GLOBAL Chart of UV Filters<sup>236</sup>

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 <sup>237</sup>	General notes
Benzophenone-3	Oxybenzone	BP3	131-57-7	205-031-5	5 % <sup>238</sup>		239
Benzophenone-4	Sulisobenzone	BP4	4065-45-6	223-772-2	5 % (as acid)		
Butyl methoxydibenzoylmethane	Avobenzone	BMBM	70356-09-1	274-581-6	3 %		
Ethylhexyl dimethyl PABA	Padimate O	EHDP	21245-02-3	244-289-3	7 % / 8 % <sup>240</sup>		
Ethylhexyl methoxycinnamate	Octinoxate	EHMC	5466-77-3	226-775-7	7.5 %		
Ethylhexyl salicylate	Octisalate	EHS	118-60-5	204-263-4	5 %		
Homosalate	Homosalate	HMS	118-56-9	204-260-8	10 %		
Octocrylene	Octocrylene	OCR	6197-30-4	228-250-8	10 % (as acid)		
Phenylbenzimidazole sulfonic acid	Ensulizole	PBSA	27503-81-7	248-502-0	3 % (as acid)	x <sup>241</sup>	
Titanium dioxide; Titanium dioxide (nano)	TiO <sub>2</sub>		13463-67-7 / 1317-70-0 / 1317-80-2	236-675-5 / 205-280-1 / 215-282-2	25 %		242
Zinc oxide; Zinc oxide (nano)	ZnO		1314-13-2	215-222-5	25 %		243

236

The sum of all chemical UV filters used to protect the product formulation (UV absorbers) in cosmetics (except perfumes and nail products) shall be less than 0.5 % (see legislation of China, Annex I).

237

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.

238

MAC = 5 % except when used to protect the product formulation that the MAC is 0.5 %.

239

Warning: "Contains benzophenone-3".

240

The first limit applies to cosmetics that are used in mucous membranes; the second limit applies to cosmetics that are not used in mucous membranes.

241

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

242

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 ≥ 99 %; median particle size based on number size distribution ≥ 30 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".

243

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 ≥ 96 %; D50 > 30 nm and D1 > 20 nm; water solubility < 50 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 X. Summary Chart of UV Filters

REGIONALISED Chart of UV Filters<sup>244</sup>

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 <sup>245</sup>	General notes	Restrictions <sup>246</sup>
4-Methylbenzylidene camphor	Enzacamene	4-MBC	38102-62-4 / 36861-47-9	253-242-6	4 %			USA, Japan
Benzophenone-5		BP5	6628-37-1		5 % (as acid)			USA, South Korea
Benzylidene camphor sulfonic acid and its salts		BCS	56039-58-8		6 % (as acid)			USA, Japan, South Korea
Bis-ethylhexyloxyphenol methoxyphenyl triazine	Bemotrizinol	BEMT	187393-00-6		3 %	x <sup>247</sup>		USA
Camphor benzalkonium methosulfate		CBM	52793-97-2	258-190-8	6 %			USA, Japan, South Korea
Diethylamino hydroxybenzoyl hexyl benzoate		DHHB	302776-68-7	443-860-6	10 %	x <sup>247</sup>		USA
Diethylhexyl butamido triazone	Isotrizinol	DBT	154702-15-5		10 %			USA, Japan
Disodium phenyl dibenzimidazole tetrasulfonate	Bisdisulizole disodium	DPDT	180898-37-7	429-750-0	10 % (as acid)			USA, Japan
Drometrizole trisiloxane		DTS	155633-54-8		15 %	x <sup>247</sup>		USA
Ethylhexyl triazone		EHT	88122-99-0	402-070-1	5 %	x <sup>247</sup>		USA
Isoamyl p-methoxycinnamate	Amiloxate	IMC	71617-10-2	275-702-5	10 %			USA, Japan

Continued on next page

244

The sum of all chemical UV filters used to protect the product formulation (UV absorbers) in cosmetics (except perfumes and nail products) shall be less than 0.5 % (see legislation of China, Annex I).

245

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.

