

# **Guidelines for Control of Cosmetic Products in Malaysia**

**January 2008 (rev01)**

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## **1. INTRODUCTION**

This guideline was prepared by the Cosmetic Technical Working Group (CTWG), comprising of the National Pharmaceutical Control Bureau (NPCB) and representatives from the cosmetic industry. The Guidelines for Control of Cosmetic Products in Malaysia is prepared in accordance to the ASEAN Cosmetic Directive.

The primary goal of the CTWG is to implement an efficient regulatory control system without compromising consumer safety by incorporating the requirements of the ASEAN Cosmetics Directives. Ensuring safety, quality and claimed benefits of cosmetic products are the fundamental principles of cosmetics product control.

### **1.1 What is cosmetic product notification**

This notification process will allow the NPCB to gather adequate information on the cosmetic products that are placed in the local market.

Under the Control of Drugs and Cosmetics (amendment) Regulations 2007, the company or person responsible for placing a cosmetic product in the local market must notify the Director of Pharmaceutical Services (DPS) through National Pharmaceutical Control Bureau (NPCB) prior to product manufacture or importation.

It is an offence for anyone to manufacture or import a cosmetic product without prior notification to the DPS.

## **2. THE REGULATION OF COSMETIC PRODUCTS**

### **2.1 Introduction**

The Government regulates the manufacture, sale and importation of cosmetic products in the following ways:

- By requiring that all cosmetic products be notified before manufacture, sale, supply by wholesale and import
- By requiring the company or person carrying out the notification be registered  
Please refer [Annex 1, part 1](#) – Membership Registration for Quest 2 system.

- By requiring the manufacture, importation and wholesale be authorized
- By conducting post-market surveillance

### **3. LEGAL ASPECTS OF COSMETIC CONTROL**

#### **3.1 Director of Pharmaceutical Services (DPS)**

The authority responsible for the regulation of cosmetic products lies with the DPS. National Pharmaceutical Control Bureau (NPCB) is a secretariat to the DPS which is responsible for the cosmetic product notification process.

#### **3.2 Definitions**

The following definitions are based on the ASEAN Cosmetic Directives:

##### **3.2.1 Cosmetic Product**

A cosmetic product shall mean “any substance or preparation intended to be placed in contact with various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition”.

Please refer to [Annex 1, part 2](#) - Illustrative list by category of cosmetic product

##### **3.2.2 Manufacturer**

A manufacturer is a company which is engaged in any process carried out in the course of making the cosmetic products. The manufacturing process includes all operations of purchase of starting materials, bulk intermediates and products, formulation and production (such as grinding, mixing, encapsulation and / or packaging), quality control, release, storage and distribution of cosmetic products and the related controls.

##### **3.2.3 Primary Assembler**

A primary assembler is a company which is engaged in a process of enclosing the product in a primary/intermediate container which is labeled or to be labeled before the product is sold or supplied in it.

### **3.2.4 Secondary Assembler**

Secondary assembler is a company which is engaged only in a process of labeling the product container where the product is already enclosed in its primary container and / or packing the product which is already enclosed in its labeled primary container into a carton which is labeled or to be labeled, before the product is sold or supplied.

### **3.2.5 Product Variant**

For the purpose of this guideline product variants shall mean, items in a range of cosmetic products, which are produced by the same manufacturer, similar in composition and are intended for the same use but are available in different colours, fragrances or flavours. In this context;

Colour shall mean, a substance used as an ingredient of cosmetic product solely to give tonality to the product;

Fragrance shall mean, a substance used as an ingredient of cosmetic product solely to impart odour to the product; and

Flavour shall mean, a substance used as an ingredient of cosmetic product solely to impart taste to the product.

## **3.3 Legislation covering the manufacturer**

Under the Control of Drugs and Cosmetics Regulations 1984, manufacturers need to ensure compliance with the ASEAN Guidelines on Good Manufacturing Practice (GMP) for Cosmetic.

A company or person responsible to notify cosmetic products must ensure that the products are manufactured in facilities that comply with the ASEAN Guidelines on Good Manufacturing Practice (GMP) for Cosmetic and Malaysian Good Storage Practice (GSP) or its equivalent.

## **4. WHO SHOULD NOTIFY THE AUTHORITY**

The company or person responsible for placing cosmetic products in the market is responsible for notifying the DPS prior to manufacture, import, supply by wholesale or sale of the products. A written authorization from the product owner is required if the company or person notifying does not own the product.

### **4.1 Criteria of company or person who notifies local authority**

Applicant must be a company incorporated in Malaysia.

### **4.2 Responsibility of company or person who notifies local authority**

The company or person placing the product in the market must be responsible for ensuring safety, quality, performance or efficacy of the cosmetic product placed in the local market and to ensure that the product complies with all existing regulations.

## **5. NOTIFICATION PROCEDURE**

Notification must be made on-line through NPCB website [www.bpfk.gov.my/Quest2](http://www.bpfk.gov.my/Quest2).

All applicants must first register for a digital certificate for access to Quest2 online system. Please refer to [Annex 1, part 3](#) for Template for Notification of Cosmetic Product.

### **5.1 Document which must accompany notification form**

A Letter of Authorization from the product owner including the list of products (if the applicant is not the product owner) authorizing the applicant to notify the products.

Additional Note:

For skin whitening product, company is required to submit original Certificate of Analysis for finish good within 1 month after product has been notified to BPFK. Failure to do so may cause product cancellation.

### **5.2 Language**

Any document and material submitted to NPCB must be in English or Bahasa Malaysia. If an applicant wishes to submit materials not published in English or Bahasa Malaysia, they must supply an authorized English or Bahasa Malaysia translation.

### **5.3 Privacy markings**

All information submitted to the NPCB will be treated as 'commercial-in-confidence', whether or not it is marked as such by the applicant.

### **5.4 Product Variant**

Variant(s) may be submitted in one application and additional variant may be added to the notified product together with appropriate fee.

### **5.5 Multiple Manufacturer**

More than one manufacturer may be submitted in one application provided the product name and formulation are identical.

### **5.6 Processing Fees**

The processing fee is RM50.00 for each product and for each variant (if any). A fee of RM500.00 is applicable for authorization to wholesale which should be renewed annually.

### **5.7 Notification validity period**

The notification of a cosmetic product shall be valid for 2 years. The renewal should be done no later than 1 month prior to expiry together with the processing fee.

### **5.8 Manufacture or importation of product**

The company or person responsible may manufacture or import the cosmetic product upon receipt of authorization given in the Notification Note from the DPS. Notification number will be generated in a period of 1-3 days after payment being received to enable printing of Notification Note by the applicant themselves.

### **5.9 Changes in notification particulars**

Any subsequent changes in particulars of the notified cosmetic product must be informed to the authority. In general, there are two types of changes; changes that require amendment to the current notification or changes that require new notification. Please refer to [Annex 1, part 4](#) for Illustrative List for Types of Changes for Notified Product



## **6. POST MARKET SURVEILLANCE**

The NPCB shall monitor compliance of cosmetic products through surveillance in the marketplace and at the premises of the company or person responsible for placing the product in the market. This involves among others, ensuring the Product Information File is in place and safety assessment of the product.

### **6.1 Product Information File (PIF)**

The company or person placing the product in the market shall be responsible for providing all information, certificates and data requested by the NPCB. The PIF does not have to take the form of a “dossier” (i.e. an extensive collection of paper records stored in a specific location). The physical location of the information (potentially in electronic format) can be anywhere, as long as the information is readily accessible on request. For further details, please refer Annex 1, part 5 for Guidelines for Product Information File (PIF).

#### **6.1.1. Language**

The PIF must be in Bahasa Malaysia or English.

#### **6.1.2. Updating**

The PIF must be kept updated of all modifications such as new ingredients, new manufacturers, new raw material suppliers, new production process, new information etc.

### **6.2 Safety Assessment of Cosmetic Product**

A cosmetic product placed on the market must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use. The company or person placing the product in the market shall ensure that safety assessment has been conducted. Please refer to Annex 1, part 6 for Guidelines for Safety Assessment of Cosmetic Product.

## **7. COSMETIC INGREDIENTS**

The company or person responsible for placing the cosmetic product in the market shall comply with the following requirements:

### **7.1 Marketing of cosmetic products containing the following ingredients is prohibited**

- substances listed in Poisons List ( unless exempted ) ; Poison Act 1952.
- substances listed in Annex II
- substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down
- colouring agents other than those listed in Annex IV, Part 1 with the exception of cosmetic products containing colouring agents intended solely to colour hair
- colouring agents listed in Annex IV, Part 1 used outside the conditions laid down, with the exception of cosmetic products containing colouring agents intended solely to colour hair
- preservatives other than those listed in Annex VI, Part 1
- preservatives listed in Annex VI, Part 1 beyond the limits and outside the conditions laid down therein, unless other concentrations are used for specific purposes apparent from the presentation of the product
- UV filters other than those listed in Annex VII, Part 1
- UV filters listed in Annex VII, Part 1 beyond the limits and outside the conditions laid down therein

### **7.2 The presence of traces of substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms to Article 3 of the ASEAN Cosmetic Directive.**

### **7.3 Marketing of cosmetic products containing the following shall be allowed:**

- the substances and other ingredients listed in Annex III, Part 2 within the limits and under the conditions laid down, up to the dates in column (g) of that Annex
- the colouring agents listed in Annex IV, Part 2, used within the limits and under the conditions laid down, until the admission dates given in that Annex

- the preservatives listed in Annex VI, Part 2, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex. However, some of these substances may be used in other concentrations for specific purposes apparent from the presentation of the product
- the UV filters listed in Part 2 of Annex VII, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex

## **8. LABELING REQUIREMENTS**

Labeling means information written or printed or graphic matter on the immediate or outer packaging and any form of leaflets.

Name of the cosmetic product means the name given to a cosmetic product, which may be an invented name, together with a trademark or the name of the manufacturer;

Immediate packaging means the container or other form of packaging immediately in contact with the cosmetic product

Outer packaging means the packaging into which the immediate packaging is placed

The company or person responsible for placing the cosmetic product in the market shall ensure that the cosmetic products comply with the labeling requirement as defined in Annex 1, part 7 for Cosmetic Labeling Requirements.

The information on the label shall be in English and/or Bahasa Malaysia.

## **9. COSMETIC CLAIMS**

As a general rule, claimed benefits of a cosmetic product shall be justified by substantial evidence and/or by the cosmetic formulation or preparation itself.

Cosmetic products should not make claims that are regarded as medicinal in nature. A guidance document on examples of non-permissible claim is provided in Appendix 7. Please refer to Annex 1, part 8 for the Cosmetic Claims Guidelines.

It is prudent for the company or person responsible for placing the cosmetic product in the market to seek legal or expert advice to ensure that the proposed claims are not in breach of existing Acts or Regulations.

## **10. GOOD MANUFACTURING PRACTICE (GMP)**

All cosmetic products must be manufactured in accordance to Cosmetic GMP Guidelines. Please refer to Annex 1, part 9 for Guidelines for Cosmetic Good Manufacturing Practice (GMP) and Annex 1, part 10 for List of Equivalent Cosmetic GMP Guidelines Recognized by ASEAN.

## **11. AUTHORIZATION FOR MANUFACTURE, IMPORT OR WHOLESALE**

This refers to the manufacture, import or wholesale authorization issued by the DPS.

### **11.1 Manufacturing authorization**

Authorizes the manufacture and sale by wholesale or supply of notified cosmetic products in the premises specified in the manufacturing authorization which is defined in the notification note.

### **11.2 Import authorization**

Authorizes the import and sale by wholesale or supply of notified cosmetic products from the address of the premise specified in the import authorization which is defined in the notification note.

### **11.3 Wholesale authorization**

Authorizes the wholesale or supply of notified cosmetic products from the address of the premise specified in the wholesale authorization which is defined in the notification note. Separate authorization is required for a wholesaler who is not involved in the product notification and importation.

## **12. PRODUCTS FOR EXPORT ONLY OR IN-TRANSIT**

Cosmetic products that are imported solely for direct re-export or locally manufactured solely for export-only are exempted from product notification requirement, as they will not impact the safety of local consumers. However, prior approval from the DPS must be obtained for such activities. The company should maintain proper records and documents. These records should be available for the inspection by the regulatory authorities at any time when required.

Country specific requirements for manufacturers or importers of cosmetic products meant solely for export or re-export must be complied with.

## **13. TEST MARKET SAMPLING OR AESTHETIC STUDIES AND IN-HOUSE EVALUATION**

A company or person responsible for placing the cosmetic product in the market may manufacture or import un-notified products for the following purposes which are subjected to prior approval from the DPS:

### **13.1 Test Market Sampling or Aesthetic Studies**

A selective, one-time entry of un-notified products to place in a study to ascertain whether the aesthetic properties of the product are well perceived by a potential group of consumers or manufacturers.

The cosmetic industry may be allowed to manufacture or import un-notified products for the sole purpose of a selective test market sampling or aesthetic studies before its notification.

### **13.2 In – House Evaluation**

In-house evaluation (Internal evaluation) is a process where product samples either from R&D or production line, minimally or fully labeled are evaluated by the company or person responsible for placing the cosmetic product in the market for the purpose of product selection, in-house sampling or demonstration and not meant for consumer use or commercial sale.

In-house evaluation is conducted on imported as well as locally produced products. The products are typically R&D samples but can also be products that are readily available in the country of origin.

#### **14. REPORTING OF ADVERSE EVENTS**

The company or person responsible for placing the cosmetic product in the market shall report to NPCB of any serious adverse event or high incidences of adverse event occurred, regardless of the source of the report (consumer, healthcare professional, etc). Please refer to Annex 1, part 11 for Guide Manual for Adverse Event Reporting.

#### **15. PRODUCT RECALL**

Product recall is a process taken by the company or person responsible for placing the cosmetic product in the market to remove or withdraw a particular product from all channels of distribution. The removal or withdrawal may be due to critical quality defects discovered or serious adverse events reported which might cause health risks to users during and after distribution of the product.

The aim of product recall is to quickly and efficiently retrieve batch(es) of product, that does not comply with Guidelines For Control of Cosmetic Products in Malaysia, or that may have an undesirable effect on humans.

The decision for recall shall be made when there is or may be risk to the user of the cosmetic product. Recalls can be initiated:

- voluntarily by the company or person responsible for placing the cosmetic product in the market
- at the directive of the DPS

##### **15.1 Degree And Level Of Recall**

The DPS uses the following criteria to classify the degree and level of recall.

### **15.1.1 Degree of Recall**

The degree of recall is classified according to the seriousness of quality defects and/or adverse events of the products.

- **Degree I**

Products with major health risks that might present serious injuries or death.

Should be under an embargo within 24 hours.

- **Degree II**

Products with minor health risks or substandard. Should be under an embargo within 72 hours.

- **Degree III**

Products with other reasons for recall. Should be under an embargo within 30 days or as specified.

### **15.1.2 Level Of Recall**

The level of recall depends on the nature of the problem, the extent of the distribution of the product and the degree of hazard involved.

- **Level A**

For all consumers (end-users).

- **Level B**

For all points of sales.

- **Level C**

To all sub-distributors (wholesalers).

- **Level D**

For Importers/manufacturers.

## **15.2 Decision On The Degree And Level Of Recall**

Unless the DPS has already specified the degree and level of particular product recall, the product recall committee will decide the degree and level based on the risks involved.

The products recall committee shall comprise of personnel who are responsible for the execution and coordination of recall.

In cases of product recall initiated by the company or person responsible for placing the cosmetic product in the market, the product recall committee must inform the DPS immediately of this decision.

### **15.3 Record Keeping**

The company or person responsible for placing the cosmetic product in the market must keep records of the primary distribution of their products, for the purpose of product recall.

## **16. CANCELLATION OF NOTIFICATION AND AUTHORIZATION**

The DPS may, at any time and without assigning any reason cancel any approval for the notification, manufacture, import and wholesale of any product.

## **17. WITHDRAWAL**

The company or person responsible for placing the cosmetic product in the market shall inform the DPS of any decision to withdraw the notification of a product before the end of the validity of the notification.

## **18. PENALTY**

Any person who contravenes any of the provisions of the guidelines and regulations commits an offence and shall be liable on conviction as stipulated under Section 30 (1) and (2) of the Control of Drugs and Cosmetics (amendment) Regulations 2007



## 19. COSMETIC ADVERTISING CODE

The objective of the code is to ensure that the marketing and advertising of cosmetics to the public is conducted in a manner that promotes the quality use of cosmetics, is socially responsible and does not mislead or deceive the consumer.

Advertisements should contain information that is reliable, accurate, truthful, informative, balanced, up to date, and capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce unjustifiable use or give rise to undue risks. Please refer to Annex 1, part 12 for Cosmetic Advertising Code.

## 20. APPENDICES:

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Annex 1, part 2	:	Illustrative list by Category of Cosmetic Product
Annex 1, part 3	:	Template for Notification of Cosmetic Product
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Annex 1, part 8	:	Cosmetic Claims Guidelines
Annex 1, part 9	:	Guidelines on Good Manufacturing Practice (GMP) for Cosmetic
Annex 1, part 10	:	List of Equivalent Cosmetic GMP Guidelines Recognized by ASEAN
Annex 1, part 11	:	Guide Manual For Adverse Event Reporting

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Annex II	:	List of Substances which Must Not Form Part of the Composition of Cosmetic Products
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Annex IV	:	List of Colouring Agent Allowed for Use in Cosmetic Products
Annex V	:	List of Excluded from the Scope of the Directive
Annex VI	:	List of Preservatives Which Cosmetic Products May Contain
Annex VII	:	List of UV Filters Which Cosmetic Products May Contain

## **Annex 1, Part 1**

Membership Registration for Quest2 System

Please refer [www.bpfk.gov.my](http://www.bpfk.gov.my) on the Quest2 online membership registration process.

## **Annex I, Part 2**

### **ILLUSTRATIVE LIST OF COSMETIC PRODUCTS BY CATEGORIES**

#### **I. BACKGROUND**

The definition of a cosmetic product which has been adopted by the ACCSQ Product Working Group on Cosmetics is that of the European Directive. In order to understand the thought processes behind the words it does help to look at the way that the original 1976 definition was modified in 1993.

**Original :** Any substance or preparation intended for placing in contact with the external parts of the human body ... or with the teeth and mucous membranes of the oral cavity with a view exclusively or principally to cleaning them<sup>1</sup>, perfuming them<sup>2</sup> or protect them<sup>3</sup> in order to keep them in good condition<sup>4</sup> change their appearance<sup>5</sup> or correct body odour<sup>6</sup>

**Current :** Any substance or preparation intended to be placed in contact with the external parts of the human body... or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly for cleaning them<sup>7</sup>, perfuming them<sup>8</sup>, changing their appearance<sup>9</sup>, and/or correcting body odours<sup>10</sup> and/or protecting<sup>11</sup> or keeping them in good condition<sup>12</sup>

By removing the words "in order to" and replacing the three functions (1-3) and three objectives (4-6) by six individual purposes (7-12), the 1993 definition removes several legal anomalies including the one that effectively excluded all decorative products from being cosmetics.

It should be noted that while the phrase "exclusively or principally" has been changed to "exclusively or mainly" reinforces the fact that the regulators recognise that cosmetic products may have functions other than six individually listed.

#### **II. ASEAN ILLUSTRATIVE LIST BY CATEGORY OF COSMETIC PRODUCTS APPEARS IN ATTACHMENT I**

This list is not exhaustive and that currently unimagined product forms and types should be considered against the definition of a cosmetic and not the list (such as ASEAN uniqueness.)