246

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

247

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



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 <sup>245</sup>	General notes	Restrictions <sup>246</sup>
Methylene bis-benzotriazolyl tetramethylbutylphenol;	Bisocotrizole	MBBT; MBBT (nano)	103597-45-1	403-800-1	10 %	x <sup>247</sup>	248	USA
Methylene bis-benzotriazolyl tetramethylbutylphenol (nano)		P25	116242-27-4		10 %			USA, Japan
Phenylene Bis-Diphenyltriazine			55514-22-2	700-823-1	5 %		249	China, South Korea, USA, Mexico, Japan, MERCOSUR, Taiwan, Eurasian Customs Union
Polyacrylamidomethyl benzylidene camphor		PBC	113783-61-2		6 %			USA, Japan, South Korea
Polysilicone-15		PS15	207574-74-1	426-000-4	10 %			USA
Potassium, sodium and triethanolamine salts of Phenylbenzimidazole sulfonic acid			Various	Various	4 % (as acid)			USA, Japan, South Korea
Salts of Terephthalylidene dicamphor sulfonic acid			Various	Various	10 % (as acid)			USA, Japan
Terephthalylidene dicamphor sulfonic acid	Ecamsule	TDSA	92761-26-7 / 90457-82-2	410-960-6	10 % (as acid)	x <sup>247</sup>		USA
Tris-biphenyl triazine; tris-biphenyl triazine (nano)		TBPT; TBPT (nano)	31274-51-8		10 %		250	USA, South Korea, China

248 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  $\geq 98.5\%$ , 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):  $\geq 120$  nm of mass distribution and/or  $\geq 60$  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.

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

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



## ANNEX XI. 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 <sup>a</sup>			
Allergenic Fragrances	X					X		X	X									
Nitrosamines	X			X	X	X	X	X	X									
Amines and aminoderivatives														X				
Nitrosating agents	X	X						X	X			X		X <sup>b</sup>		X		
Phthalates	X							X	X	X								
Metals/ Metalloids/ Non metals																X	X	X
Glycol-ethers	X <sup>c</sup>							X		X								
Residues from Surfactants	X <sup>c</sup>		X <sup>d</sup>					X		X								
Colorants	X				X	X									X		X	X
Preservatives	X <sup>c</sup>				X	X		X	X						X			
UV Filters	X				X	X												

<sup>a</sup> The electrophoretic variant NA-MEKC may also be used.

<sup>b</sup> Only nitrites.

<sup>c</sup> With derivatization.

<sup>d</sup> Only alkylphenols (APs) and alkylphenol ethoxylates (APEOs).