## **ILLUSTRATIVE LIST BY CATEGORY OF COSMETIC PRODUCTS**

- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.).
- Face masks (with the exception of chemical peeling products).
- Tinted bases (liquids, pastes, powders).
- Make-up powders, after-bath powders, hygienic powders etc.
- Toilet soaps, deodorant soaps, etc.
- Perfumes, toilet waters and eau de Cologne.
- Bath and shower preparations (salts, foams, oils, gels, etc.).
- Depilatories.
- Deodorants and anti-perspirants.
- Hair care products.
  - hair tints and bleaches,
  - products for waving, straightening and fixing,
  - setting products,
  - cleansing products (lotions, powders, shampoos),
  - conditioning products (lotions, creams, oils),
  - hairdressing products (lotions, lacquers, brilliantines).
- Shaving products (creams, foams, lotions, etc.).
- Products for making-up and removing make-up from the face and the eyes
- Products intended for application to the lips.
- Products for care of the teeth and the mouth.
- Products for nail care and make-up.
- Products for external intimate hygiene.
- Sunbathing products.
- Products for tanning without sun.
- Skin-whitening products.
- Anti-wrinkle products



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- ☐ Single product
- ☐ A range of product variants similar in composition for the same use but differs in colours, flavours etc.
- ☐ Palette(s) in a range of one product type
- ☐ Combination products in a single kit
- ☐ Others (please specify)

[Please attach in a separate sheet if there are more than one manufacturer/assembler]

[illegible][illegible][illegible]

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*A secondary assembler is a company which is engaged only in a process of labelling the product container where the product is already enclosed in its primary container and/or packing the product which is already enclosed in its labelled primary container into a carton which is labelled or to be labelled, before the product is sold or supplied.*

- ❑ Secondary assembler

[illegible][illegible][illegible]

7. Name of company:

[illegible][illegible]

Tel: [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ] Fax: [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

[illegible]

8. Name of person:

[illegible]

Tel: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] Email: [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

[illegible]



Note: If the applicant is a service provider authorised by the company, he is required to provide a letter of authorisation or any additional particulars as required by the regulatory authority.

### PARTICULARS OF IMPORTER

9. Name of Importer:

[illegible]

Address of importer:

[illegible][illegible]

## PRODUCT INGREDIENT LIST

10. Please check the following boxes

- ☐ I have examined the latest revisions of the Annexes II to VII of the ASEAN Cosmetic Ingredient Listing as published in the latest amendment of the ASEAN Cosmetic Directive and confirmed that the product in this notification does not contain any prohibited substances and is in compliance with the restrictions and conditions stipulated in the Annexes.
- ☐ I undertake to respond to and cooperate fully with the regulatory authority with regard to any subsequent post-marketing activity initiated by the authority.

**[To submit ingredient list with percentages of restricted ingredients and packaging materials as required by member country]**

No	Full Ingredient name (use INCI or approved nomenclature in standard references)
1	
2	
3	
4	
5	
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7	
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10	
11	
12	

## DECLARATION

1. I hereby declare on behalf of my company that the product in the notification meets all the requirements of the ASEAN Cosmetic Directive, its Annexes and Appendices, which have been transposed into local legislation.
2. I undertake to
  - i. Ensure that the product's technical and safety information is made readily available to the regulatory authority concerned ("the Authority") and to keep records of the distribution of the products for product recall purposes;
  - ii. Notify the Authority of fatal or life threatening serious adverse event<sup>2</sup> as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 7 calendar days after first knowledge;
  - iii. Complete the Adverse Cosmetic Event Report Form<sup>3</sup> within 8 calendar days from the date of my notification to the Authority in para 2ii. above, and to provide any other information as may be requested by the Authority;
  - iv. Report to the Authority of all other serious adverse events that are not fatal or life threatening as soon as possible, and in any case, no later than 15 calendar days after first knowledge, using the Adverse Cosmetic Event Report Form;
  - v. Notify the Authority of any change in the particulars submitted in this notification;
  - vi. Ensure that if and when directed by the authority I will recall the product from the market, and discontinue selling or supplying the product
3. I declare that the particulars given in this notification are true, all data, and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies.
4. I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product that I have declared to the Authority.
5. I understand that I cannot place reliance on the acceptance of my product notification by the authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority.

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[Name and Signature of person representing the local company]

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[Company stamp]

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[Date]

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<sup>2</sup> As defined in the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products

<sup>3</sup> Set out in Appendix I to the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products

### **Annex 1, Part 4**

#### **ILLUSTRATIVE LIST FOR TYPES OF CHANGES FOR NOTIFIED PRODUCT**

It will depend on the types of changes involved, as indicated in the table below:

<b>Types of Change</b>	<b>Product Notification</b>
Brand name	New
Company change due to change of distribution rights	New
Product types	New
Product presentation(single product, palettes in a range, etc)	Amendment
Intended use	New
Product name	New
Formulation	New
Manufacturer and or assembler (name and/or address)	New
Name and/or address of company without change of distribution rights	Amendment
Person representing company	Amendment
Pack sizes, packaging materials, labels.	Amendment, but not applicable if the information need not be submitted in Product Notification Form.
Additional importer	Amendment

**Annex 1, Part 5**



**ASEAN**

**ASEAN Cosmetic Directive  
Guidelines for Product Information File (PIF)**

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## 1. Introduction and Objective

The ASEAN Cosmetic Directive (ACD) requires persons or companies placing a product on the market to keep a product information file “readily accessible to the regulatory authority of the Member State concerned at the address specified on the label in accordance with article 6 of this Directive”.

The main objective of this ASEAN Product Information File (PIF) Guideline\* is to provide companies placing a cosmetic product in the market recommendations on how to organize and compile the PIF based on a recommended PIF format. This document also provides guidance on who is responsible to keep the PIF and some guiding points for PIF audits.

*\*This Guideline is not a legal document and as such, compliance is not a mandatory requirement.*

## 2. PIF Organization

### 2.1 Product Information Required under ACD

Article 8 of the ACD spells out the list of information required in the PIF:

- a) The qualitative and quantitative composition of the product, in case of perfume compositions, the name and code number of the composition and the identity of the supplier;
- b) Specifications of the raw materials and finished product;
- c) The method of manufacture complying with the good manufacturing practice as laid down in the ASEAN Guidelines
- d) Assessment of the safety for human health of the finished product, its ingredients, their chemical structure and level of exposure;
- e) Existing data on undesirable effects on human health resulting from use of the cosmetic product; and
- f) Supporting data for claimed benefits of cosmetic products should be made available; to justify the nature of its effect;

Article 9 of the ACD requires the company to provide information on the method of analysis to the regulatory authority:

- a) The available methods used by the manufacturer to check the ingredients of cosmetic products corresponding with the Certificate of Analysis; and
- b) The criteria used for microbiological control of cosmetic products and chemical purity of ingredients of cosmetic products and/or methods for checking compliance with those criteria”

### 2.2 Recommended PIF format

In view of the above ACD requirements, companies placing products in the market need to organize the PIF in such a way that it meets the requirements and be easily consulted by the Authorities. It is recommended that the PIF be organised into 4 parts as follows:

- Part I: Administrative Documents and Product Summary
- Part II: Quality Data of Raw Material
- Part III: Quality Data of Finished Product
- Part IV: Safety and Efficacy Data

A Table of Contents should be provided for each of the 4 parts.

## **Part I: Administrative Documents and Product Summary**

The first part of the PIF contains the administrative documents and key summary information that are specific to a single product; i.e. this part would provide an ample overview of the finished product.

### **A. Administrative documentation**

- Copy of the Notification form bearing the acknowledgement receipt from the Authorities; this will include the identity of the product, the address of the manufacturer, assembler, importer and company placing the product in the market;
- Authorisation letter by product owner or agreement letter related to the product, if required by the legislation of the Member Country;
- Any other relevant administrative documents that may be prescribed by the local Authorities e.g. Licence to Operate, Certificate of Incorporation of the Company;

### **B. Qualitative and Quantitative formula of the product (INCI or other ACD approved reference names and corresponding concentrations of the ingredients):**

- For fragrance materials, name and code number of the composition and the identity of the supplier;

### **C. Product presentation and label, including:**

- Outer and inner labels (photographs and/or drawings will be useful);
- Consumer information leaflets and instruction for use if part of the product as sold to the consumer;

### **D. Manufacturing Statement:**

- A statement by the manufacturer or company that the product was manufactured according to the ASEAN GMP Guidelines or any ACC approved equivalent GMP Guidelines;
- Provide the batch coding system/ key of the product;

### **E. Safety Assessment (summary) as per the ASEAN Guidelines for the Safety Assessment of a Cosmetic Product:**

- Safety statement (signed statement of opinion, including the name and qualifications of the safety assessor);

### **F. Confirmed undesirable effects on human health (summary);**

### **G. On-pack product claim support (summary):**

- Summary report of the Efficacy Assessment of the product, based on its composition or on tests performed;

## **Part II: Quality Data of Raw Materials**

The second part of the PIF should include full technical information on the quality of the raw materials/ ingredients:

### **A. Specifications and test methods of raw material/ ingredients:**

- Specifications of each ingredient including water specification, if appropriate;
- Method of analysis corresponding to the specifications for each ingredient, including identification of the ingredients;



- For fragrance materials, specify the name and code number of the fragrance, name and address of the supplier, declaration of compliance with the latest IFRA guidelines;
- B. Data on the safety of the raw materials based on data from the supplier, on published data or on reports from Scientific Committees like the ASEAN Cosmetic Scientific Body (ACSB), the EU Scientific Committee on Consumer Products (SCCP) or the US Cosmetic Ingredient Review Board (CIR);

### **Part III: Quality Data of Finished Product**

The third part of the PIF supplies the detailed technical information on the quality of the finished product:

- A. Qualitative and Quantitative formula of the product (INCI or other approved ACD reference names and corresponding concentrations of the ingredients):
  - The formula should specify the functions of each raw material/ ingredient;
- B. Manufacturing:
  - Manufacturer contact details: name, country and address of manufacturer, assembler and packager;
  - Summary of the Manufacturing Process;
  - Additional detailed information on the manufacturing process, quality controls and related manufacturing documents should be made available upon request by the Authority;
- C. Specifications and test methods of the finished product:
  - The criteria used for microbiological control of cosmetic products and chemical purity of ingredients of cosmetic products;
  - Method of Analysis corresponding to the specifications for checking compliance;
- D. Product Stability Summary Report, for product durability below 30 months:
  - The stability testing data and report or stability assessment to support the expiry date;

### **Part IV: Safety and Efficacy Data**

The fourth and final part of the PIF provides detailed information on the safety assessment and data of the finished product and also relevant efficacy data to support any claims made on the product.

- A. Safety Assessment:
  - Signed assessment report of the safety for human health of the finished product based on its ingredients, their chemical structure and level of exposure;
  - Curriculum Vitae of the safety assessor;
- B. The latest compiled report on confirmed or recorded adverse events or undesirable effects on human health resulting from use of the cosmetic product:
  - The adverse event report in the PIF is expected to be updated by the company on a regular basis;
- C. On-pack product claim support:
  - Full signed report of the Efficacy Assessment of the product, based on its composition or on tests performed;
  - Supporting data including literature review for claimed benefits of cosmetic products should be made available to justify the nature of its effect;

### 3. Who is responsible to keep the PIF

Article 8 of the ACD states that the company or person responsible for placing the cosmetic product in the market shall keep the PIF readily accessible to the regulatory authority at the address specified on the label, which, according to the labelling requirements [Appendix II, C (e)] is “the name and address of the company or person placing the product on the local market”. The definition of such has been given in the “Guidance document on product notification to the Regulatory Authority” as “the local company responsible for placing the cosmetic product in the market, which may be a local manufacturer or an agent appointed by a manufacturer to market the product or the company that is responsible for bringing in the product for sale in the country, etc.” This clearly refers to a company or person having an address in the local market, and to the company or person responsible for bringing in the product into that market; whether this is an importer, a manufacturer or a distributor.

It is recommended that the PIF is kept for a minimum period of 3 years after the product is last placed in the market.

### 4. PIF Audits

#### 4.1 Types of audits:

Since the PIF must be at the address specified on the label, Authorities can audit the PIF at that address. There are 2 possibilities:

- **Routine audits:** The Authorities will announce these audits in advance. It is recommended that the audit be announced sufficiently in advance (i.e. at least 1 month) for the company to prepare for the audit;
- **Ad-hoc audits:** these may be triggered by results found on samples from the market, by consumer complaints, etc. It is recommended that the audit be announced at least 48 hours in advance. In case of extreme urgency the auditing can take place without announcement;

#### 4.2 Documents to be made readily available:

While the whole PIF should be available, in order to facilitate the preparation of the industry, in particular the SMEs as well as the importers/ distributors, the documents in Part I of the PIF should be made readily available especially for initial investigative audits.

#### 4.3 Documents to be made accessible to Authorities within reasonable time:

Upon specific request from the Authorities, documents, detailed information or reports in other parts of the PIF should be available and made accessible to the Authorities within an agreed upon timeframe: within 15 to 60 calendar days or shorter, depending on the urgency of the audit.

#### 4.4 Proprietary Information:

Noting that due to trade secrets, the product owner may not disclose some of the product information in any part of the PIF, to the distributor/importer, the person or company placing the product in the market will need to make their own arrangements with the product owner to provide the relevant and necessary information directly to the Authorities upon request.

#### ***4.5 Background or supplementary documents:***

In general the information provided in the PIF should be sufficient for review to ensure “the safety, quality and claimed benefits of all cosmetic products marketed in ASEAN” as specified in article 1(a) of the ASEAN Harmonized Cosmetic Regulatory Scheme.

However, in some specific cases, other background or supplementary information supporting the PIF documents (e.g. product experience, microbiological challenge tests, additional confirmatory test methods, production records, etc.) may be necessary. The company or person responsible for placing the product in the market should then make all efforts to provide the requested information to the Authorities.

#### ***4.6 Document media:***

There are no specific requirements on what media type the PIF documents should be presented. Hence the company may choose any suitable media i.e. paper, electronic, etc. provided they are convenient and could be easily consulted by the Authorities.

**Annex 1, Part 6**



**ASEAN**

**GUIDELINES FOR THE  
SAFETY ASSESSMENT OF  
A COSMETIC PRODUCT**

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## OBJECTIVE:

1. The purpose of this Guideline is to help the Cosmetic Industry in assessing the safety of the product as well as the Regulators in auditing the data contained in the Product Information File (PIF). This guideline serves to highlight some of the important considerations in the safety assessment of cosmetic product in line with Article 8 d of the ASEAN Cosmetics Directive <sup>1</sup> which requires an “assessment of the safety for human health of the finished product, its ingredients, its chemical structure and its level of exposure”. This safety assessment is to be performed by a qualified professional defined as the “Safety Assessor”.

### 1. GENERAL APPROACH

2. The provisions of Article 3 of the ASEAN Cosmetic Directive stipulates that *A cosmetic product put on the market must not cause damage to the human health when applied under normal or reasonably foreseeable condition of use taking into account in particular of the product presentation, its labeling, instruction for its use and disposal warning statements as well as any other information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the market.*

3. Hence cosmetic products have to be safe both for consumers and, if relevant, for involved professionals (e.g. hairdressers, beauticians, etc.).

4. As far as skin is concerned, the two main untoward reactions to be avoided are skin irritation and skin sensitisation <sup>2</sup>. Cosmetic products are often applied on areas exposed to environmental factors. Thus, care has also to be taken to avoid photo-induced reactions such as photoirritation and photosensitisation <sup>2</sup>.

5. Products applied on the scalp or the face may come in contact with the eye. Consequently, eye tolerance has to be addressed with optimal attention as a major component of the safety assessment for a cosmetic product.

6. Systemic toxicity that may result from percutaneous absorption or from accidental (children) or reasonably foreseeable (e.g. oral hygiene products, lipsticks) oral intake should also be considered.

7. Ensuring the safety of a cosmetic product requires a global approach throughout the life of the product from the choice of raw materials to the marketing follow-up. A number of issues have to be taken into account, including:

- Applying Cosmetic Good Manufacturing Practice Guidelines (ASEAN Cosmetic Directive - Technical Documents) or approved equivalent;
- Careful selection of cosmetic ingredients, making sure that they will be safe at a given concentration in a given finished product;
- Checking local tolerance of the finished product;

- Selection of adequate packaging to maintain the quality of the product and to avoid, as far as possible, risks of misuse or accident;
- Quality control, mainly microbiological and chemical;
- Stability studies e.g. to evaluate shelf life, preservative effectiveness (challenge test), compatibility of the product and the packaging, etc;
- Appropriate labelling - presentation of the product, instructions for use and disposal, warnings (if relevant) and appropriate action to take in case of accident;
- Adequate procedures in case of side effects with the marketed product - case-by-case treatment, appropriate medical, dermatological, ophthalmological etc., advice as necessary, follow-up of the product on the market and consumer comments, information storing etc. In case of Serious Adverse Event, the procedure must be identical to the ASEAN Cosmetic Committee approved Guidelines (Annex I)
- Ensuring corrective action/ follow-up, if any visible product change or adulteration is advised from the market place;

8. Although it is not possible to attain zero risk or to obtain absolute safety in any kind of human activity, including cosmetology, reasonable efforts have to be made to reduce the risk from cosmetic products to the minimum, according to the state of the art at the time.

9. There is no formalistic approach to the safety evaluation process. The actual process will vary from product to product according to the novelty of the product composition and to the relevance and adequacy of information available. However, as a general rule, the major basis for safety evaluation is provided by considering the toxicological profile of its ingredients<sup>3</sup>.

10. From a scientific point of view, in almost all cases finished product testing does not require the use of toxicological tests in animals. In general, all questions which are posed at this stage can be answered by utilising other information sources, including human data from skin compatibility tests ethically performed on the skin of human volunteers<sup>4</sup>.

## 2. INGREDIENTS

11. Cosmetic ingredients are mostly chemicals and often mixtures of chemicals of synthetic origin or natural extracts. The careful selection of ingredients is the key issue for ensuring the safety of the finished product.

12. The structure of the chemical determines its chemical and biological reactivity e.g., Barratt, 1995 <sup>5</sup>. This has to be considered from two points of view: cosmetic interest and safety. Other considerations are the degree of chemical purity, the possible interactions with other ingredients in the formulation and potentiation of skin penetration. In general, the presence of impurities is technically unavoidable. But these impurities have to be of no significant toxicological relevance in the finished product. Particular attention should be taken to the possibility of interaction between impurities (e.g. formation of nitrosamines) and the presence of pesticide residues, toxic metals and/or transmissible spongiform encephalopathies (TSE) in ingredients of botanical origin or extracted from animals.

13. Based on the state of knowledge, possible interactions between ingredients with potential safety relevance have to be considered. Influence on skin penetration may also be of importance, especially for sensitisation and systemic risks <sup>6</sup>. Skin penetration can be assessed using *in vitro* methods <sup>6</sup>. Determination of allergic potential may also require testing of ingredients formulated with suitable vehicles.

14. On the other hand, the safety-in-use of an ingredient largely depends on the exposure conditions (type of formulation, concentration, frequency and duration of contact, body area involved, effect of the sun, etc.) taking into account normal conditions of use and foreseeable misuse.

### 2.1 INGREDIENTS TO BE AVOIDED

15. For each raw material, it is necessary to check whether it is covered by current legislation and, if so, whether the proposed usage is within the prescribed parameters. The following ingredients must be excluded:

- Ingredients prohibited under the ASEAN Cosmetics Directive in Annex II <sup>1</sup>;
- Ingredients restricted under the Cosmetics Directive when used beyond the allowed conditions and restrictions laid down in Annex III <sup>1</sup>;
- Ingredients with toxicological data incompatible with the intended concentration and use;
- Ingredients which do not have sufficient toxicological data and/or safety in use experience;
- Ingredients which are not properly characterized either chemically or through the extraction process for natural extracts
- For colouring agents, preservatives and/or UV filters, ingredients must be substances listed in Annexes IV, VI or VII respectively, within the limits and under the restrictions laid down in these annexes

16. Data to be taken into consideration, besides those directly relating to toxicity, include positive identification of the ingredient, potential impurities of relevance, physico-chemical properties and analytical chemistry, potential interaction with other ingredients of the formulation and possible role in skin penetration.



17. The toxicological profile of a raw material is obtained by analysing available data, published or not, concerning the raw material. These data may include results of *in vitro*, *in vivo* and clinical testing, as well as results of epidemiological studies where available.  
It is clear that new ingredients or ingredients used in a novel application require particular attention.

## 2.2 SOURCES OF TOXICOLOGICAL DATA

18. The main sources of toxicological data on ingredients are the suppliers. Raw material manufacturers have to comply with national legislation on chemicals / dangerous substances (occupational safety, transport, packaging and labelling). Most effort should be made to collect toxicological data and other relevant information from the suppliers. It may be necessary to encourage the supplier to conduct additional studies. Because these data can be needed for regulatory purposes other than the Cosmetics Directive, the use of alternative (non-animal) test methods is restricted to those which are generally accepted (e.g. OECD guidelines).

19. Other sources of toxicological data may be obtained from:

- Scientific literature, databases (e.g. Toxline, Medline), reports issued by the US Cosmetic Ingredient Review (CIR) program, the EU Scientific Committee on Consumer Products (SCCP) or the ASEAN Cosmetic Scientific Body (ACSB), the Research Institute for Fragrance Materials (RIFM) monographs, reports by ECETOC, NTP, BIBRA, etc.;
- Safety Data Sheets;
- In-house experience with the particular ingredient and cosmetic products containing it;
- Expert judgment based on similarities with chemically related substances.

20. Ingredients listed in Annexes III to VII of the ASEAN Cosmetics Directive do not need supporting evidence provided that they are used as specified in the Annexes. In the case of substances in Annex VI in which concentrations higher than those specified may be used for other functions, supporting information is likely to be necessary.

21. The composition of fragrances and flavours is generally not available to the cosmetic manufacturer and use should be made of the safety evaluation as well as conformity to the latest International Fragrance Association (IFRA) Guidelines which have to be provided by the supplier <sup>7</sup>.

## 2.3 CONDITIONS OF USE AND EXPOSURE

22. Evaluation of the safety of ingredients is certainly not adequate as a stand-alone procedure but has to include considerations of exposure (magnitude, route, duration, frequency, etc.) <sup>3</sup>

23. The following parameters have to be considered<sup>8</sup>:

- Class of cosmetic product(s) in which the ingredient is used;
- Method of application (e.g. rubbed-in, sprayed, applied and washed off, etc.);
- Concentration of ingredient in product;
- Quantity of product used for each application;

- Frequency of application;
- Total area of skin contact;
- Site of contact (e.g. mucous membrane, sunburnt skin);
- Duration of contact (e.g. rinse-off products, leave-on products);
- Reasonably foreseeable misuse which may increase exposure;
- Type of consumers (e.g. children, people with sensitive skin);
- Projected number of consumers;
- Application to skin areas exposed to sunlight;
- Quantity likely to enter the body.

This last point, which relates to systemic availability, is a critical issue in safety evaluation - the information is mainly provided by percutaneous absorption data.

### 3. SAFETY EVALUATION OF FINISHED PRODUCTS

24. The assessment of the safety of any cosmetic product clearly relates to the manner of use. This factor is most important since it determines the amount of substance which may be absorbed through the skin or mucous membranes, or ingested or inhaled.

25. As mentioned above, the main sources of information are the toxicological characteristics of ingredients and the available human experience (including market experience, beauticians, factory workers, etc.) with similarly composed products. Each ingredient has to be considered carefully. Particular attention should be paid to new and novel ingredients. Open questions of safety assessment are defined by expert judgement in each individual case after careful review of all available information.

26. In general, the potential of a cosmetic product for sensitisation, genotoxicity and all other types of systemic (toxic) effects will be evaluated on the basis of the properties of the ingredients. Adequate consideration of human exposure is, however, of paramount importance for the interpretation of available data. This involves an examination of the potential role of the vehicle. This holds particularly true for percutaneous absorption or quantitative data concerning any other route of entry into the systemic circulation. The question of possible interaction between different ingredients will usually be evaluated on the basis of experience (similarities, published data on related compounds/mixtures, theoretical considerations, etc.) and may be controlled using *in vitro* testing and/or skin compatibility tests.

27. For assessing the safety-in-use of a finished product, especially the local tolerance, it can be very useful to compare it with other formulae successfully marketed by the company.

28. If the new product is a simple variant of an existing product, or if the formulation only consists of raw materials or ingredients previously used in similar products at common use levels, then it is likely that no additional safety data will be needed.

29. If raw materials are used in new ways, then additional safety data may be required by the safety assessor.

30. If novel raw materials or raw materials new to the company are to be used, then more detailed information will be necessary.

31. Local tolerance largely depends on the whole formulation. Consequently, even with known and safe in- use ingredients, it may be necessary to check the skin compatibility of a new formulation by appropriate testing.

32. When exhaustive analysis of toxicological data on ingredients appears insufficient to define with certainty the local tolerance of the finished product, additional experiments can be performed *in vitro* and/or in human volunteers.

33. *In vitro* testing may be carried out to complement available information with the necessary use of appropriate benchmarks. For ocular safety, methods such as those listed below are available:

- BCOP - Bovine Cornea Opacity and Permeability Test;
- FLT or TEP - Fluorescein Leakage Test or Trans Epithelial Permeability

- HET-CAM - Hen's Egg Test - Chorioallantoic Membrane;
- RBC - Red Blood Cell Test;
- TEA - Tissue Equivalent Assay.

34. Skin compatibility or tolerance may be checked using reconstructed skin models and/or ethically conducted trials on human volunteers.

35. Clinical trials in man should be based on the principles of Good Clinical Practice (GCP) such as that of the EU. The following type of tests may be performed:

- Open epicutaneous application (single or repeated);
- Closed epicutaneous application (single or repeated);
- Controlled application tests;
- Further testing may involve in-use tests and /or market tests.

#### **4. SAFETY CLAIMS**

36. If a safety claim is to be made, e.g., “dermatologically tested”, it has to be supported by adequate evidence. In most cases, appropriate human testing on the finished product will be necessary rather than animal testing. The testing must meet all necessary ethical requirements for a clinical trial<sup>9; 10</sup>. One important prerogative in this respect is the safety assessment by a suitably qualified and experienced person before the trial starts<sup>4</sup>.

## 5. RESPONSIBILITIES OF THE SAFETY ASSESSOR

37. The person in charge of assessing the safety of the product is called the safety assessor. The safety assessor is responsible for determining:

- Whether or not the ingredients present in the formula meet the requirements of the legislation in respect of the concentration for authorised substances, absence of substances prohibited by the law and, more generally, in respect of all legal requirements;
- Whether or not particular endpoint(s) have to be considered for a given ingredient;
- Whether the data available are relevant and sufficient;
- Whether or not interactions of toxicological relevance and/or modifications to penetration are likely to occur;
- Whether or not complementary data are needed either on ingredients or on the finished product.

38. A modern approach to safety assessment is based on a thorough analysis of available data and conditions of exposure. Ideally, the development of the formulation should take into account these elements from the start by a close collaboration between safety assessor and formulator.

39. A proper choice of ingredient at an adequate concentration level is sufficient to avoid the major risks (e.g. genotoxicity, carcinogenicity, systemic toxicity) and also to avoid, to a large degree, sensitisation. Testing on finished products is unnecessary in most cases to assess these risks, provided potential interactions between ingredients and role of vehicle are considered.

In most cases, the knowledge of all information available is sufficient to assess the safety of finished products. In the case of totally new ingredients, new combinations of ingredients or new formulation processes without safety-in-use experience, additional testing may be needed.

However, in all cases, all information on ingredients and formulations should be made accessible by the suppliers and formulator to the safety assessor to ensure an adequate safety assessment.

40. The Safety Assessor should possess qualification in relevant fields *for example* a diploma in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline and be suitably trained in the safety assessment of cosmetics.

41. The role and responsibility of the safety assessor have to be emphasised. It is in the interest of the company to select a person knowledgeable in the field of safety evaluation applied to cosmetics and who is responsible and ethical.

42. The Safety Assessor does not need to be an employee of the company and can belong to an external organization or institution, as long as he has the required qualification.

43. The safety assessor must:

- Have recognised competence and ethics in the field;

- Have access both to the toxicological and to the analytical information pertinent from a safety view point. Some questions are likely to be raised by the safety assessor concerning, e.g. purity of raw materials, impurity profile - if available, and control procedures applied, detailed information on a test mentioned or referred to by the supplier, quantitative analysis of an impurity with a potential toxicological relevance, etc;
- Not be involved with the commercial aspects related to the product;

44. Safety assessment may require human testing to check skin compatibility of both cosmetic ingredients and finished products. Any such trials have to be carried out following the appropriate ethical requirements<sup>9; 10</sup>.

45. The judgment of the safety assessor relies on:

- The knowledge and experience of toxicological properties and safety-in-use of the known ingredients;
- The history of safety-in-use of products containing the same or similar ingredients;
- The expert judgment of the set of data available on an unknown, new or novel ingredient;
- If necessary, the results of additional data obtained either on one or more ingredients or on the finished product.

46. The safety assessor may conclude:

- The product is safe as such without special warnings or precautions;
- The product is safe provided a given type of packaging is used or provided a warning is added or the mode of use and usage instructions are defined more precisely or provided a complementary test with favourable results is performed;
- The product is not safe for the proposed use;
- That available data are not sufficient to determine whether or not the product will be safe and that further studies need to be carried out to obtain the required information;
- Specific safety claim(s) may or may not be used.

47. A product cannot be marketed if the conclusion of the safety assessor is that the product may not be marketed safely under the normal or reasonably foreseeable conditions of use. Recommendations by the safety assessor which are relevant for the safety-in-use of the product have to be followed. They are part of the safety statement the assessor signs which should be presented, together with the qualifications of the safety assessor, to the relevant regulatory authorities (inspectors) when required.

48. Selecting the safety assessor thus appears to be a key issue for the manufacturer of cosmetic products. It is not only a legal issue: it may also have importance for other aspects such as, for example, the image of the company as well as product liability implications.

## 6. Raw Material Supplier Responsibilities

### 1. Chemicals

49. Provide its customers with adequate information as to the safety of the ingredients supplied:
- Physical/chemical/microbiological specifications-purity
  - Absence of Annex II ingredients beyond unavoidable traces (e.g. heavy metals)
  - Toxicity studies:
    - Acute toxicity
    - Dermal absorption
    - Skin (and eye) irritation
    - Mucous membrane irritation (if necessary)
    - Skin sensitisation
    - Sub-chronic toxicity
    - Mutagenicity
    - Photo toxicity and photo mutagenicity (if necessary)
    - Human data (if available)

### 2. Botanicals Extracts:

50. Provide its customers with adequate information as to the safety of the ingredients supplied:
- Proper identification of the plant/part used
  - Physical/chemical/microbiological specifications-purity
  - Pesticide level
  - Absence of Annex II ingredients beyond unavoidable traces (e.g. heavy metals)
  - Toxicity studies:
    - Skin irritation – sensitisation
    - Photo toxicity – photo sensitisation (if necessary)
    - Mutagenicity

### 3. Animal Extracts:

51. Provide its customers with adequate information as to the safety of the ingredients supplied:
- Proper identification of the animal/part used
  - Physical/chemical/microbiological specifications-purity
  - Absence of Transmissible Spongiform Encephalopathy
  - Absence of Annex II ingredients beyond unavoidable traces (e.g. hormones, antibiotics, etc)
  - Toxicity studies:
    1. Skin irritation – sensitisation
    2. Photo toxicity – photo sensitisation (if necessary)
    3. Mutagenicity



#### **4. Fragrances and flavours:**

52. Provide its customers with adequate information as to the safety of the fragrances supplied:
- Certificate of compliance with latest IFRA Guidelines
  - Maximum safe concentration depending of the product type

#### **7. Manufacturer Responsibilities**

53. Including:
- Careful selection of cosmetic ingredients, making sure they will be safe at a given concentration in a given finished product
  - Checking local tolerance of the finished product
  - Selection of adequate packaging to maintain the quality of the product and to avoid, as far as possible, risks of misuse or accident
  - Applying ASEAN Cosmetic Good Manufacturing Practices
  - Quality control, mainly microbiological and chemical
  - Appropriate labelling: presentation of the product, instruction for use and disposal, warnings (if relevant) and appropriate actions to take in case of accident
  - Adequate procedures in case of side effects with the marketed product
  - Ensures corrective action, follow-up if visible product change or adulteration is advised from the market place
  - Proper selection of the Safety Assessor

#### **8. Distributor Responsibilities**

54. Including:
- Make sure the manufacturer has the adequate systems to ensure product safety (including GMP)
  - Collect information on post marketing experience and transfer such information to the manufacturer on a timely basis, determine trends and keep adequate records
  - Report any Serious Adverse Event to the Authorities

#### **9. Regulator Responsibilities**

55. Including:
- Ensure public health and safety
  - Audits samples from the market
  - Audit PIF
  - Inspection of company premises
  - In case of Serious Adverse Event collaborate with the Industry to take proper actions
  - In case of product testing showing potential risk for human health or adulterated product, take appropriate measures to remove the product from the market, communicate with the public and take appropriate action on the responsible company/person

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## **Annex 1, Part 7**

### **ASEAN COSMETIC LABELING REQUIREMENTS**

#### **A. OBJECTIVE**

1. This document provides guidance for the labeling requirements of cosmetic products to which Article 6 of the ASEAN Cosmetic Directive 05/01/ACCSQPWG apply.

#### **B. SCOPE AND DEFINITIONS**

1. For the purpose of this document:

*Name of the cosmetic product* means the name given to a cosmetic product, which may be an invented name, together with a trade mark or the name of the manufacturer;

*Immediate packaging* means the container or other form of packaging immediately in contact with the cosmetic product;

*Outer packaging* means the packaging into which is placed the immediate packaging;

*Labeling* means information written or printed or graphic matter on the immediate or outer packaging and any form of leaflets;

#### **C. LABELING OF COSMETIC PRODUCTS**

1. The following particulars shall appear on the outer packaging of cosmetic products or, where there is no outer packaging, on the immediate packaging of cosmetic products:
  - a) The name of the cosmetic product and its function, unless it is clear from the presentation of the product;
  - b) Instructions on the use of the cosmetic product, unless it is clear from the product name or presentation;
  - c) Full ingredient listing. The ingredients must be declared in descending order of weight at the time they are added. Perfume and aromatic compositions and their raw materials may be referred to by the word "perfume", "fragrance", "aroma" or "flavor". Ingredients in concentrations of less than 1% may be listed in any order after those of concentration of more than 1%. Coloring agents may be listed in any order after the other ingredients, in accordance with the color index number or denomination adopted in Annex IV.

For decorative cosmetic products marketed in several color shades, all coloring agents used in the range may be listed, provided that the terms "may contain" or "+/-" be added.

The ingredients shall be specified using the nomenclature from the latest edition of standard references (Refer to appendix A). Botanicals and

extract of botanicals should be identified by its genus and species. The genus may be abbreviated;

The following shall not, however, be regarded as ingredients:

- Impurities in the raw materials used;
- Subsidiary technical materials used in the preparation but not present in the final products;
- Materials used in strictly necessary quantities as solvents, or as carriers, for perfume and aromatic compositions;

- d) Country of manufacture;
- e) The name and address of the company or person responsible for placing the product on the local market;
- f) The contents given by weight or volume, in either metric or both metric and imperial system;
- g) The manufacturer's batch number;
- h) The manufacturing or the expiry date of the product in clear terms (e.g. month/year). The date shall be clearly expressed and shall consist either of the month and year or the day, month and year in that order. The date of minimum durability shall be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with article 3. It should be preceded by the words "expiry date" or "best before". If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

Indication of the expiry date shall be mandatory for cosmetic products the minimum durability of which is less than 30 months.

- i) Special precautions to be observed in use, especially those listed in the column "Conditions of use and warnings which must be printed on the label in Annexes \_\_", which must appear on the label as well as any special precautionary information on the cosmetic products.

Member countries may require specific warnings based on local needs for declaration of ingredients from animal origin. In this case:

- i. There must be a statement (of any format) on the product label signaling the presence of ingredients of animal origin;
- ii. For ingredients of bovine or porcine origin, the exact animal must be declared;

- 2. In cases where the size, shape or nature of the container or package does not permit the particulars laid down in paragraphs 1 (a) – (i) to be displayed, the use of leaflets, pamphlets, hang tags, display panel, shrink wrap, etc. shall be allowed. However the following particulars at least shall appear on small immediate packaging:
  - a) The name of the cosmetic product;
  - b) The manufacturer's batch number;
- 3. The particulars referred to in paragraphs 1 and 2 shall be easily legible, clearly comprehensible and indelible;
- 4. The particulars listed in paragraph 1 shall appear in English and/or National Language and/or a language understood by the consumer where the product is marketed. Member Countries may require that the information in paragraphs a),

b), e), f) and i) be in the national language or a language easily understood by the consumer;

## **APPENDIX A**

### **List of Standard References to be used for Cosmetic Ingredient Nomenclature**

1. International Cosmetic Ingredient Dictionary;
2. British Pharmacopeia;
3. United States Pharmacopeia;
4. Chemical Abstract Services;

## **Annex 1, Part 8**

### **ASEAN COSMETIC CLAIM GUIDELINE**

#### **1. Introduction**

The evaluation of product claims cannot be separated from the consideration of whether a product is a cosmetic or not. Whether a product can be considered to be a cosmetic product depends on several factors, claims are an important element of this process. This guideline provides a simple 5-step decision-making process that helps to identify products and claims which can be considered to be cosmetics. The document also provides some examples of unacceptable claims for cosmetic products. However, it is not to be taken as the final authority nor as an exhaustive list.

#### **2. Decision Process to identify cosmetic products and allowable claims (See summary chart below)**

##### **a. Composition of cosmetics**

The product should contain only ingredients that comply with the annexes of ACD, and does not contain any ingredients that are banned in the ACD.

##### **b. Target site of application of cosmetics**

The product should be intended to be placed in contact with the various 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.

Products that are intended to be ingested, injected or placed in contact with other parts of the human body e.g. the mucous membranes of the nasal passage or the internal genitalia cannot be considered to be cosmetic products.

##### **c. Intended main function of cosmetics**

The product should be applied to the permitted parts of the human body with a view exclusively or mainly to clean them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition.

Note that products may have a secondary, minor function that is outside the above scope. Some examples of acceptable secondary claim areas are given below. Note that this is not an exhaustive list.

- |                   |              |
|-------------------|--------------|
| ● Dandruff        | ● Caries     |
| ● Cellulite       | ● Hair loss  |
| ● Bust contouring | ● Acne       |
| ● Anti-bacterial  | ● Mouth wash |

##### **d. Product presentation of cosmetics**

The product should not be presented as treating or preventing disease in human beings. The following features of the product should be taken into account

- i. Product claims and the context in which the claims are made
- ii. Labeling and packaging/packaging inserts (including graphics)
- iii. Promotional literature, including testimonials and literature issued by third parties on behalf of the supplier
- iv. Advertisements

- v. The product form and the way it is to be used e.g. capsule, tablet, injection etc.
- vi. Particular target of the marketing information e.g. specific population groups with, or particularly vulnerable to, specific diseases or adverse conditions.

e. Physiological effects of cosmetics

Every product that has an effect on the functioning of the body also has an effect on its metabolism. Cosmetic products typically have effects that are not permanent, and have to be used regularly to maintain their effects.

As a first point of guidance, claims that can be reasonably expected for product types given in the Illustrative List of Cosmetic Products (Annexe 1 ACD) can be considered to be cosmetic in nature.