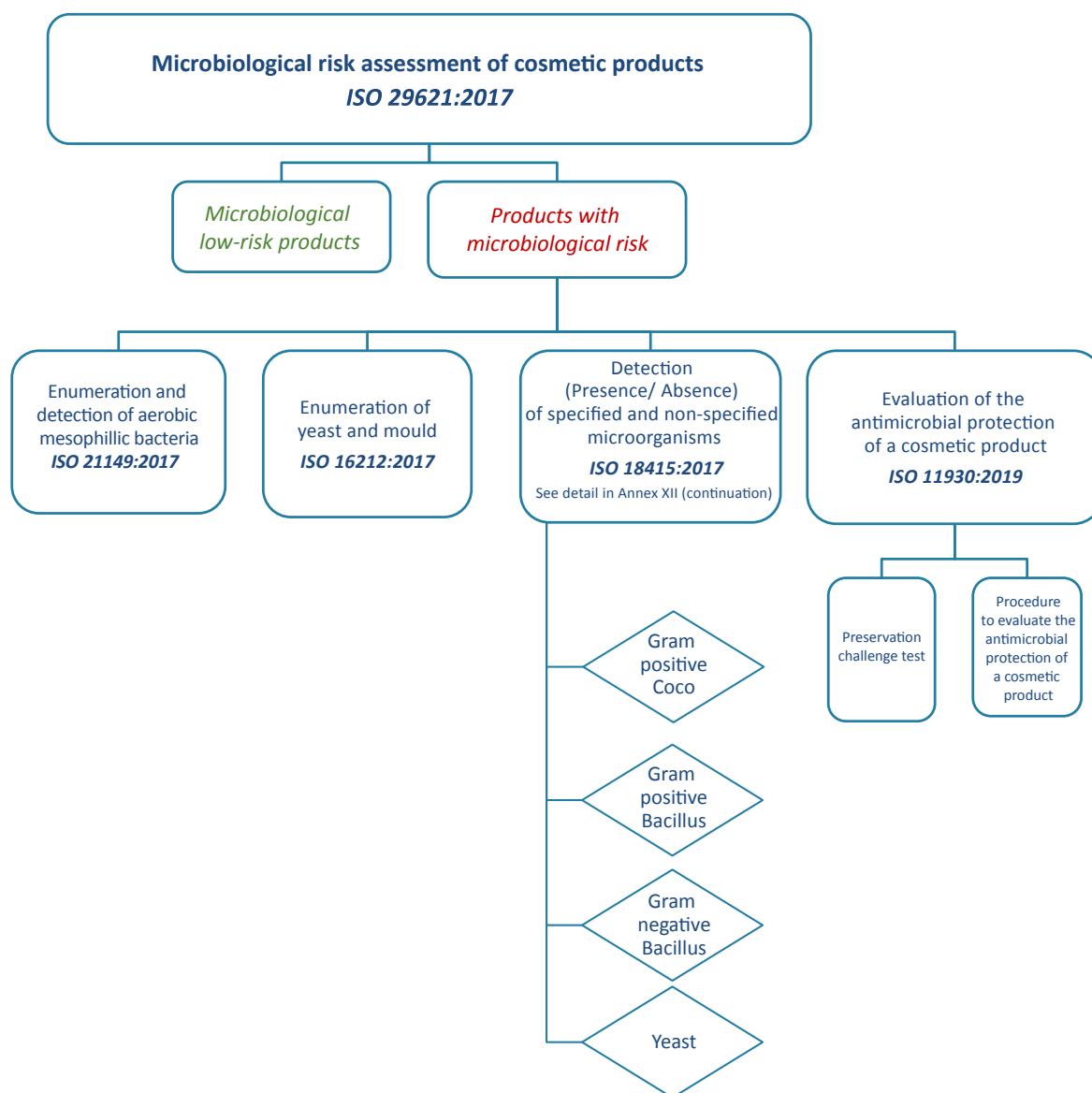
### ACRONYMS:

**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 Analyser); **MS** (Mass Spectrometry); **MS<sup>2</sup>** (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 XII. Microbiological control

The following decision tree summarises the most frequent stages in carrying out the microbiological control analyses and their respective ISO Standards<sup>251,252</sup>:



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

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 12353:2013 Chemical disinfectants and antiseptics. Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity.

252 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.