Section 3. below gives some examples of unacceptable claims for cosmetic products. Note that it is not an exhaustive list.

**3. Some examples of unacceptable claims commonly observed for cosmetics under the product types.**

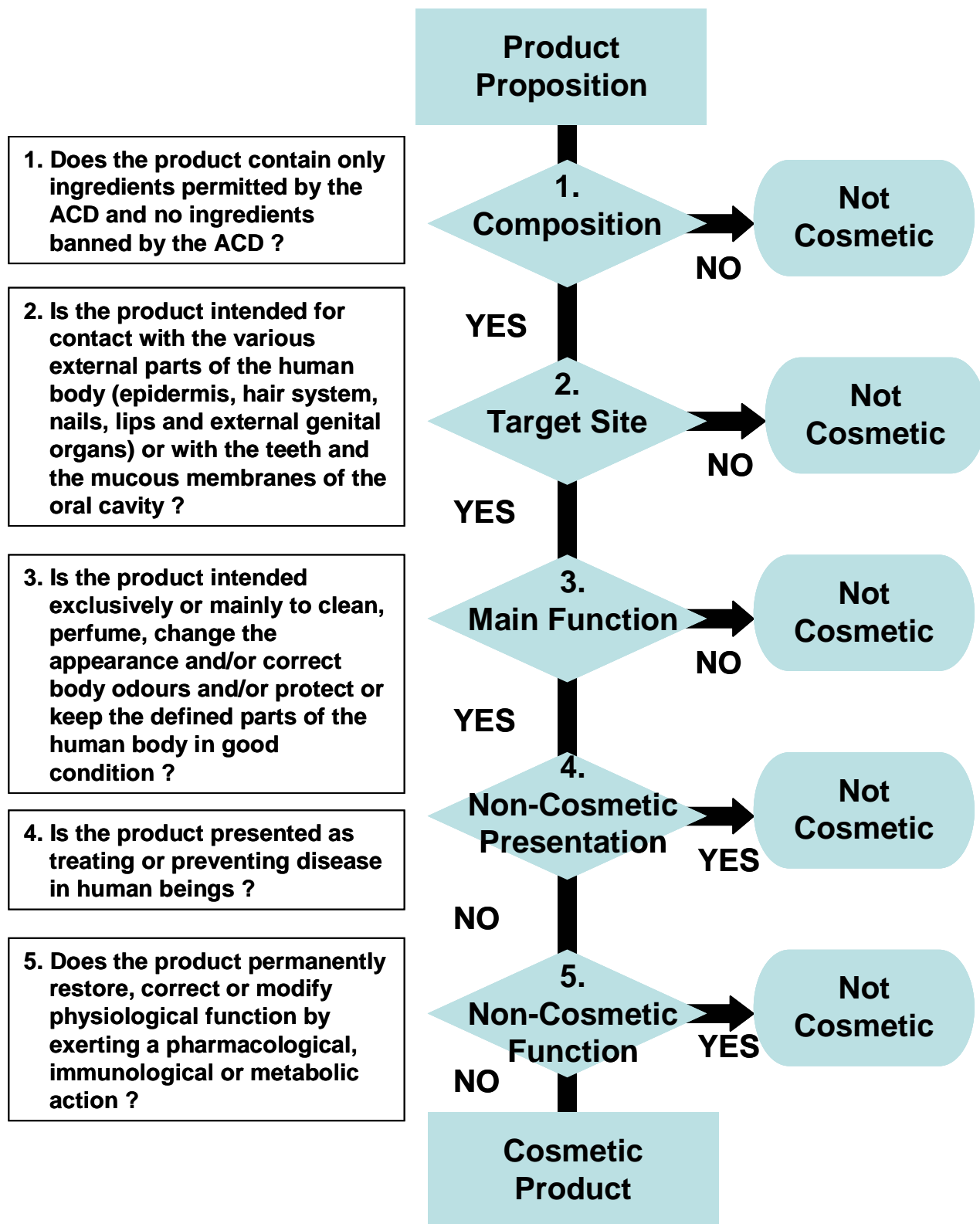
Product Type	Unacceptable claims
Hair care products	<ul style="list-style-type: none"> <li>• Eliminates dandruff permanently</li> <li>• Restores hair cells</li> <li>• Hair loss can be arrested or reversed</li> <li>• Stimulates hair growth</li> </ul>
Depilatories	<ul style="list-style-type: none"> <li>• Stops/retards/prevents hair growth</li> </ul>
Nail products	<ul style="list-style-type: none"> <li>• Reference to growth resulting from nourishment</li> </ul>
Skin products	<ul style="list-style-type: none"> <li>• Prevents, reduces or reverses the physiological changes and degeneration conditions brought about by aging</li> <li>• Removes scars</li> <li>• Numbing effect</li> <li>• Prevents, heals, treats or stops acne</li> <li>• Treatment of cellulite</li> <li>• Lose centimetres</li> <li>• Reduces/controls swelling/oedema</li> <li>• Removes/burns fat</li> <li>• Fungicidal action</li> <li>• Virucidal action</li> </ul>
Oral or dental hygiene products	<ul style="list-style-type: none"> <li>• Treatment or prevention of dental abscess, gumboils, inflammation, mouth ulcers, periodontitis, pyorrhoea, periodontal disease, stomatitis, thrush or any oral diseases or infections</li> <li>• Whitens tetracycline-induced stains</li> </ul>
Deodorants & Anti-perspirants	<ul style="list-style-type: none"> <li>• Completely prevents sweating/perspiration</li> </ul>
Perfumes/fragrances/colognes	<ul style="list-style-type: none"> <li>• Aphrodisiac or hormonal attraction</li> </ul>

Note that claims can be softened i.e. made less functional and more cosmetic in nature by the use of modifiers. An example of this would be a claim for removing all oil from skin. This claim could be softened as follows,

- Helps to remove oil from skin
- Reduces the shine of oily skin
- Suitable for oily skin types
- Makes your skin feel less oily



## Decision process to identify cosmetic products & claims



## **Annex 1, Part 9**

### **ASEAN GUIDELINES FOR COSMETIC GOOD MANUFACTURING PRACTICE**

#### **PREAMBLE**

The GMP Guidelines have been produced to offer assistance to the cosmetic industry in compliance with the provisions of the ASEAN Cosmetic Directive. As this document is particularly intended for cosmetic products, clear delineation from drug or pharmaceutical product GMP should be kept in mind.

The Good Manufacturing Practices presented here is only a general guideline for the manufacturers to develop its own internal quality management system and procedures. The important objective must be met in any case, i.e. the final products must meet the quality standards appropriate to their intended use to assure consumer's health and benefit.

#### **1. INTRODUCTION**

The objective of the Cosmetic Good Manufacturing Practice (GMP) guidelines is to ensure that products are consistently manufactured and controlled to the specified quality. It is concerned with all aspects of production and quality control.

##### **1.1 General Consideration**

- 1.1.1 In the manufacture of cosmetic products, overall control and monitoring is essential to ensure that the consumer receives products of specified quality.
- 1.1.2 The quality of a product depends on the starting materials, production and quality control processes, building, equipment and personnel involved.

##### **1.2 Quality Management System**

- 1.2.1 A quality system should be developed, established and implemented as a means by which stated policies and objectives will be achieved. It should define the organisational structure, functions, responsibilities, procedures, instructions, processes and resources for implementing the quality management.
- 1.2.2 The quality system should be structured and adapted to the company's activities and to the nature of its products and should take into consideration appropriate elements stated in this

Guidelines.

- 1.2.3 The quality system operation should ensure that if necessary, samples of starting materials, intermediate, and finished products are taken, tested to determine their release or rejection on the basis of test results and other available evidence related to quality.

## **2. PERSONNEL**

There should be an adequate number of personnel having knowledge, experience, skill and capabilities relevant to their assigned function. They should be in good health and capable of handling the duties assigned to them.

### **2.1 Organisation, Qualification and Responsibilities**

- 2.1.1 The organisational structure of the company shall be such that the production and the quality control sections are headed by different persons, neither of whom shall be responsible to the other.
- 2.1.2 The head of production should be adequately trained and experienced in cosmetic manufacturing.  
  
He should have authority and responsibilities to manage production of products covering operations, equipment, production personnel, production areas and records.
- 2.1.3 The head of quality control should be adequately trained and experienced in the field of quality control. He should be given full authority and responsibility in all quality control duties such as establishment, verification and implementation of all quality control procedures. He should have the authority to designate/assign when appropriate, personnel, to approve starting materials, intermediates, bulk and finished products that meet the specification or to reject those which do not conform to the relevant specification or which were not manufactured in accordance with approved procedures and under the defined conditions.
- 2.1.4 The responsibilities and authority of key personnel should be clearly defined.
- 2.1.5 An adequate number of trained personnel should be appointed to execute direct supervision in each section of the production and the quality control unit.

## **2.2 Training**

- 2.2.1 All personnel directly involved in the manufacturing activities should be appropriately trained in manufacturing operations in accordance to GMP principles. Special attention should be given to training of personnel working with any hazardous materials
- 2.2.2 Training in GMP should be conducted on a continuous basis.
- 2.2.3 Records of training should be maintained and its effectiveness assessed periodically.

## **3. PREMISES**

The premises for manufacturing should be suitably located, designed, constructed and maintained.

- 3.1 Effective measures should be taken to avoid any contamination from the surrounding environment and from pests.
- 3.2 Household products containing non-hazardous materials/ingredients and cosmetic products can share the same premises and equipment provided that due care should be exercised to prevent cross contamination and risk of mix-up.
- 3.3 Painted line, plastic curtain and flexible barrier in the form of rope or tape may be employed to prevent mix-up.
- 3.4 Appropriate changing rooms and facilities should be provided. Toilets should be separated from the production areas to prevent product contamination/cross contamination.
- 3.5 Defined areas should be provided for, wherever possible and applicable:
  - 3.5.1 Materials receiving.
  - 3.5.2 Material Sampling
  - 3.5.3 Incoming goods and quarantine.
  - 3.5.4 Starting materials storage.
  - 3.5.5 Weighing and dispensing.
  - 3.5.6 Processing.
  - 3.5.7 Storage of bulk products.

- 3.5.8 Packaging.
- 3.5.9 Quarantine storage before final release of products.
- 3.5.10 Storage of finished products.
- 3.5.11 Loading and unloading.
- 3.5.12 Laboratories.
- 3.5.13 Equipment washing.
- 3.6 Wall and ceiling, where applicable should be smooth and easy to maintain. The floor in processing areas should have a surface that is easy to clean and sanitise.
- 3.7 Drains should be of adequate size and should have trapped gullies and proper flow. Open channels should be avoided where possible, but if required they should be able to facilitate cleaning and disinfection.
- 3.8 Air intakes and exhausts and associated pipework and ducting, when applicable, should be installed in such a way as to avoid product contamination.
- 3.9 Buildings should be adequately lit and properly ventilated appropriate to the operations. .
- 3.10 Pipework, light fittings, ventilation points and other services in manufacturing areas should preferably be installed in such a way as to avoid uncleanable recesses and run outside the processing areas.
- 3.11 Laboratories should preferably be physically separated from the production areas.
- 3.12 Storage areas should be of adequate space provided with suitable lighting, arranged and equipped to allow dry, clean and orderly placement of stored materials and products.
  - 3.12.1 Such areas should be suitable for effective separation of quarantined materials and products. Special and segregated areas should be available for storage of flammable and explosive substances, highly toxic substances, rejected and recalled materials or returned goods.
  - 3.12.2 Where special storage conditions e.g. temperature, humidity and security are required, these should be provided.

- 3.12.3 Storage arrangements should permit separation of different labels and other printed materials to avoid mix-up.

## **4. EQUIPMENT**

Equipment should be designed and located to suit the production of the product.

### **4.1 Design and Construction**

- 4.1.1 The equipment surfaces coming into contact with any in-process material should not react with or adsorb the materials being processed.
- 4.1.2 Equipment should not adversely affect the product through leaking valves, lubricant drips and through inappropriate modifications or adaptations.
- 4.1.3 Equipment should be easily cleaned.
- 4.1.4 Equipment used for flammable substances should be explosion proof.

### **4.2 Installation and Location**

- 4.2.1 Equipment should be located to avoid congestion and should be properly identified to assure that products do not become admixed or confused with one another.
- 4.2.2 Water, steam and pressure or vacuum lines, where applicable, should be installed so as to be easily accessible during all phases of operation. They should be clearly identified.
- 4.2.3 Support systems such as heating, ventilation, air conditioning, water (such as potable, purified, distilled), steam, compressed air and gases (example nitrogen) should function as designed and identifiable.

### **4.3 Maintenance**

Weighing, measuring, testing and recording equipment should be serviced and calibrated regularly. All records should be maintained.

## **5. SANITATION AND HYGIENE**

Sanitation and hygiene should be practised to avoid contamination of the manufacturing of products. It should cover personnel, premises, equipment/apparatus and production materials and containers.

### **5.1 Personnel**

- 5.1.1 Personnel should be healthy to perform their assigned duties. Regular medical examination must be conducted for all production personnel involved with manufacturing processes.
- 5.1.2 Personnel must practise good personal hygiene..
- 5.1.3 Any personnel shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products should not be allowed to handle raw materials, packaging materials, in-process materials, and finished products.
- 5.1.4 Personnel should be instructed and encouraged to report to their immediate supervisor any conditions (plant, equipment or personnel) that they consider may adversely affect the products.
- 5.1.5 Direct physical contact with the product should be avoided to ensure protection of the product from contamination. Personnel should wear protective and clean attire appropriate to the duties they perform,.
- 5.1.6 Smoking, eating, drinking and chewing, , food, drinks and smoking materials and other materials that might contaminate are not permitted in production, laboratory, storage or other areas where they might adversely affect product quality.
- 5.1.7 All authorised personnel entering the production areas should practice personal hygiene including proper attire.

### **5.2 Premises**

- 5.2.1 Adequate employee's washing and well ventilated toilet facilities should be provided and separated from the production area.
- 5.2.2 Suitable locker facilities should be provided at appropriate location for the storage of employees' clothing and personal belongings.

- 5.2.3 Waste material should be regularly collected in suitable receptacles for removal to collection points outside the production area.
- 5.2.4 Rodenticides, insecticides, fumigating agents and sanitising materials must not contaminate equipment, raw materials, packaging materials, in-process materials or finished products.

### **5.3 Equipment and Apparatus**

- 5.3.1 Equipment and utensils should be kept clean.
- 5.3.2 Vacuum or wet cleaning methods are preferred. Compressed air and brushes should be used with care and avoided if possible, as they increase the risk of product contamination.
- 5.3.3 Standard operating procedures must be followed for cleaning and sanitising of major machines.

## **6. PRODUCTION**

### **6.1 Starting Materials**

#### **6.1.1 Water**

Special attention should be paid to water, since it is an important raw material. Water production equipment and water systems should supply quality water. Water systems should be sanitized according to well-established procedures.

The chemical and microbiological quality of water used in production should be monitored regularly, according to written procedures and any anomaly should be followed by corrective action.

The choice of method for water treatment such as deionisation, distillation or filtration depends on product requirement. The storage as well as delivery system should be properly maintained.

#### **6.1.2 Verification of materials**

All deliveries of raw materials and packaging materials should be checked and verified for their conformity to specifications and be traceable to the product.

Samples of raw materials should be physically checked for conformity to specifications prior to release for use. The raw materials should be clearly labelled. All goods must be clean and



checked for appropriate protective packing to ensure no leakage, perforation or exposure.

### **6.1.3 Rejected materials**

Deliveries of raw materials that do not comply with specification should be segregated and disposed according to standard operating procedures.

## **6.2 Batch Numbering System**

- 6.2.1 Every finished product should bear a production identification number which enables the history of the product to be traced..
- 6.2.2 A batch numbering system should be specific for the product and a particular batch number should not be repeated for the same product in order to avoid confusion.
- 6.2.3 Whenever possible, the batch number should be printed on the immediate and outer container of the product.
- 6.2.4 Records of batch number should be maintained.

## **6.3 Weighing and Measurement**

- 6.3.1 Weighing should be carried out in the defined areas using calibrated equipment.
- 6.3.2 All weighing and measurement carried out should be recorded and , where applicable, counterchecked.

## **6.4 Procedure and Processing**

- 6.4.1 All starting materials used should be approved according to specifications.
- 6.4.2 All manufacturing procedures should be carried out according to written procedures 6.4.3 All required in-process controls should be carried out and recorded.
- 6.4.4 Bulk products should be properly labelled until approved by Quality Control, where applicable.
- 6.4.5 Particular attention should be paid to problem of cross-contamination in all stages of processing.

## **6.5 Dry Products**

Handling of dry materials and products should be given special attention. Where possible, dust-containing production system, central vacuum system or other suitable methods should be employed.

## **6.6 Wet Products**

- 6.6.1 Liquids, creams and lotions should be produced in such a way as to protect the product from microbial and other contamination.
- 6.6.2 The use of closed systems of production and transfer is recommended.
- 6.6.3 Where pipe-lines are used for delivery of ingredients or bulk products, care should be taken to ensure that the systems are easy to clean.

## **6.7 Labelling and Packaging**

- 6.7.1 Packaging line should be inspected for clearance prior to operation. Equipment should be clean and functional. All materials and products from previous packaging operation should have been removed.
- 6.7.2 Samples should be taken and checked at random during labelling and packaging operations.
- 6.7.3 Each labelling and packaging line should be clearly identified to avoid mix-up.
- 6.7.4 Excess labels and packaging materials should be returned to store and recorded. Any rejected packaging materials should be disposed off accordingly..

## **6.8 Finished Product: Quarantine and Delivery to Finished Stock**

- 6.8.1 All finished products should be approved by Quality Control prior to release.

## **7. QUALITY CONTROL**

### **7.1 Introduction**

Quality control is an essential part of GMP. It provides assurance that cosmetic products will be of consistent quality appropriate to their intended use.

7.1.1 A quality control system should be established to ensure that products contain the correct materials of specified quality and quantity and are manufactured under proper conditions according to standard operating procedures.

7.1.2 Quality control involves sampling, inspecting and testing of starting materials, in process, intermediate, bulk, and finished products. It also includes where applicable, environmental monitoring programs, review of batch documentation, sample retention program, stability studies and maintaining correct specifications of materials and products.

### **7.2 Reprocessing**

7.2.1 The methods of reprocessing should be evaluated to ensure that they do not affect the quality of the product.

7.2.2 Additional testing of any finished product which has been reprocessed should be performed.

### **7.3 Returned Products**

7.3.1 Returned products should be identified and stored separately either in allocated area or by moveable barrier such as rope or tape.

7.3.2 All returned products should be tested if necessary, in addition to physical evaluation before being released for distribution.

7.3.3 Returned products which do not comply with the original specification should be rejected.

7.3.4 Rejected products should be disposed according to appropriate procedures.

7.3.5 Records of returned products must be maintained.

## **8. DOCUMENTATION**

### **8.1 Introduction**

The documentation system should include the complete history of each batch, from starting materials to finished products. The system should record executed activities for maintenance, storage, quality control, primary distribution and other specific matters related to GMP.

- 8.1.1 There should be a system for preventing the use of any superseded document.
- 8.1.2 If an error is made or detected on a document, it should be corrected in such a manner that the original entry is not lost and correction is made close to the original entry, initialled and dated.
- 8.1.3 Where documents bear instructions they should be clearly written step by step.
- 8.1.4 Documents should be dated and authorised.
- 8.1.5 Documents should be readily available to relevant parties.

### **8.2 Specifications**

All specifications should be approved by authorised personnel.