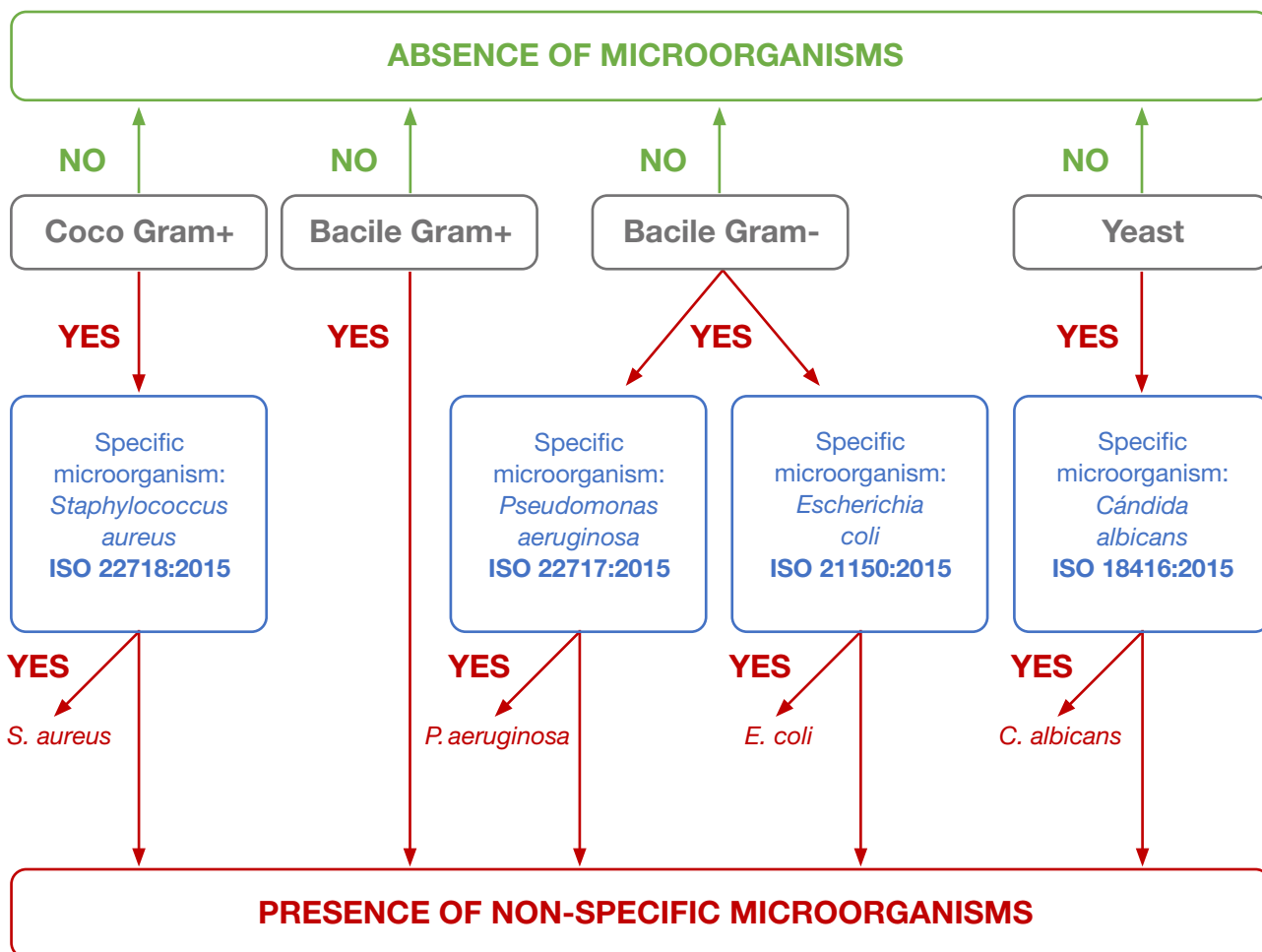
Note 2. A product whose packaging prevents the ingress of microorganisms is considered a microbiological low-risk product during its use.

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



### ANNEX XII. Microbiological control (continuation)

The following diagram summarises the path to apply the Standard ISO 18415:2017 and the conclusions that may be drawn from it<sup>253</sup>:



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





## ANNEX XIII. Checklists

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

		✓/x/NA
<b>1. DESCRIPTION OF CP</b>		
<b>Presentation</b>	CP Name	
	CPNP notification certificate	
	Conformity with Directive 87/357/EEC	
	CP Presentation (single item, set/kit, tester)	
	CP Category <b>See section 1.1 CP Categories</b>	
<b>Labelling</b>	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 <i>"ingredients"</i> <ul style="list-style-type: none"> <li>• Parfum or Aroma + the mention of other substances (Annex III) when required</li> <li>• Colorants by CI (if range: <i>"may contain"</i> or <i>"+/-"</i>)</li> </ul>	
Particular precautions for use, those listed in annexes III to VI and particulars		
<b>2. DESCRIPTION OF THE METHOD OF MANUFACTURING &amp; GMPs</b>		
	Description of the method of manufacturing	
	Declaration of compliance with GMPs	
	Batch number coding traceability method	
<b>3. PROOF OF THE EFFECT CLAIMED FOR THE CP</b>		
<b>4. DATA ON ANIMAL TESTING</b>		
<b>5. CP SAFETY REPORT (CPSR)</b>		
<b>CPSR PART A</b>	<b>See section 1.2 Checklist of Cosmetic Product Safety Report (CPSR Part A)</b>	
<b>CPSR PART B</b>	Assessment conclusion ( <i>Safe, safe with restrictions or unsafe</i> )	
	Labelled warnings and instructions of use	
	Reasoning for assessment conclusion	
	Assessor's credentials and approval	