- 8.2.1 Raw and packaging material specifications should include :
  - (a) Name of material
  - (b) Description of the material
  - (c) Testing parameters and acceptance limits
  - (d) Technical drawings, where applicable.
  - (e) Special precautions e.g. storage and safety conditions, if necessary.
- 8.2.2 Bulk and finished product specifications should include :
  - (a) Name of product
  - (b) Description
  - (c) Physical properties

- (d) Chemical assay and/or microbiological assays and their acceptance limits ; if necessary
- (e) Storage conditions and safety precautions, if necessary

### **8.3 Documents for Production**

#### **8.3.1 Master Formula**

The Master formula should be available upon request. This document should contain the following information :

- (a) Product name and product code/number.
- (b) Intended packaging materials, and storage conditions
- (c) List of raw materials used
- (d) List of equipment used.
- (e) In-process controls with their limits in processing and packaging, where applicable.

#### **8.3.2 Batch Manufacturing Record ( BMR )**

- (a) Batch Manufacturing Records should be prepared for each batch of product.
- (b) Each BMR should include the following :
  - i. Name of product
  - ii. Batch formula
  - iii. Brief manufacturing process
  - iv. Batch or code number
  - v. Date of the start and finish of processing and packaging
  - vi. Identity of individual major equipment and lines or location used
  - vii. Records of cleaning of equipment used for processing as appropriate
  - viii. In-process control and laboratory results, such as pH and temperature test records
  - ix. Packaging line clearance inspection records
  - x. Any sampling performed during various steps of processing
  - xi. Any investigation of specific failure or discrepancies
  - xii. Results of examinations on packed and labelled products

### 8.3.3 Records for Quality Control

- (a) Records for each testing, assay result and release or rejection of starting materials, intermediates, bulk and finished product should be maintained.
- (b) These records may include :
  - i. Date of test
  - ii. Identification of the material
  - iii. Supplier name
  - iv. Date of receipt
  - v. Original batch number if any
  - vi. Batch number
  - vii. Quality control number
  - viii. Quantity received
  - ix. Date of sampling
  - x. Quality control results

## 9. INTERNAL AUDITS

An internal audit consists of an examination and assessment of all or part of a quality system with the specific purpose of improving it. An internal audit may be conducted by outside or independent specialists or a team designated by the management for this purpose. Such internal audits may also be extended to suppliers and contractors, if necessary. A report should be made at the completion of each internal audit.

## 10. STORAGE

### 10.1 Storage Areas

- 10.1.1 Storage areas should be of sufficient capacity to allow orderly storage of the various categories of materials and products such as starting and packaging materials, intermediates, bulk and finished products, products in quarantine, and released, rejected, returned, or recalled products.
- 10.1.2 Storage areas should be designed or adapted to ensure good storage conditions. They should be clean, dry and well-maintained. Where special storage conditions are required ( temperature and humidity ) these should be provided, checked and monitored.
- 10.1.3 Receiving and dispatch bays should protect materials and products from weather. Reception areas should be designed

and equipped to allow incoming materials to be cleaned if necessary before storage.

- 10.1.4 Storage areas for quarantine products should be clearly demarcated.
- 10.1.5 Wherever possible sampling area for starting materials should be provided to prevent contamination.
- 10.1.6 Hazardous materials should be safely and securely stored.

## **10.2 Stock Handling and Control**

### **10.2.1 Receiving Products**

- 10.2.1.1 Upon receipt, each incoming delivery should be checked against the relevant documentation and physically verified by label description, type and quantity.
- 10.2.1.2 The consignment should be carefully inspected for defects and damage. Records should be retained for each delivery.

### **10.2.2 Control**

- 10.2.2.1 Records should be maintained showing all receipts and issues of products.
- 10.2.2.2 Issues should observe the principle of stock rotation (first in - first out).
- 10.2.2.3 All labels and containers of products should not be altered, tampered or changed.

## **11. CONTRACT MANUFACTURING AND ANALYSIS**

The conditions of contract manufacturing and analysis should be clearly defined, agreed, and controlled so as to avoid misunderstandings, which could result in a product or work of unsatisfactory quality. All aspects of contracted work should be specified to obtain a quality product conforming to the agreed standards.

There should be a written contract between the principal and the contract manufacturer to clearly establish the duties and responsibilities of each party.

## 12. COMPLAINTS

- 12.1 A person responsible for handling complaints and deciding the measures to be taken should be designated. If this person is different from the authorised person, the latter should be made aware of any complaint, investigation or recall.
- 12.2 There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint involving a possible product defect.
- 12.3 Complaints involving product defects should be recorded with all the original details and investigated.
- 12.4 If a product defect is discovered or suspected in a batch, consideration should be given to whether other batches should be checked in order to determine whether they are also affected. In particular, other batches that may contain reprocessed product from the defective batch should be investigated.
- 12.5 Where necessary, appropriate follow-up action, possibly including product recall, should be taken after investigation and evaluation of the complaint.
- 12.6 All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.
- 12.7 Complaint records should be regularly reviewed for an indication of specific or recurring problems that require attention and might justify the recall of marketed products.
- 12.8 The competent authority should be informed if a manufacturer is considering action following possibly faulty manufacture and product deterioration, which may lead to serious safety issues.

## 13. PRODUCT RECALLS

There should be a system of recall from the market of products known or suspected to be defective.

- 13.1 A person responsible for the execution and co-ordination of recalls should be designated, as well as sufficient personnel, to handle all aspects of recalls with the appropriate degree of urgency.
- 13.2 Written procedures for recall should be established and regularly reviewed. Recall operations should be capable of being initiated promptly.



- 13.3 The primary distribution records should be readily available to the person(s) responsible for recalls, and they should contain sufficient information of distributors.
- 13.4 The progress of the recall process should be recorded and a final report issued, including a reconciliation between the delivered and recovered quantities of the products.
- 13.5 The effectiveness of the arrangements for recalls should be evaluated from time to time.
- 13.6 A written instruction should be established to ensure recalled products are stored securely in a segregated area while awaiting decision..

## **14. GLOSSARY**

### **14.1 Batch**

A quantity of any cosmetic product produced in a given cycle of manufacture that is uniform in character and quality.

### **14.2 Batch Number**

A designation in numbers and/or letters or combination of both that identifies the complete history of the batch, quality control and distribution.

### **14.3 Bulk Product**

Any processed product which will have to undergo the packaging operation in order to become a finished product.

### **14.4 Calibration**

Combination of checking an instrument and adjusting it to bring it within its limits for accuracy according to recognized standards.

### **14.5 Date of Manufacture**

Date of manufacturing of a batch of product.

### **14.6 Documentation**

All written procedures, instructions and records involved in the manufacture and quality control of products.

## **14.7 Product**

Any substance or preparation intended to be used, or capable or purported or claimed to be capable of being used, in or for cleansing, improving, altering or beautifying the complexion, skin, hair or teeth.

## **14.8 Finished Product**

A product which has undergone all stages of manufacturing operations.

## **14.9 In-Process Control**

Checks and tests instituted and carried out in the course of the manufacture of a product including checks and tests done on environment and equipment in order to ensure that the end product will comply with its specification.

## **14.10 Intermediate Product**

Any processed substance or mixture of substances which has to undergo one or more stages of processing to become a bulk product.

## **14.11 Manufacture or Manufacturing**

The complete set of activities to produce a product, comprising of production and quality control, from acquisition of all raw materials through processing and subsequent packaging and release for distribution of the finished product.

## **14.12 Packaging**

The part of production cycle applied to a bulk product to obtain the finished product.

## **14.13 Packaging Material**

Any material used in the packaging of a bulk product to obtain the finished product.

## **14.14 Processing**

The part of production cycle starting from weighing of raw materials to obtaining a bulk product.

## **14.15 Production**

All operations starting from processing to packaging to obtain a finished product.

#### **14.16 Quality Control**

All measures taken during manufacturing which are designed to ensure the uniform output of product that will conform to established specifications.

#### **14.17 Quarantine**

The status of materials or products set apart physically or by system, while awaiting a decision for their rejection or release for processing, packaging or distribution.

#### **14.18 Raw Materials**

Any ingredient to be used in the formulation of a cosmetic product.

#### **14.19 Rejected**

The status of materials or products which are not permitted to be used for processing, packaging or distribution.

#### **14.20 Released**

The status of materials or products which are allowed to be used for processing, packaging or distribution.

#### **14.21 Returned Product**

Finished products sent back to the manufacturer.

#### **14.22 Sanitation**

Hygienic control on manufacturing premises, personnel, equipment and material handling.

#### **14.23 Specification of Materials**

A description of a starting material or finished product in terms of its chemical, physical and biological characteristics, if applicable. A specification normally includes descriptive and numerical clauses stating standards and tolerated deviations.

#### **14.24 Starting Materials**

Raw materials and packaging materials used in the production of products.

## **15. REFERENCES**

- 15.1 Good Manufacturing Practices for Pharmaceutical Products, World Health Organisation ( WHO ) Technical Report Series No : 823, 1992
- 15.2 Good Storage Practice, 1<sup>st</sup> Edition, January 1995, ISBN 983-9870-14-9, National Pharmaceutical Control Bureau, Malaysia
- 15.3 Cosmetic Good Manufacturing Practices, COLIPA – The European Cosmetic Toiletry and Perfumery Association, July 1994
- 15.4 Australian Code of Good Manufacturing Practice for Therapeutic Goods – Sunscreen Products, Therapeutic Goods Administration ( TGA ), Australia, February 1994
- 15.5 Guidelines on Good Manufacturing Practice ( GMP ) for Traditional Medicines, National Pharmaceutical Control Bureau, Malaysia, 1<sup>st</sup> Edition, 1999

## **Annex 1, Part 10**

List of Equivalent Cosmetic GMP Guidelines Recognized by ASEAN

- ❖ **WHO for pharmaceuticals**
- ❖ **PIC/S Australia for pharmaceuticals**
- ❖ **ISO D/S 22716**
- ❖ **COLIPA draft 1994**
- ❖ **US CTFA draft April 28, 2005**

## **Annex 1, Part 11**

### **A GUIDE MANUAL FOR ADVERSE EVENT REPORTING.**

#### **Introduction:**

Pursuant to the ASEAN Cosmetic Directive, Article 3 (1) and the Discussion Paper on Post Marketing Surveillance/Product Safety, adopted by the ASEAN Cosmetic Committee in its second meeting held in Bangkok June 7-8, 2004, it is important to harmonize the mechanism to gather and, if necessary, take action on important safety information arising from post marketing surveillance of cosmetic products.

Thus, agreed definitions and terminology, as well as procedures, will not only ensure uniform standards in the adverse event reporting process but will also facilitate product safety information sharing among ASEAN Regulatory Authorities.

There are two issues within the broad subject of safety data management that are appropriate for harmonization at this time:

- The development of standard definitions and terminology for key aspects of adverse event reporting, and
- The appropriate mechanism for handling adverse event reporting

This Guide shall be revised as necessary, to take into account technical progress and regulatory developments.

#### **Definitions and terminologies**

##### **a. Adverse Event:**

Any genuine harmful or unintended event reasonably attributable to the normal or foreseeable use of a given cosmetic product.

##### **b. Serious Adverse Event:**

A serious event is any untoward medical occurrence that:

- Results *in death*,
- Is life threatening (the term life threatening refers to an event in which the person was at risk of death at the time of the event;
- Requires in-patient hospitalization, *or*
- Results in persistent or significant disability/incapacity

## **Who should the industry report to?**

The company or person responsible for placing the cosmetic product in the market shall report to the regulatory authority of the ASEAN Member State where the adverse event occurred, regardless of the source of the report (consumer, healthcare professional, etc).

## **What should be reported?**

### **a. Every cases-of serious Adverse Event:**

All serious adverse events should be reported. Non-serious adverse events are not required to be reported.

Whenever there is reasonable suspicion that the cosmetic product might be the cause of the reaction, reporting is necessary for all serious adverse events as defined in section 2.2 The expression “reasonable suspicion” is meant to convey in general that there are evidences to suggest a causal relationship or an association.

### **b. High incidence of Adverse Event (Non-serious/severe reactions)**

There are “non-serious” adverse events that occur at a high incidence (as defined by the ratio of events to units sold) of a single “severe” reaction type that may necessitate rapid communication to the regulatory authority. However, appropriate medical and scientific judgment should be applied for each situation of non-serious, single “severe”<sup>1</sup> adverse reaction that has a high incidence before reporting to the regulatory authority.

## **When to report an Adverse Event?**

### **a. Fatal or Life Threatening Adverse Events**

Fatal or life threatening adverse event qualify for very rapid reporting to the regulatory authority, which shall be notified (e.g. by telephone, facsimile transmission, email or in writing) as soon as possible but no later than 7 calendar days after first knowledge, followed by completing the Adverse Cosmetic Event Report Form (Appendix I) within an additional 8 calendar days and providing any other information as may be requested by the regulatory authority.

### **b. Other serious Adverse Events**

All other serious adverse events (as defined in section 2.2) that are not fatal or life threatening must be reported as soon as possible, but no later than 15 calendar days after first knowledge.

<sup>1</sup> To ensure no confusion or misunderstanding between the terms “serious” and “severe”, which are not synonymous, the following note of clarification is provided:

The term “severe” is often used to describe the intensity (severity) of a specific event (as in mild, moderate, severe reaction); the event itself, however, may be of relatively minor significance (such as skin irritation, headache). Seriousness, not severity, serves as a guide for defining regulatory reporting obligations.

**COSMETIC PRODUCT [CONFIDENTIAL]****APPENDIX 1**

To:  
Name & Address of the Regulatory Authority  
Department  
Telephone no.  
Fax no.  
Email address

**FOR OFFICIAL  
USE ONLY**

Date received:  
Product Notification No.

**REPORT FORM FOR ADVERSE COSMETIC EVENT****I. Company Particulars**

Name and address of Company		
Name & designation of person reporting		
Tel No.:	Fax No.:	Email:

**II. Product Particulars**

Product Name (as in product notification)	
Ingredient listing & pack size	(Please attach a separate list)
Product Type/Intended use	
Name of Manufacturer & country of manufacture	
Expiry or manufacturing date	
Batch No.	

**III. Details of Adverse Event**

Name/ Initials of person			
Identification or Passport no.			
Age		Sex	
Ethnic group / Nationality			
Date of onset of adverse event			
Description of adverse event (please use and attach a separate report if necessary)			
Delay between last application of the product and onset of symptoms: ___ min(s) ___ hour(s) ___ day(s) How was the product used:			
Is the person hospitalised due to the adverse reaction?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Did person seek medical attention?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Outcome	<input type="checkbox"/> Recovered (Date: _____) <input type="checkbox"/> Death (Date: _____) <input type="checkbox"/> Not yet recovered <input type="checkbox"/> Unknown		
Source of report	<input type="checkbox"/> Healthcare professional <input type="checkbox"/> Consumer <input type="checkbox"/> Others (specify)		

[Signature of person making report & date of report]



# **COSMETIC ADVERTISING CODE**

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  - 2.3 Trust, Fear and Superstition
  - 2.4 Acts of Violence or illegal Activities
  - 2.5 Use of infant, Children and Young People
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## **1. INTRODUCTION**

### **1.1 Scope**

This code is drawn up with the intention to provide guidance to cosmetics industry in developing advertising message in Ethical manner. Responsibility for observing the code rests primary with the advertiser.

### **1.2 Definition**

For the purpose of this code unless the context indicates otherwise, the following terms shall have the following meaning:-

#### **Cosmetic**

any substance or preparation intended to be used, or capable or purported or claimed to be capable of being used, on the various external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or the teeth and the mucous membranes of the oral cavity for the exclusive or main purpose of cleaning, perfuming or protecting them, or of keeping them in good condition, or of changing or modifying their appearance, or correcting body odours."

#### **Advertisement**

Applies to advertising wherever it may appear. It does not cover publicity for the products which appears in media other than in space or time paid for by the advertiser. It includes advertising in leaflets, circular, poster, outdoor signs and point of sales materials.

#### **Media**

Media shall mean any means of mass communications used to disseminate information or messages publicly, may it be of light or sound or both including television/cable television radio, magazines, newspapers, cinema, outdoor signs.

#### **Advertiser**

It shall mean the person or entity on whose account or for whom the advertisement is prepared and disseminated.

Children

It shall mean person below twelve years of age.

Infant

It shall mean person below one year of age.

### **1.3 Objective**

The object of the code is to ensure that the marketing and advertising of cosmetics to the public is conducted in a manner that promotes the quality use of cosmetics, is socially responsible and does not mislead or deceive the consumer

## **2. PRINCIPLES**

Advertisements should contain information that is reliable, accurate, truthful, informative, balanced, up to date, and capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce unjustifiable use or give rise to undue risks.

### **2.1 Standard of Morality or Decency**

Advertisements should not contain statements or visual presentation which are, or likely to be interpreted to be contrary or offensive to the standard of morality or decency prevailing in the Malaysian society or in any way defamatory or humiliating to any segment of the public.

### **2.2 Honesty or Truthful Presentation**

a. Advertisements should not be so framed as to abuse the trust of the consumer or exploit his/her lack of experience or knowledge.

b. All descriptions, claims and comparisons which relate to matters of objectively ascertainable fact should be capable of substantiation, and advertisers and advertising agencies are

required to hold such substantiation ready for production without delay when required by Authorized party.

### **2.3 Fear, Superstition, Religious**

- a. Advertisement should not play on fear without justifiable reason
- b. Advertisements should not exploit superstitions.
- c. Advertisements should not directly or by implication exploit the religious requirements/beliefs of any community.

### **2.4 Acts of Violence or illegal Activities**

- a. Advertisement should not contain anything which might lead or lend support to acts of violence, nor should they appear to condone such acts.
- b. Advertisement should not contain anything which might lead/ encourage or lend support to criminal or illegal activities, nor should they appear to condone such activities.

### **2.5 Use of infant, Children and Young People**

Advertisements addressed to infant, children or young people or likely to be seen by them, shall not contain anything whether an illustration or otherwise, which result in harming them physically, mentally or morally or which exploit their credulity, natural sense of loyalty or their lack of experience.

### **2.6 Imitation**

- a. Advertisements shall not be similar in general layout, copy, slogans, visual presentation, music or sound effects to other advertisement as to likely mislead or confuse.
- b. Particular care shall be taken in the packaging and labeling of goods to avoid causing confusion with competing products.

### **3. COMPARISON**

#### **3.1 Disparagement and Denigration**

- a. Direct comparison advertisements against competitors' products or service are strictly not allowed.
- b. Comparison advertising may be permitted provided it does not use symbols, slogans, titles, or statements that are clearly identified or directly associated with competitive brands. Competitive claims inviting comparison with a group of products or with other products categories (without identifying any specific brands) may be allowed provided these are adequately substantiated.
- c. Advertisements should not directly or indirectly disparage, ridicule or unfairly attack competitors, competing products or services including distinguishing feature of their advertising campaigns such as specific layout, copy, slogan, visual presentation, music/jingle or sound effects.
- d. Advertisement shall not contain any statement which either expressly, or by implication disparage any profession, product, services or advertisers in an unfair or misleading way.

#### **3.2 Before and After Effects**

- a. "Before" and "after" situation must reflect truthful and factual comparisons. Comparisons of the "antecedent" situation with the "subsequent" situation must not be exaggerated or misleading.
- b. Advertising comparing "before" and "after" situations should cite with prominence the specific time elapsed between the two situations.

### **4. TESTIMONIAL**

- a. Advertisements shall not contain or refer to any testimonial or endorsement unless it is genuine and related to the personal experience over a reasonable period or time of the person giving it. Testimonials or endorsements which are obsolete or

otherwise no longer applicable, (e.g. where there has been a significant change in formulation of the product concerned) shall not be used.

b. Care shall be taken, where a testimonial is given by a person with professional qualifications that in indicating those qualifications the advertisers do not cause the person giving the testimonial to transgress any regulations of the professional institution to which he belongs.

c. Testimonials of professionals should observe the ethics of their professions and not violate regulations of the government bodies or institutions regulating that profession.

## **5. TEST, TRIALS AND RESEARCH RESULTS**

a. Reference expressly or by implication to test, trials, research and the likely may only be used if they are fully substantiated and not misleading. References to tests or trials conducted in a named hospital, clinic, institute, laboratory or college or by named professional or official organization are permissible only if authorized and approved by the authority of the institution or organization concerned.

b. Test, trial and research in supporting medicinal claims are not allowed to be used in the advertisement.

## **6. HYPERBOLE WORDS/SUPERLATIVE/CLAIMS**

a. All claims in the Advertisement should be substantiated and able to provide when being challenged by authority or competitors.

b. Advertisement may contain hyperbole words or superlative or claims only when it can be substantiated when challenge.

**Annexe II Part 1****List of substances which must not form part of the composition of cosmetic products**

Substance	CAS Number	Ref. No
Aminophylline	317-34-0	A1136
Methylene chloride (Dichloromethane)	75-09-2	A1138
Theophylline	58-55-9	A1137
Chlorofluorocarbons		A1138
Diethylene glycol when used in products intended to come into contact with the mucous membranes of the oral cavity		A1137
N-5-Chlorobenzoxazol-2-yl acetamide	8024-12-2	1
$\beta$ -Acetoxyethyl trimethylammonium hydroxide (acetylcholine and its salts)	60-31-1	2
Deanol aceglumate	3342-61-8	3
Spironolactone	52-01-7	4
[4-(4-Hydroxy-3-iodophenoxy)-3,5-diodophenyl] acetic acid and its salts		5
Methotrexate	59-05-2	6
Aminocaproic acid and its salts	60-32-2	7
Cinchophen, its salts, derivatives and salts of these derivatives	132-60-5	8
Thyropropic acid and its salts	51-26-3	9
Trichloroacetic acid	76-03-9	10
<i>Aconitum napellus</i> L. (leaves, roots and galenical preparations)		11
Aconitine (principal alkaloid of <i>Aconitum napellus</i> L.) and its salts	302-27-2	12
<i>Adonis vernalis</i> L. and its preparations		13
Epinephrine	51-43-4	14
<i>Rauwolfia serpentina</i> alkaloids and their salts		15
Alkyne alcohols, their esters, ethers and salts		16
Isoprenaline	949-36-0	17
Allyl isothiocyanate	57-06-7	18
Alloclamide and its salts	5486-77-1	19
Nalorphine, its salts and ethers	62-67-9	20
Sympathomimetic amines acting on the central nervous system: any		21



## Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products

Substance	CAS Number	Ref. No
substance contained in the first list of medicaments which are subject to medical prescription and are referred to in resolution (69) 2 of the Council of Europe		
Aniline, its salts and its halogenated and sulphonated derivatives	62-53-3	22
Betoxycaine and its salts	3818-62-0	23
Zoxazolamine	61-80-3	24
Procainamide, its salts and derivatives	614-39-1	25
Benzidine	92-87-5	26
Tuaminoheptane, its isomers and salts	123-82-0	27
Octodrine and its salts	543-82-8	28
2-Amino-1,2-bis (4-methoxyphenyl) ethanol and its salts		29
1,3-dimethylpentylamine and its salts	105-41-9	30
4-Aminosalicylic acid and its salts	65-49-6	31
Toluidines, their isomers, salts and halogenated and sulphonated derivatives	-	32
Xylidines, their isomers, salts and halogenated and sulphonated derivatives	-	33
Imperatorin (9-(3-methylbut-2-enyloxy) furo(3,2-g) chromen-7-one)	482-44-0	34
<i>Ammi majus</i> (Bishop's weed) and its galenical preparations		35
2,3-Dichloro-2-methylbutane	507-45-9	36
Substances with androgenic effect	-	37
Anthracene oil	120-12-7	38
Antibiotics	-	39
Antimony and its compounds	7440-36-0	40
<i>Apocynum cannabinum</i> L. and its preparations	-	41
Apomorphine (5,6,6a,7-tetrahydro-6-methyl-4H-dibenzo (de,g)-quinoline-10,11-dihydric alcohol) and its salts	314-19-2	42
Arsenic and its compounds	7440-38-2	43
<i>Atropa belladonna</i> L. and its preparations		44
Atropine, its salts and derivatives	51-55-8	45
Barium salts, with the exception of barium sulphate, barium sulphide under the conditions laid down in Annex III, Part 1, and lakes, salts and pigments prepared from the colouring agents listed with the reference (3) in Annex IV, Part 1 and Annex IV, Part 2.	-	46
Benzene	1076-43-3	47
Benzimidazol-2(3H)-one	-	48
Benzazepines and benzadiazepines	-	49
1-Dimethylaminomethyl- 1-methylpropyl benzoate (amylocaine) and its salts	644-26-8	50
2,2,6-Trimethyl-4-piperidyl benzoate (benzamine) and its salts	62-53-3	51

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Isocarboxazide	59-63-2	52
Bendroflumethiazide and its derivatives	73-48-3	53
Beryllium and its compounds	7440-41-7	54
Bromine, elemental	7726-95-6	55
Bretylum tosilate	61-76-7	56
Carbromal	77-65-6	57
Bromisoval	499-67-2	58
Brompheniramine and its salts	82-95-1	59
Benzilonium bromide	1050-48-2	60
Tetrylammonium bromide	71-91-0	61
Brucine	357-57-3	62
Tetracaine and its salts	56583-43-8	63
Mofebutazone	2210-63-1	64
Tolbutamide	64-77-7	65
Carbutamide	339-43-5	66
Phenylbutazone	50-33-9	67
Cadmium and its compounds	7440-43-9	68
Cantharides, <i>Cantharis vesicatoria</i>	-	69
(1R,2S)-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride (cantharidin)	56-25-7	70
Phenprobamate	673-31-4	71
Nitroderivatives of carbozol	-	72
Carbon disulphide	75-15-0	73
Catalase	-	74
Cephaeline and its salts	483-17-0	75
Chenopodium ambrosioides (essential oil)	-	76
2,2,2-Trichloroethane-1,1-diol	302-17-0	77
Chlorine	7782-50-5	78
Chlorpropamide	94-20-2	79
Diphenoxylate hydrochloride	3810-80-8	80
4-Phenylazophenylene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)	3118-97-6	81
Chlorzoxazone	95-25-0	82
2-Chloro-6-methylpyrimidin-4-yl dimethylamine (crimidine-ISO)	535-89-7	83
Chlorprothixene and its salts	113-59-7	84
Clofenamide	671-95-4	85
N, N-bis (2-chloroethyl) methylamine N-oxide and its salts	-	86
Chlormethine and its salts	51-75-2	87

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Cyclophosphamide and its salts	50-18-0	88
Mannomustine and its salts	576-68-1	89
Butanilcaine and its salts	3785-21-5	90
Chlormezanone	80-77-3	91
Triparanol	78-41-1	92
2-[2-(4-Chlorophenyl)-2-phenylacetyl] indane 1,3-dione (chlorophacinone-ISO)	-	93
Chlorphenoxamine	77-38-3	94
Phenaglycodol	80-08-0	95
Chloroethane	75-00-3	96
Chromium; chromic acid and its salts	7440-47-3	97
<i>Calviceps purpurea</i> Tul., its alkaloids and galenical preparations	-	98
<i>Conium maculatum</i> L. (fruit, powder, galenical preparations)	-	99
Glycyclamide	664-95-9	100
Cobalt benzenesulphonate	-	101
Colchicine, its salts and derivatives	64-86-8	102
Colchicoside and its derivatives	477-29-2	103
<i>Colchicum autumnale</i> L. and its galenical preparations	-	104
Convallatoxin	508-75-8	105
<i>Anamirta cocculus</i> L. (fruit)		106
<i>Croton tiglium</i> (oil)		107
1-Butyl-3-(N-crotonoylsulphanilyl) urea		108
Curare and curarine	8063-06-7 22260-42-0	109
Synthetic curarizants	-	110
Hydrogen cyanide and its salts	74-90-8	111
2- $\alpha$ -Cyclohexylbenzyl (N,N,N',N'-tetraethyl) trimethylenediamine phenetamine	3590-16-7	112
Cyclomenol and its salts	5591-47-9	113
Sodium hexacyclonate	7009-49-6	114
Hexapropymate	358-52-1	115
Dextropropoxyphene	469-62-5	116
O,O-Diacetyl-N-allyl-N-normorphine	-	117
Pipazetate and its salts	2169-75-7	118
5-( $\alpha$ , $\beta$ -Dibromophenethyl)-5-methylhydantoin		119
N,N'-Pentamethylenebis (trimethylammonium) salts, e.g. Pentamethonium bromide	541-20-8	120
N,N'-[(Methylimino)diethylene]bis(ethyltrimethylammonium) salts, e.g. azamethonium bromide	306-53-6	121

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Cyclarbamate	5779-54-4	122
Clofenotane; DDT (ISO)	-	123
Hexamethylenebis (trimethylammonium) salts, e.g. hexamethonium bromide*	-	124
Dichloroethanes (ethylene chlorides)	-	125
Dichloroethylenes (acetylene chlorides)	-	126
Lysergide and its salts	50-37-3	127
2-Diethylaminoethyl 3-hydroxy-4-phenylbenzoate and its salts		128
Cinchocaine and its salts	61-12-1	129
3-Diethylaminopropyl cinnamate	-	130
O,O-Diethyl O-4-nitrophenyl phosphorothioate (parathion-ISO)	56-38-2	131
[Oxalylbisiminoethylene] bis[(o-chlorobenzyl) diethylammonium] salts, e.g. ambenonium chloride	-	132
Methypylon and its salts	125-64-4	133
Digitaline and all heterosides of <i>Digitalis purpurea</i> L.	71-63-6	134
7-[2-Hydroxy-3-(2-hydroxyethyl-N-methylamino)propyl] theophylline (xanthinol)	-	135
Dioxethedrin and its salts	497-75-6	136
Piprocuarium	-	137
Propyphenazone	479-92-5	138
Tetrabenazine and its salts	58-46-8	139
Captodiamine	486-17-9	140
Mefeclozazine and its salts	1243-33-0	141
Dimethylamine	103-83-3	142
1,1-Bis (dimethylaminomethyl) propyl benzoate (amydracaine, alypine) and its salts	-	143
Methapyrilene and its salts	91-80-5	144
Metamfepramone and its salts	15351-09-4	145
Amitriptyline and its salts	50-48-6	146
Metformin and its salts	657-24-9	147
Isosorbide dinitrate	87-33-2	148
Malononitrile	109-77-3	149
Succinonitrile	110-61-2	150
Dinitrophenol isomers	-	151
Inproquone	436-40-8	152
Dimevamide and its salts	60-46-8	153
Diphenylpyraline and its salts	147-20-6	154
Sulfinpyrazone	57-96-5	155
N-(3-Carbamoyl-3,3-diphenylpropyl)-N,N-	71-81-8	156

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
diisopropylmethylammonium salts, e.g. isopropamide iodide		
Benactyzine	302-40-9	157
Benzatropine and its salts	86-13-5	158
Cyclizine and its salts	82-92-8	159
5,5-Diphenyl-4-imidazolidone	3254-93-1	160
Probenecid	57-66-9	161
Disulfiram; thiram (ISO)	97-77-8	162
Emetine, its salts and derivatives	483-18-1	163
Ephedrine and its salts	299-42-3	164
Oxanamide and its derivatives	126-93-2	165
Eserine or physostigmine and its salts	57-47-6	166
Esters of 4-aminobenzoic acid, with a free amino group, with the exception of that given in Annex VII Part 2		167
Choline salts and their esters, e.g. choline chloride	67-48-1	168
Caramiphen and its salts	77-22-5	169
Diethyl 4-nitrophenyl phosphate	311-45-5	170
Metethoheptazine and its salts	509-84-2	171
Oxpheneridine and its salts	546-32-7	172
Ethoheptazine and its salts	77-15-6	173
Metheptazine and its salts	469-78-3	174
Methylphenidate and its salts	113-45-1	175
Doxylamine and its salts	469-21-6	176
Tolboxane	2430-46-8	177
4-Benzyloxyphenol, 4-methoxyphenol and 4-ethoxyphenol	103-16-2, 150-76-5, 622-62-8	178
Parethoxycaine and its salts	94-23-5	179
Fenozolone	15302-16-6	180
Glutethimide and its salts	77-21-4	181
Ethylene oxide	75-21-8	182
Bemegride and its salts	64-65-3	183
Valnoctamide	4171-13-5	184
Haloperidol	52-86-8	185
Paramethasone	53-33-8	186
Fluanisone	1480-19-9	187
Trifluoperidol	749-13-3	188
Fluoresone	2924-67-6	189
Fluorouracil	-	190

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

Substance	CAS Number	Ref. No
Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in Annex III, Part 1	7664-39-3	191
Furfuryltrimethylammonium salts, e.g. furtrethonium iodide	541-64-0	192
Galantamine	1953-04-4	193
Progestogens	-	194
1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO) (lindane)	58-89-9	195
(1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4:5,8-dimethanonaphthalene (endrin-ISO)	72-20-8	196
Hexachloroethane	67-72-1	197
(1R,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8-dimethanonaphthalene (isodrin-ISO)	465-73-6	198
Hydrastine, hydrastinine and their salts	118-08-1, 6592-85-4	199
Hydrazides and their salts	-	200
Hydrazine, its derivatives and their salts	302-01-2	201
Octamoxin and its salts	4684-87-1	202
Warfarin and its salts	81-81-2	203
Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and salts of the acid	-	204
Methocarbamol	532-03-6	205
Propatynitrate	2921-92-8	206
4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin	-	207
Fenadiazole	1008-65-7	208
Nitroxoline and its salts	4008-48-4	209
Hyoscyamine, its salts and derivative	101-31-5	210
<i>Hyoscyamus niger</i> L. (leaves, seeds, powder and galenical preparations)	-	211
Pemoline and its salts	2152-34-3	212
Iodine	7553-56-2	213
Decamethylenebis (trimethylammonium) salts, e.g. decamethonium bromide	541-22-0	214
Ipecacuanha ( <i>Cephaelis ipecacuanha</i> Brot. and related species) (roots, powder and galenical preparations)	8012-96-2	215
(2-isopropylpent-4-enoyl)urea (apronalide)	528-92-7	216
$\alpha$ -Santonin [(3S,5aR,9bS)-3,3a,4,5,5a,9b-hexahydro-3,5a,9-trimethylnaphtho [1,2-b] furan-2,8-dione]	481-06-1	217
<i>Lobelia inflata</i> L. and its galenical preparations	-	218
Lobeline and its salts	90-69-7	219
Barbiturates	-	220
Mercury and its compounds except those special cases included in	7439-97-6	221

## Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products

Substance	CAS Number	Ref. No
Annex VI, Part 1		
3,4,5-Trimethoxyphenethylamine and its salts	54-04-6	222
Metaldehyde	9002-91-9	223
2-(4-Allyl-2-methoxyphenoxy)-N,N-diethylacetamide and its salts	305-13-5	224
Coumetarol	4366-18-1	225
Dextromethorphan and its salts	125-71-3	226
2-Methylheptylamine and its salts	540-43-2	227
Isometheptene and its salts	503-01-5	228
Mecamylamine	60-40-2	229
Guaifenesin	93-14-1	230
Dicoumarol	66-76-2	231
Phenmetrazine, its derivatives and salts	134-49-6	232
Thiamazole	60-57-1	233
3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H,5H,pyrano(3,2-c)-(1) benzopyran-5-one (cyclocoumarol)	518-20-7	234
Carisoprodol	78-44-4	235
Meprobamate	57-53-4	236
Tefazoline and its salts	1082-56-0	237
Arecoline	63-75-2	238
Poldine methylsulfate	545-80-2	239
Hydroxyzine	68-88-2	240
2-Naphthol	135-19-3	241
1-and 2-Naphthylamines and their salts	-	242
3-(1-Naphthyl)-4-hydroxycoumarin	-	243
Naphazoline and its salts	835-31-4	244
Neostigmine and its salts (e.g. neostigmine bromide)	114-80-7, 114-80-7	245
Nicotine and its salts	54-11-5	246
Amyl nitrites	463-04-7	247
Inorganic nitrites, with the exception of sodium nitrite	-	248
Nitrobenzene	98-95-3	249
Nitrocresols and their alkali metal salts		250
Nitrofurantoin	67-20-9	251
Furazolidone	67-45-8	252
Propane-1 2,3-triyl trinitrate	55-63-0	253
Acenocoumarol	152-72-7	254
Alkali pentacyanonitrosylferrate (2-)	-	255
Nitrostilbenes, their homologues and their derivatives,	-	256

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

Substance	CAS Number	Ref. No
Noradrenaline and its salts	-	257
Noscapine and its salts	128-62-1	258
Guanethidine and its salts	55-65-2	259
Oestrogens	-	260
Oleandrin	465-16-7	261
Chlortalidone	77-36-1	262
Pelletierine and its salts	2858-66-4	263
Pentachloroethane	76-01-7	264
Pentaerithrityl tetranitrate	78-11-5	265
Petrichloral	78-12-6	266
Octamylamine and its salts	502-85-2	267
Picric acid	88-89-1	268
Phenacemide	63-98-9	269
Difencloxadine	5617-26-5	270
2-Phenylindan-1,3-dione (phenindione)	83-12-5	271
Ethylphenacemide	90-49-3	272
Phenprocoumon	435-97-2	273
Fenylramidol	553-69-5	274
Triamterence and its salts	-	275
Tetraethyl pyrophosphate; TEPP (ISO)	107-49-3	276
Tritolyl phosphate	1330-78-5	277
Psilocybine	520-53-6	278
Phosphorus and metal phosphides	7723-14-0	279
Thalidomide and its salts	50-35-1	280
<i>Physostigma venenosum</i> Balf.	-	281
Picrotoxin	124-87-8	282
Pilocarpine and its salts	92-13-7	283
$\alpha$ -Piperidin-2-yl benzyl acetate laevorotatory threoform (Levophacetoperane) and its salts	24558-01-8	284
Pipradrol and its salts	467-60-7	285
Azacyclonol and its salts	115-46-8	286
Bietamiverine	479-81-2	287
Butopiprine and its salts	55837-15-5	288
Lead and its compounds	7439-92-1	289
Coniine	458-88-8	290
<i>Prunus laurocerasus</i> L. ('cherry laurel water')	-	291
Metyrapone	54-36-4	292
Radioactive substances, as defined by Directive 96/29/Euratom	-	293



## Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products

Substance	CAS Number	Ref. No
(1) laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.		
<i>Juniperus sabina</i> L. (leaves, essential oil and galenical preparations)	-	294
Hyoscine, its salts and derivatives	114-49-8	295
Gold salts	-	296
Selenium and its compounds with the exception of selenium disulphide under the conditions set out under Annex III, Part 1, reference No 49	7782-49-2	297
<i>Solanum nigrum</i> L. and its galenical preparations		298
Sparteine and its salts	90-39-1	299
Glucocorticoids	-	300
<i>Datura stramonium</i> L. and its galenical preparations	-	301
Strophantines, their aglucones and their respective derivatives	-	302
Strophantus species and their galenical preparations	-	303
Strychnine and its salts	-	304
Strychnos species and their galenical preparations	-	305
Narcotics, natural and synthetic.		306
Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH <sub>2</sub> groups) and their salts	63-74-1	307
Sultiame	61-56-3	308
Neodymium and its salts	7440-0033-8	309
Thiotepa	52-24-4	310
<i>Pilocarpus jaborandi</i> Holmes and its galenical preparations	-	311
Tellurium and its compounds	13494-80-9	312
Xylometazoline and its salts	526-36-3	313
Tetrachloroethylene	127-18-4	314
Carbon Tetrachloride	56-23-5	315
Hexaethyl tetraphosphate	757-58-4	316
Thallium and its compounds	7440-28-0	317
<i>Thevetia neriifolia</i> Juss. glycoside extract		318
Ethionamide	536-33-4	319
Phenothiazine and its compounds	92-84-2	320
Thiourea and its derivatives ni detsil eno eht fo noitpecxe eht htiw , 1x III, Part Anne	62-56-6	321
Mephesisin and its esters	59-47-2	322
Vaccines, toxins or serums listed in the Annex to the Second Council Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products	-	323