## 1.1 Cosmetic product categories

CP CATEGORIES	CP TYPE
<b>A. COSMETIC PRODUCTS FOR BABIES &amp; CHILDREN</b>	1.- Shampoos
	2.- Conditioners
	3.- Lotions
	4.- Oils
	5.- Creams
	6.- Talcs
	7.- Other products for babies-children
<b>B. COSMETIC PRODUCTS FOR AROUND THE EYES</b>	1.- Eye pencils, eyebrow pencils
	2.- Eyeliner
	3.- Eye shadows
	4.- Eye make-up remover
	5.- Mascaras
	6.- Other products for the area around the eyes
<b>C. COSMETIC PRODUCTS FOR THE LIPS</b>	1.- Lipsticks
	2.- Lip-gloss
	3.- Lip protectors
	4.- Lip liners
	5.- Other products for the lips
<b>D. COSMETIC PRODUCTS FOR THE FACE</b>	1.- Make-up base (liquid, cream)
	2.- Blushes
	3.- Face powders
	4.- Face creams
	5.- Face lotions
	6.- Face masks
	7.- Facial correctors
	8.- Make-up remover
	9.- Facial cleansing products
	10.- Other products for the face
<b>E. COSMETIC PRODUCTS FOR THE SKIN</b>	1.- Body make-up base
	2.- Body creams
	3.- Hands creams
	4.- Body lotions
	5.- Body oils
	6.- Body powders
	12.- Other products for the skin

*Continued on next page*



CP CATEGORIES	CP TYPE
<b>F. COSMETIC PRODUCTS FOR WASHING AND BODY HYGIENE</b>	1.- Soaps
	2.- Bath gels
	3.- Bath foams
	4.- Bath powders
	5.- Bath oils
	6.- Bath lotions
	7.- Bath salts
	8.- Bath shampoos
	9.- Aromatic bath tablets
	10.- Talcs
	11.- Moisturizing towels and cloths
	12.- Other products for washing and body hygiene
<b>G. DEODORANTS AND ANTI-PERSPIRANT PRODUCTS</b>	1.- Deodorants
	2.- Anti-perspirants
	3.- Deodorants and anti-perspirants for intime hygiene
	4.- Other deodorants and anti-perspirants products
<b>H. COSMETIC PRODUCTS FOR THE NAILS</b>	1.- Nail polish base
	2.- Cuticle softener
	3.- Nail cream
	4.- Nail polish
	5.- Nail polish remover
	6.- Nail oils
	7.- Nail gloss
	8.- Other products for the nails
<b>I. COSMETIC PRODUCTS FOR PERFUMERY</b>	1.- Eau de toilette
	2.- Eau de cologne
	3.- Eau de tender
	4.- Eau de parfum
	5.- Body mist
	6.- Other products for perfumery
<b>J. SHAVE AND AFTER-SHAVE PRODUCTS</b>	1.- Shave cream
	2.- Shave lotion
	3.- Shave foam
	4.- After-shave lotion
	5.- After-shave balsam
	6.- Other shave and after-shave products
<b>K. COSMETIC SCALP PRODUCTS</b>	REFER TO INDITEX SUSTAINABILITY DEPARTMENT
<b>L. PRODUCTS FOR MOUTH AND DENTAL HYGIENE</b>	
<b>M. PRODUCTS FOR TANNING AND SUN PROTECTION</b>	
<b>N. HAIR REMOVAL PRODUCTS</b>	
<b>O. PRODUCTS FOR BLEACHING THE SKIN</b>	
<b>P. OTHER PRODUCTS</b>	