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Tranylcypromine and its salts	155-09-9	324
Trichloronitromethane (chloropicrine)	76-06-2	325
2,2,2-Tribromoethanol (tribromoethyl alcohol)	75-80-9	326
Trichlormethine and its salts	817-09-4	327
Tretamine	51-18-3	328
Gallamine triethiodide	65-29-2	329
Urginea scilla Stern. and its galenical preparations	-	330
Veratrine, its salts and galenical preparations	. 8051-02-3	331
<i>Schoenoocaulon officinale</i> Lind. (seeds and galenical preparations)	-	332
<i>Veratrum</i> Spp. and their preparations	-	333
Vinyl chloride monomer	75-01-4	334
Ergocalciferol and cholecalciferol (vitamins D2 and D3)	50-14-6 & 67-97-0	335
Salts of o-alkyldithiocarbonic acids	-	336
Yohimbine and its salts	146-48-5	337
Dimethyl sulfoxide	67-68-5	338
Diphenhydramine and its salts	147-24-0	339
4-tert-Butylphenol	98-54-4	340
4-tert-Butylpyrocatechol	98-29-3	341
Dihydrotachysterol	67-96-9	342
Dioxane	123-91-1	343
Morpholine and its salts	110-91-8	344
Pyrethrum album L. and its galenical preparations		345
2-(4-Methoxybenzyl-N-(2-pyridyl)amino)ethyldimethylamine maleate	141-05-9	346
Tripelennamine	91-81-6	347
Tetrachlorosalicylanilides	-	348
Dichlorosalicylanilides	-	349
Tetrabromosalicylanilides	-	350
Dibromosalicylanilides	-	351
Bithionol	97-18-7	352
Thiuram monosulphides	-	353
Thiuram disulphides	-	354
Dimethylformamide	68-12-2	355
4-Phenylbut-3-en-2-one	122-57-6	356
Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol except for normal content in natural essences used	-	357
Furocoumarines (e.g. trioxysalan*, 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used.	-	358

## Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products

Substance	CAS Number	Ref. No
In sun protection and in bronzing products, furocoumarines shall be below 1mg/kg		
Oil from the seeds of <i>Laurus nobilis</i> L.		359
Safrole except for normal content in the natural essences used and provided the concentration does not exceed: <ul style="list-style-type: none"> <li>100 ppm in the finished product</li> <li>50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children.</li> </ul>	94-59-7	360
5,5'-Di-isopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihypiodite	-	361
3'-ethyl-5',6',7,8'-tetrahydro-5',5',8',8'-tetramethyl-2'-acetonaphthone, or 7-acetyl-6-ethyl-1,1,4,4-tetramethyl-1,2,3,4-tetrahydronaphthalen		362
o-Phenylenediamine and its salts	95-54-5	363
4-Methyl-m-phenylenediamine and its salts	95-80-7	364
Aristolochic acid and its salts, <i>Aristolochia</i> spp. and their preparations	313-67-7	365
Chloroform	67-66-3	366
2,3,7,8,-Tetra chlorodibenzo-p-dioxin	-	367
2,6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)	828-00-2	368
Pyrithione sodium (INNM)	3811-73-2	369
N-(Trichloromethylthio)-4- cyclohexene-1,2-dicarboximide (Captan)	133-06-02	370
2,2'-Dihydroxy-3,3',5,5',6,6'-hexachlorodiphenylmethane (Hexachlorophene)	70-30-4	371
6-(Piperidiny)-2,4-pyrimidinediamine-3-oxide (minoxidil) and its salts	58-18-4	372
3,4',5-Tribromosalicylanilide	24556-65-8	373
<i>Phytolacca</i> Spp. and their preparations		374
Tretinoin (retinoic acid and its salts)	302-79-4	375
1-Methoxy-2,4-diaminobenzene (2,4 - diaminoanisole - CI 76050) and their salts	615-05-4	376
1-Methoxy-2,5-diaminobenzene (2,5 - diaminoanisole) and their salts	5307-02-8	377
Colouring agent CI 12140	-	378
Colouring agent CI 26105	-	379
Colouring agent CI 42555 Colouring agent CI 42555-1 Colouring agent CI 42555-2	-	380
Amyl 4-dimethylaminobenzoate, mixed isomers (Padimate A (INN))	-	381
Entry deleted	-	382
2-Amino-4-nitrophenol	99-57-0	383
2-Amino-5-nitrophenol	121-88-0	384
11 $\alpha$ -Hydroxypregn-4-ene-3, 20-dione and its esters	-	385

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Colouring agent CI 42640	-	386
Colouring agent CI 13065	-	387
Colouring agent CI 42535	-	388
Colouring agent CI 61554	-	389
Anti-androgens of steroidal structure	-	390
Zirconium and its compounds, with the exception of the substances listed under reference number 50 in Annex III, Part One, and the zirconium lakes, pigments or salts of the colouring agents listed in Annex IV, Part 1	7440-67-7	391
Entry deleted		392
Acetonitrile	75-05-8	393
Tetrahydrozoline and its salts	84-22-0	394
Hydroxy-8-quinoline and its sulphate, except for the uses provided for in Annex III, Part 1 No 51	148-24-3	395
Dithio-2,2'-bispyridine-dioxide 1,1' (additive with trihydrated magnesium sulphate) - (pyrithione disulphide + magnesium sulphate)	-	396
Colouring agent CI 12075 and its lakes, pigments and salts	-	397
Colouring agent CI 45170 and CI 45170:1	-	398
Lidocaine	137-58-6	399
1,2-Epoxybutane	106-88-7	400
Colouring agent CI 15585	-	401
Strontium lactate	-	402
Strontium nitrate	10042-76-9	403
Strontium polycarboxylate	-	404
Pramocaine	140-65-8	405
4-Ethoxy-m-phenylenediamine and its salts	-	406
2,4-Diaminophenylethanol and its salts	-	407
Catechol	120-80-9	408
Pyrogallol	87-66-1	409
Nitrosamines	-	410
Secondary alkyl- and dialkanolamines and their salts	-	411
4-Amino-2-nitrophenol	119-34-6	412
2-Methyl-m-phenylenediamine	823-40-5	413
4-tert-Butyl-3-methoxy-2,6-dinitrotoluene (Musk Ambrette)	83-66-9	414
Entry deleted		415
Cells, tissues or products of human origin	-	416
3,3- Bis(4-hydroxyphenyl)phthalide (Phenolphthalein)	77-09-8	417
3-Imidazol-4-ylacrylic acid and its ethyl ester (urocanic acid)	104-98-3	418

## Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products

Substance	CAS Number	Ref. No
<p>From the date referred to in Article 22(1) of Regulation (EC) No 999/2001 of the European Parliament and of the Council (1), the specified risk materials as designated in Annex V to that Regulation, and ingredients derived therefrom.</p> <p>Until that date, the specified risk materials as designated in Annex XI Part A to Regulation (EC) No 999/2001, and ingredients derived therefrom.</p> <p>However, tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer:</p> <ul style="list-style-type: none"> <li>— Transesterification or hydrolysis at at least 200 degrees C and at an appropriate corresponding pressure, for 20 minutes (glycerol, fatty acids and fatty acid esters),</li> <li>— Saponification with NaOH 12M (glycerol and soap):</li> <li>— Batch process: at 95 degrees C for three hours</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>— Continuous process: at 140 degrees C, two bars (2 000 hPa) for eight minutes or equivalent conditions.</li> </ul>	-	419
Crude and refined coal tars	-	420
1,1,3,3,5,-Pentamethyl-4,6-dinitroindane (moskene)	116-66-5	421
5-tert-Butyl-1,2,3-trimethyl-4,6-dinitrobenzene (musk tibetene).	145-39-1	422
Alanroot oil ( <i>Inula helenium</i> ) when used as a fragrance ingredient.	97676-35-2	423
Benzyl cyanide when used as a fragrance ingredient.	140-29-4	424
Cyclamen alcohol when used as a fragrance ingredient.	4756-19-8	425
Diethyl maleate when used as a fragrance ingredient.	141-05-9	426
Dihydrocoumarine when used as a fragrance ingredient.	119-84-6	427
2,4-Dihydroxy-3-methylbenzaldehyde when used as a fragrance ingredient.	6248-20-0	428
3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol) when used as a fragrance ingredient.	40607-48-5	429
4,6-Dimethyl-8-tert-butylcoumarin when used as a fragrance ingredient.	17874-34-9	430
Dimethyl citraconate when used as a fragrance ingredient.	617-54-9	431
7,11-Dimethyl-4,6,10-dodecatrien-3-one, when used as a fragrance ingredient.	26651-96-7	432
6,10-Dimethyl-3,5,9-undecatrien-2-one, when used as a fragrance ingredient.	141-10-6	433
Diphenylamine, when used as a fragrance ingredient.	122-39-4	434

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Ethyl acrylate, when used as a fragrance ingredient.	140-88-5	435
Fig leaf absolute ( <i>Ficus carica</i> ), when used as a fragrance ingredient.	68916-52-9	436
Trans-2-Heptenal, when used as a fragrance ingredient.	18829-55-5	437
Trans-2-Hexenal diethyl acetal, when used as a fragrance ingredient.	67746-30-9	438
Trans-2-Hexenal dimethyl acetal, when used as a fragrance ingredient.	18318-83-7	439
Hydroabietyl alcohol, when used as a fragrance ingredient.	13393-93-6	440
6-Isopropyl-2-decahydronaphthalenol, when used as a fragrance ingredient.	34131-99-2	441
7-Methoxycoumarin, when used as a fragrance ingredient.	531-59-9	442
4-(4-Methoxyphenyl)-3-butene-2-one, when used as a fragrance ingredient.	943-88-4	443
1-(4-Methoxyphenyl)-1-penten-3-one, when used as a fragrance ingredient.	104-27-8	444
Methyl trans-2-butenolate, when used as a fragrance ingredient.	623-43-8	445
7-Methylcoumarin, when used as a fragrance ingredient.	2445-83-2	446
5-Methyl-2,3-hexanedione, when used as a fragrance ingredient.	13706-86-0	447
2-Pentylidenecyclohexanone, when used as a fragrance ingredient.	25677-40-1	448
3,6,10-Trimethyl-3,5,9-undecatrien-2-one, when used as a fragrance ingredient.	1117-41-5	449
Verbena oil ( <i>Lippia citriodora</i> Kunth.), when used as a fragrance ingredient.	8024-12-2	450
Methyleugenol (CAS No 93-15-2) except for normal content in the natural essences used and provided that the concentration does not exceed: (a) 0,01 % in fine fragrance (b) 0,004 % in eau de toilette (c) 0,002 % in fragrance cream (d) 0,001 % in rinse-off products (e) 0,0002 % in other leave-on products and oral hygiene products	93-15-2	451
6-(2-Chloroethyl)-6-(2-methoxyethoxy)-2,5,7,10-tetraoxa-6-silaundecane	37894-46-5	452
Cobalt dichloride	7646-79-9	453
Cobalt sulphate	10124-43-3	454

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Nickel monoxide	1313-99-1	455
Dinickel trioxide	1314-06-3	456
Nickel dioxide	12035-36-8	457
Trinickel disulphide	12035-72-2	458
Tetracarbonylnickel	13463-39-3	459
Nickel sulphide	16812-54-7	460
Potassium bromate	7758-01-2	461
Carbon monoxide	630-08-0	462
Buta-1,3-diene	106-99-0	463
Isobutane, if it contains = 0,1 % w/w Butadiene	75-28-5	464
Butane, if it contains = 0,1 % w/w Butadiene	106-97-8	465
Gases (petroleum), C3-4, if they contain > 0,1 % w/w Butadiene	68131-75-9	466
Tail gas (petroleum), catalytic cracked distillate and catalytic cracked naphtha fractionation absorber, if it contains > 0,1 % w/w Butadiene	68307-98-2	467
Tail gas (petroleum), catalytic polymn. naphtha fractionation stabiliser, if it contains > 0,1 % w/w Butadiene	68307-99-3	468
Tail gas (petroleum), catalytic reformed naphtha fractionation stabiliser, hydrogen sulfide-free, if it contains > 0,1 %w/w Butadiene	68308-00-9	469
Tail gas (petroleum), cracked distillate hydrotreater stripper, if it contains > 0,1 % w/w Butadiene	68308-01-0	470
Tail gas (petroleum), gas oil catalytic cracking absorber, if it contains > 0,1 % w/w Butadiene	68308- 03-2	471
Tail gas (petroleum), gas recovery plant, if it contains > 0,1 % w/w Butadiene	68308-04-3	472
Tail gas (petroleum), gas recovery plant deethaniser, if it contains > 0,1 % w/w Butadiene	68308-05-4	473
Tail gas (petroleum), hydrodesulfurised distillate and hydrodesulfurised naphtha fractionator, acid-free, if it contains > 0,1 % w/w Butadiene	68308-06-5	474
Tail gas (petroleum), hydrodesulfurised vacuum gas oil stripper, hydrogen sulfide-free, if it contains > 0,1 % w/w Butadiene	68308-07-6	475
Tail gas (petroleum), isomerised naphtha fractionation stabiliser, if it contains > 0,1 % w/w Butadiene	68308-08-7	476
Tail gas (petroleum), light straight-run naphtha stabiliser, hydrogen	68308-09-8	477

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
sulfide-free, if it contains > 0,1 % w/w Butadiene		
Tail gas (petroleum), straight-run distillate hydrodesulferised, hydrogen sulfide-free, if it contains > 0,1 % w/w Butadiene	68308-10-1	478
Tail gas (petroleum), propane-propylene alkylation feed prep deethaniser, if it contains > 0,1 % w/w Butadiene	68308-11-2	479
Tail gas (petroleum), vacuum gas oil hydrodesulferised, hydrogen sulfide-free, if it contains > 0,1 % w/w Butadiene	68308-12-3	480
Gases (petroleum), catalytic cracked overheads, if they contain > 0,1 % w/w Butadiene	68409-99-4	481
Alkanes, C1-2, if they contain > 0,1 % w/w Butadiene	68475-57-0	482
Alkanes, C2-3, if they contain > 0,1 % w/w Butadiene	68475-58-1	483
Alkanes, C3-4, if they contain > 0,1 % w/w Butadiene	68475-59-2	484
Alkanes, C4-5, if they contain > 0,1 % w/w Butadiene	68475-60-5	485
Fuel-gases, if they contain > 0,1 % w/w Butadiene	68476-26-6	486
Fuel gases, crude oil distillates, if they contain > 0,1 % w/w Butadiene	68476-29-9	487
Hydrocarbons, C3-4, if they contain > 0,1 % w/w Butadiene	68476-40-4	488
Hydrocarbons, C4-5, if they contain > 0,1 % w/w Butadiene	68476-42-6	489
Hydrocarbons, C2-4, C3-rich, if they contain > 0,1 %w/w Butadiene	68476-49-3	490
Petroleum gases, liquefied, if they contain > 0,1 % w/w Butadiene	68476-85-7	491
Petroleum gases, liquefied, sweetened, if they contain > 0,1 % w/w Butadiene	68476-86-8	492
Gases (petroleum), C3-4, isobutane-rich, if they contain > 0,1 % w/w Butadiene	68477-33-8	493
Distillates (petroleum), C3-6, piperylene-rich, if they contain > 0,1 % w/w Butadiene	68477-35-0	494
Gases (petroleum), amine system feed, if they contain > 0,1 % w/w Butadiene	68477-65-6	495
Gases (petroleum), benzene unit hydrodesulferised off, if they contain > 0,1 % w/w Butadiene	68477-66-7	496
Gases (petroleum), benzene unit recycle, hydrogen-rich, if they contain > 0,1 % w/w Butadiene	68477-67-8	497
Gases (petroleum), blend oil, hydrogen-nitrogen-rich, if they contain > 0,1 % w/w Butadiene	68477-68- 9	498



**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Gases (petroleum), butane splitter overheads, if they contain > 0,1 % w/w Butadiene	68477-69-0	499
Gases (petroleum), C2-3, if they contain > 0,1 % w/w Butadiene	68477-70-3	500
Gases (petroleum), catalytic-cracked gas oil depropaniser bottoms, C4-rich acid-free, if they contain > 0,1 % w/w Butadiene	68477-71-4	501
Gases (petroleum), catalytic-cracked naphtha debutaniser bottoms, C3-5-rich, if they contain > 0,1 % w/w Butadiene	68477-72-5	502
Gases (petroleum), catalytic cracked naphtha depropaniser overhead, C3- rich acid-free, if they contain > 0,1 % w/w Butadiene	68477-73-6	503
Gases (petroleum), catalytic cracker, if they contain > 0,1 % w/w Butadiene	68477-74-7	504
Gases (petroleum), catalytic cracker, C1-5-rich, if they contain > 0,1 % w/w Butadiene	68477-75-8	505
Gases (petroleum), catalytic polymd. naphtha stabiliser overhead, C2-4-rich, if they contain > 0,1 % w/w Butadiene	68477-76-9	506
Gases (petroleum), catalytic reformed naphtha stripper overheads, if they contain > 0,1 % w/w Butadiene	68477-77-0	507
Gases (petroleum), catalytic reformer, C1-4-rich, if they contain > 0,1 % w/w Butadiene	68477-79-2	508
Gases (petroleum), C6-8 catalytic reformer recycle, if they contain > 0,1 % w/w Butadiene	68477-80-5	509
Gases (petroleum), C6-8 catalytic reformer, if they contain > 0,1 % w/w Butadiene	68477-81-6	510
Gases (petroleum), C6-8 catalytic reformer recycle, hydrogen-rich, if they contain > 0,1 % w/w Butadiene	68477-82-7	511
Gases (petroleum), C3-5 olefinic-paraffinic alkylation feed, if they contain > 0,1 % w/w Butadiene	68477-83-8	512
Gases (petroleum), C2-return stream, if they contain > 0,1 % w/w Butadiene	68477-84-9	513
Gases (petroleum), C4-rich, if they contain > 0,1 % w/w Butadiene	68477-85-0	514
Gases (petroleum), deethaniser overheads, if they contain > 0,1 % w/w Butadiene	68477-86-1	515
Gases (petroleum), deisobutaniser tower overheads, if they contain > 0,1 % w/w Butadiene	68477-87-2	516
Gases (petroleum), depropaniser dry, propene-rich (Cas No 68477-90-7), if they contain > 0,1 % w/w Butadiene		517
Gases (petroleum), depropaniser overheads, if they contain > 0,1 %	68477-91-8	518