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

	✓/✗/NA
<b>1. Quantitative and qualitative composition of the CP</b>	
<i>The complete product composition: name, identity (incl. INCI, CAS, EINECS/ELINCS...) and the amount of each raw material (% in weight)</i>	
<i>Compliance with i+Cosmetics</i>	
<i>Suppliers of the raw materials</i>	
<i>Intended function of each substance</i>	
<i>Quantity, molecular formula and analytical specifications of chemically well-defined substances</i>	
<i>Definition, nature and quantity of complex ingredients (incl. purity criteria and test methods)</i>	
<i>Fragrance (or flavour)</i>	
<i>Flavour name</i>	
<i>Code number</i>	
<i>Manufacturer of supplier</i>	
<i>Declaration of allergens<sup>254</sup></i>	
<i>IFRA Declaration<sup>255</sup></i>	
<i>Safety assessment of fragrance</i>	
<b>2. Physical/chemical characteristics and stability of the CP</b>	
<i>Physical and chemical specifications of <b>raw materials</b> (pH, odour, density, viscosity,...)</i>	
<i>Physical and chemical specifications of <b>CP</b> (pH, odour, density, viscosity,...)</i>	
<i>Stability of the cosmetic product</i>	
<ul style="list-style-type: none"> <li>• <i>Stability test</i></li> <li>• <i>Minimum durability or period-after-opening (PAO)</i></li> </ul>	
<b>3. Microbiological quality<sup>256</sup></b>	
<i>Microbiological quality of the <b>raw materials</b></i>	
<i>Microbiological quality of the <b>CP</b></i>	
<i>Risk assessment and identification of microbiologically low-risk products (ISO 29621:2017)</i>	
<i>Microbiological quality test</i> <ul style="list-style-type: none"> <li>• <i>Enumeration and detection of aerobic mesophilic bacteria (ISO 21149:2017)</i></li> <li>• <i>Enumeration of yeast and mould (ISO 16212:2017)</i></li> <li>• <i>Detection of specified and non-specified microorganisms (ISO 18415:2017)</i></li> </ul>	
<i>Evaluation of the antimicrobial protection of a CP (ISO 11930:2019)</i> <ul style="list-style-type: none"> <li>• <i>Preservation efficacy test (Preservative challenge test)</i></li> <li>• <i>Evaluation of the overall antimicrobial protection of a CP</i></li> </ul>	

*Continued on next page*

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

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

256 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.



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



## 1.2.1 Declaration of Allergens

Name of Common Ingredients Glossary	CAS Number	Concentration (%) <sup>257</sup>	Labelling <sup>258</sup>
Alpha-Isomethyl ionone	127-51-5		
Amyl cinnamal	122-40-7		
Amylcinnamyl alcohol	101-85-9		
Anise alcohol	105-13-5		
Benzyl alcohol	100-51-6		
Benzyl benzoate	120-51-4		
Benzyl cinnamate	103-41-3		
Benzyl salicylate	118-58-1		
Butylphenyl methylpropional / Lialial <sup>259</sup>	80-54-6		
Cinnamal	104-55-2		
Cinnamyl alcohol	104-54-1		
Citral	5392-40-5		
Citronellol	106-22-9 / 26489-01-0		
Coumarin	91-64-5		
Eugenol	97-53-0		
Evernia furfuracea extract	90028-67-4		
Evernia prunastri extract	90028-68-5		
Farnesol	4602-84-0		
Geraniol	106-24-1		
Hexyl cinnamal	101-86-0		
Hydroxycitronellal	107-75-5		
Isoeugenol	97-54-1 / 5932-68-3		
Limonene	5989-27-5		
Linalool	78-70-6		
Methyl 2-octynoate	111-12-6		

257 In final cosmetic product.

258 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.

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



## ANNEX XIV. 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 cancel or destroy, or to order destruction of 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](http://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](http://www.inditex.com) or [Inditex supplier Extranet](#).





**INDITEX**

Sustainability Department

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