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
w/w Butadiene		
Gases (petroleum), dry sour, gas-concn.-unit-off, if they contain > 0,1 % w/w Butadiene	68477-92-9	519
Gases (petroleum), gas concn. reabsorber distn., if they contain > 0,1 % w/w Butadiene	68477-93-0	520
Gases (petroleum), gas recovery plant depropaniser overheads, if they contain > 0,1 % w/w Butadiene	68477-94-1	521
Gases (petroleum), Girbatol unit feed, if they contain > 0,1 % w/w Butadiene	68477-95-2	522
Gases (petroleum), hydrogen absorber off, if they contain > 0,1 % w/w Butadiene	68477-96-3	523
Gases (petroleum), hydrogen-rich, if they contain > 0,1 % w/w Butadiene	68477-97-4	524
Gases (petroleum), hydrotreater blend oil recycle, hydrogen-nitrogen-rich, if they contain > 0,1 % w/w Butadiene	68477-98-5	525
Gases (petroleum), isomerised naphtha fractionator, C4-rich, hydrogen sulfide-free, if they contain > 0,1 % w/w Butadiene	68477-99-6	526
Gases (petroleum), recycle, hydrogen-rich, if they contain > 0,1 % w/w Butadiene	68478-00-2	527
Gases (petroleum), reformer make-up, hydrogen-rich, if they contain > 0,1 % w/w Butadiene	68478-01-3	528
Gases (petroleum), reforming hydrotreater, if they contain > 0,1 % w/w Butadiene	68478-02-4	529
Gases (petroleum), reforming hydrotreater, hydrogen-methane-rich, if they contain > 0,1 % w/w Butadiene	68478-03-5	530
Gases (petroleum), reforming hydrotreater make-up, hydrogen-rich, if they contain > 0,1 % w/w Butadiene	68478-04-6	531
Gases (petroleum), thermal cracking distn., if they contain > 0,1 % w/w Butadiene	68478-05-7	532
Tail gas (petroleum), catalytic cracked clarified oil and thermal cracked vacuum residue fractionation reflux drum, if it contains > 0,1 % w/w Butadiene	68478-21-7	533
Tail gas (petroleum), catalytic cracked naphtha stabilisation absorber, if it contains > 0,1 % w/w Butadiene	68478-22-8	534
Tail gas (petroleum), catalytic cracker, catalytic reformer and hydrodesulfurised combined fractionator, if it contains > 0,1 % w/w Butadiene	68478-24-0	535
Tail gas (petroleum), catalytic cracker refractionation absorber, if it	68478-25-1	536

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
contains > 0,1 % w/w Butadiene		
Tail gas (petroleum), catalytic reformed naphtha fractionation stabiliser, if it contains > 0,1 % w/w Butadiene	68478-26-2	537
Tail gas (petroleum), catalytic reformed naphtha separator, if it contains > 0,1 % w/w Butadiene	68478-27-3	538
Tail gas (petroleum), catalytic reformed naphtha stabiliser, if it contains > 0,1 % w/w Butadiene	68478-28-4	539
Tail gas (petroleum), cracked distillate hydrotreater separator, if it contains > 0,1 % w/w Butadiene	68478-29-5	540
Tail gas (petroleum), hydrodesulfurised straight-run naphtha separator, if it contains > 0,1 % w/w Butadiene	68478-30-8	541
Tail gas (petroleum), saturate gas plant mixed stream, C4-rich, if it contains > 0,1 % w/w Butadiene	68478-32-0	542
Tail gas (petroleum), saturate gas recovery plant, C1-2-rich, if it contains > 0,1 % w/w Butadiene	68478-33-1	543
Tail gas (petroleum), vacuum residues thermal cracker, if it contains > 0,1 % w/w Butadiene	68478-34-2	544
Hydrocarbons, C3-4-rich, petroleum distillate, if they contain > 0,1 % w/w Butadiene	68512-91-4	545
Gases (petroleum), catalytic reformed straight-run naphtha stabiliser overheads, if they contain > 0,1 % w/w Butadiene	68513-14-4	546
Gases (petroleum), full-range straight-run naphtha dehexaniser off, if they contain > 0,1 % w/w Butadiene	68513-15-5	547
Gases (petroleum), hydrocracking depropaniser off, hydrocarbon-rich, if they contain > 0,1 % w/w Butadiene	68513-16-6	548
Gases (petroleum), light straight-run naphtha stabiliser off, if they contain > 0,1 % w/w Butadiene	68513-17-7	549
Gases (petroleum), reformer effluent high-pressure flash drum off, if they contain > 0,1 % w/w Butadiene	68513-18-8	550
Gases (petroleum), reformer effluent low-pressure flash drum off, if they contain > 0,1 % w/w Butadiene	68513-19-9	551
Residues (petroleum), alkylation splitter, C4-rich, if they contain > 0,1 % w/w Butadiene	68513-66-6	552
Hydrocarbons, C1-4, if they contain > 0,1 % w/w Butadiene	68514-31-8	553
Hydrocarbons, C1-4, sweetened, if they contain > 0,1 % w/w Butadiene	68514-36-3	554
Gases (petroleum), oil refinery gas distn. off, if they contain > 0,1 %	68527-15-1	555

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
w/w Butadiene		
Hydrocarbons, C1-3, if they contain > 0,1 % w/w Butadiene	68527-16-2	556
Hydrocarbons, C1-4, debutanizer fraction, if they contain > 0,1 % w/w Butadiene	68527-19-5	557
Gases (petroleum), benzene unit hydrotreater depentaniser overheads, if they contain > 0,1 % w/w Butadiene	68602-82-4	558
Gases (petroleum), C1-5, wet, if they contain > 0,1 % w/w Butadiene	68602-83-5	559
Gases (petroleum), secondary absorber off, fluidised catalytic cracker overheads fractionator, if they contain > 0,1 % w/w Butadiene	68602-84-6	560
Hydrocarbons, C2-4, if they contain > 0,1 % w/w Butadiene	68606-25-7	561
Hydrocarbons, C3, if they contain > 0,1 % w/w Butadiene	68606-26-8	562
Gases (petroleum), alkylation feed, if they contain > 0,1 % w/w Butadiene	68606-27-9	563
Gases (petroleum), depropaniser bottoms fractionation off, if they contain > 0,1 % w/w Butadiene	68606-34-8	564
Petroleum products, refinery gases, if they contain > 0,1 % w/w Butadiene	68607-11-4	565
Gases (petroleum), hydrocracking low-pressure separator, if they contain > 0,1 % w/w Butadiene	68783-06-2	566
Gases (petroleum), refinery blend, if they contain > 0,1 % w/w Butadiene	68783-07-3	567
Gases (petroleum), catalytic cracking, if they contain > 0,1 % w/w Butadiene	68783-64-2	568
Gases (petroleum), C2-4, sweetened, if they contain > 0,1 % w/w Butadiene	68783-65-3	569
Gases (petroleum), refinery, if they contain > 0,1 % w/w Butadiene	68814-67-5	570
Gases (petroleum), platformer products separator off, if they contain > 0,1 % w/w Butadiene	68814-90-4	571
Gases (petroleum), hydrotreated sour kerosine depentaniser stabiliser off, if they contain > 0,1 % w/w Butadiene	68911-58-0	572
Gases (petroleum), hydrotreated sour kerosine flash drum, if they contain > 0,1 % w/w Butadiene	68911-59-1	573
Gases (petroleum), crude oil fractionation off, if they contain > 0,1 % w/w Butadiene	68918-99-0	574
Gases (petroleum), dehexaniser off, if they contain > 0,1 % w/w	68919-00-6	575

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Butadiene		
Gases (petroleum), distillate unifiner desulfurisation stripper off, if they contain > 0,1 % w/w Butadiene	68919-01-7	576
Gases (petroleum), fluidised catalytic cracker fractionation off if they contain > 0,1 % w/w Butadiene	68919-02-8	577
Gases (petroleum), fluidised catalytic cracker scrubbing secondary absorber off, if they contain > 0,1 % w/w Butadiene	68919-03-9	578
Gases (petroleum), heavy distillate hydrotreater desulfurisation stripper off, if they contain > 0,1 % w/w Butadiene	68919-04-0	579
Gases (petroleum), light straight run gasoline fractionation stabiliser off, if they contain > 0,1 % w/w Butadiene	68919-05-1	580
Gases (petroleum), naphtha unifiner desulfurisation stripper off, if they contain > 0,1 % w/w Butadiene	68919-06-2	581
Gases (petroleum), platformer stabiliser off, light ends fractionation, if they contain > 0,1 % w/w Butadiene	68919-07-3	582
Gases (petroleum), preflash tower off, crude distn., if they contain > 0,1 % w/w Butadiene	68919-08-4	583
Gases (petroleum), straight-run naphtha catalytic reforming off, if they contain > 0,1 % w/w Butadiene	68919-09-5	584
Gases (petroleum), straight-run stabiliser off, if they contain > 0,1 % w/w Butadiene	68919-10-8	585
Gases (petroleum), tar stripper off, if they contain > 0,1 % w/w Butadiene	68919-11-9	586
Gases (petroleum), unifiner stripper off, if they contain > 0,1 % w/w Butadiene	68919-12-0	587
Gases (petroleum), fluidised catalytic cracker splitter overheads, if they contain > 0,1 % w/w Butadiene	68919-20-0	588
Gases (petroleum), catalytic cracked naphtha debutanizer, if they contain > 0,1 % w/w Butadiene	68952-76-1	589
Tail gas (petroleum), catalytic cracked distillate and naphtha stabiliser, if it contains > 0,1 % w/w Butadiene	68952-77-2	590
Tail gas (petroleum), catalytic hydrodesulfurised naphtha separator, if it contains > 0,1 % w/w Butadiene	68952-79-4	591
Tail gas (petroleum), straight-run naphtha hydrodesulfurised, if it contains > 0,1 % w/w Butadiene	68952-80-7	592
Tail gas (petroleum), thermal-cracked distillate, gas oil and naphtha absorber, if it contains > 0,1 % w/w Butadiene	68952-81-8	593

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Tail gas (petroleum), thermal cracked hydrocarbon fractionation stabiliser, petroleum coking, if it contains > 0,1 % w/w Butadiene	68952-82-9	594
Gases (petroleum), light steam-cracked, butadiene conc., if they contain > 0,1 % w/w Butadiene	68955-28-2	595
Gases (petroleum), sponge absorber off, fluidised catalytic cracker and gas oil desulfuriser overhead fractionation, if they contain > 0,1 % w/w Butadiene	68955-33-9	596
Gases (petroleum), straight-run naphtha catalytic reformer stabiliser overhead, if they contain > 0,1 % w/w Butadiene	68955-34-0	597
Gases (petroleum), crude distn. and catalytic cracking, if they contain > 0,1 % w/w Butadiene	68989-88-8	598
Hydrocarbons, C4, if they contain > 0,1 % w/w Butadiene	87741-01-3	599
Alkanes, C1-4, C3-rich, if they contain > 0,1 % w/w Butadiene	90622-55-2	600
Gases (petroleum), gas oil diethanolamine scrubber off, if they contain > 0,1 % w/w Butadiene	92045-15-3	601
Gases (petroleum), gas oil hydrodesulfurisation effluent, if they contain > 0,1 % w/w Butadiene	92045-16-4	602
Gases (petroleum), gas oil hydrodesulfurisation purge, if they contain > 0,1 % w/w Butadiene	92045-17-5	603
Gases (petroleum), hydrogenator effluent flash drum off, if they contain > 0,1 % w/w Butadiene	92045-18-6	604
Gases (petroleum), naphtha steam cracking high-pressure residual, if they contain > 0,1 % w/w Butadiene	92045-19-7	605
Gases (petroleum), residue visbreaking off, if they contain > 0,1 % w/w Butadiene	92045-20-0	606
Gases (petroleum), steam-cracker C3-rich, if they contain > 0,1 % w/w Butadiene	92045-22-2	607
Hydrocarbons, C4, steam-cracker distillate, if they contain > 0,1 % w/w Butadiene	92045-23-3	608
Petroleum gases, liquefied, sweetened, C4 fraction, if they contain > 0,1 % w/w Butadiene	92045-80-2	609
Hydrocarbons, C4, 1,3-butadiene- and isobutene-free, if they contain > 0,1 % w/w Butadiene	95465-89-7	610
Raffinates (petroleum), steam-cracked C4 fraction cuprous ammonium acetate extn., C3-5 and C3-5 unsatd., butadiene-free, if they contain > 0,1 % w/w Butadiene	97722-19-5	611
Benzo[def]chrysene (=benzo[a]pyrene)	50-32-8	612

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Pitch, coal tar-petroleum, if it contains > 0,005 % w/w benzo[a]pyrene	68187-57-5	613
Distillates (coal-petroleum), condensed-ring arom., if they contain > 0,005 % w/w benzo[a]pyrene	68188-48-7	614
Entry deleted		615
Entry deleted		616
Creosote oil, acenaphthene fraction, acenaphthene-free, if it contains > 0,005 % w/w benzo[a]pyrene	90640-85-0	617
Pitch, coal tar, low-temp., if it contains > 0,005 % w/w benzo[a]pyrene	90669-57-1	618
Pitch, coal tar, low-temp., heat-treated, if it contains > 0,005 % w/w benzo[a]pyrene	90669-58-2	619
Pitch, coal tar, low-temp., oxidised, if it contains > 0,005 % w/w benzo[a]pyrene	90669-59-3	620
Extract residues (coal), brown, if they contain > 0,005 % w/w benzo[a]pyrene	91697-23-3	621
Paraffin waxes (coal), brown-coal high-temp. tar, if they contain > 0,005 % w/w benzo[a]pyrene	92045-71-1	622
Paraffin waxes (coal), brown-coal high-temp. tar, hydrotreated, if they contain > 0,005 % w/w benzo[a]pyrene	92045-72-2	623
Waste solids, coal-tar pitch coking, if they contain > 0,005 % w/w benzo[a]pyrene	92062-34-5	624
Pitch, coal tar, high-temp., secondary, if it contains > 0,005 % w/w benzo[a]pyrene	94114-13-3	625
Residues (coal), liq. solvent extn., if they contain > 0,005 % w/w benzo[a]pyrene	94114-46-2	626
Coal liquids, liq. solvent extn. soln., if they contain > 0,005 % w/w benzo[a]pyrene	94114-47-3	627
Coal liquids, liq. solvent extn., if they contain > 0,005 % w/w benzo[a]pyrene	94114-48-4	628
Paraffin waxes (coal), brown-coal high-temp. tar, carbon-treated, if they contain > 0,005 % w/w benzo[a]pyrene	97926-76-6	629
Paraffin waxes (coal), brown-coal high-temp tar, clay-treated, if they contain > 0,005 % w/w benzo[a]pyrene	97926-77-7	630
Paraffin waxes (coal), brown-coal high-temp tar, silicic acid-treated, if they contain > 0,005 % w/w benzo[a]pyrene	97926-78-8	631

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Absorption oils, bicyclo arom. and heterocyclic hydrocarbon fraction, if they contain > 0,005 % w/w benzo[a]pyrene	101316-45-4	632
Aromatic hydrocarbons, C20-28, polycyclic, mixed coal-tar pitch-polyethylene polypropylene pyrolysis-derived, if they contain > 0,005 % w/w benzo[a]pyrene	101794-74-5	633
Aromatic hydrocarbons, C20-28, polycyclic, mixed coal-tar pitch-polyethylene pyrolysis-derived, if they contain > 0,005 % w/w benzo[a]pyrene	101794-75-6	634
Aromatic hydrocarbons, C20-28, polycyclic, mixed coal-tar pitch-polystyrene pyrolysis-derived, if they contain > 0,005 % w/w benzo[a]pyrene	101794-76-7	635
Pitch, coal tar, high-temp., heat-treated, if it contains > 0,005 % w/w benzo[a]pyrene	121575-60-8	636
Dibenz[a,h]anthracene	53-70-3	637
Benz[a]anthracene	56-55-3	638
Benzo[e]pyrene	192-97-2	639
Benzo[j]fluoranthene	205-82-3	640
Benz(e)acephenanthrylene	205-99-2	641
Benzo(k)fluoranthene	207-08-9	642
Chrysene	218-01-9	643
2-Bromopropane	75-26-3	644
Trichloroethylene	79-01-6	645
1,2-Dibromo-3-chloropropane	96-12-8	646
2,3-Dibromopropan-1-ol	96-13-9	647
1,3-Dichloropropan-2-ol	96-23-1	648
$\alpha$ , $\alpha$ , $\alpha$ -Trichlorotoluene	98-07-7	649
$\alpha$ -Chlorotoluene	100-44-7	650
1,2-Dibromoethane	106-93-4	651
Hexachlorobenzene	118-74-1	652
Bromoethylene	593-60-2	653
1,4-Dichlorobut-2-ene	764-41-0	654
Methyloxirane	75-56-9	655



**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
(Epoxyethyl)benzene	96-09-3	656
1-Chloro-2,3-epoxypropane	106-89-8	657
R-1-Chloro-2,3-epoxypropane	51594-55-9	658
1,2-Epoxy-3-phenoxypropane	122-60-1	659
2,3-Epoxypropan-1-ol	556-52-5	660
R-2,3-Epoxy-1-propanol	57044-25-4	661
2,2'-Bioxirane	1464-53-5	662
(2RS,3RS)-3-(2-Chlorophenyl)-2-(4-fluorophenyl)-[1H-1,2,4-triazol-1-yl)methyl]oxirane .	133855-98-8	663
Chloromethyl methyl ether	107-30-2	664
2-Methoxyethanol	109-86-4	665
2-Ethoxyethanol	110-80-5	666
Oxybis[chloromethane], bis (Chloromethyl) ether	542-88-1	667
2-Methoxypropanol	1589-47-5	668
Propiolactone	57-57-8	669
Dimethylcarbamoyl chloride	79-44-7	670
Urethane	51-79-6	671
2-Methoxyethyl acetate	110-49-6	672
2-Ethoxyethyl acetate	111-15-9	673
Methoxyacetic acid	625-45-6	674
Dibutyl phthalate	84-74-2	675
bis(2-Methoxyethyl) ether	111-96-6	676
bis(2-Ethylhexyl) phthalate	117-81-7	677
bis(2-Methoxyethyl) phthalate	117-82-8	678
2-Methoxypropyl acetate	70657-70-4	679
2-Ethylhexyl[[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]-methyl]thio] acetate	80387-97-9	680
Acrylamide, unless regulated elsewhere in this Directive	79-06-1	681
Acrylonitrile	107-13-1	682

## Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products

Substance	CAS Number	Ref. No
2-Nitropropane	79-46-9	683
Dinoseb, its salts and esters with the exception of those specified elsewhere in this list	88-85-7	684
2-Nitroanisole	91-23-6	685
4-Nitrobiphenyl	92-93-3	686
Dinitrotoluene technical grade	121-14-2	687
Binapacryl	485-31-4	688
2-Nitronaphthalene	581-89-5	689
2,3-Dinitrotoluene	602-01-7	690
5-Nitroacenaphthene	602-87-9	691
2,6-Dinitrotoluene	606-20-2	692
3,4-Dinitrotoluene	610-39-9	693
3,5-Dinitrotoluene	618-85-9	694
2,5-Dinitrotoluene	619-15-8	695
Dinoterb, its salts and esters	1420-07-1	696
Nitrofen	1836-75-5	697
Dinitrotoluene	25321-14-6	698
Diazomethane	334-88-3	699
1,4,5,8-Tetraaminoanthraquinone (Disperse Blue 1)	2475-45-8	700
Dimethylnitrosoamine	62-75-9	701
1-Methyl-3-nitro-1-nitrosoguanidine	70-25-7	702
Nitrosodipropylamine	621-64-7	703
2,2'-(Nitrosoimino)bisethanol	1116-54-7	704
4,4'-Methylenedianiline	101-77-9	705
4,4'-(4-Iminocyclohexa-2,5-dienylidenemethylene) dianiline hydrochloride	569-61-9	706
4,4'-Methylenedi-o-toluidine	838-88-0	707
o-Anisidine	90-04-0	708
3,3'-Dimethoxybenzidine	119-90-4	709

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Salts of o-dianisidine		710
o-Dianisidine based azo dyes		711
3,3'-Dichlorobenzidine	91-94-1	712
Benzidine dihydrochloride	531-85-1	713
[[1,1'-Biphenyl]-4,4'-diyl]diammonium sulphate	531-86-2	714
3,3'-Dichlorobenzidine dihydrochloride	612-83-9	715
Benzidine sulphate	21136-70-9	716
Benzidine acetate	36341-27-2	717
3,3'-Dichlorobenzidine dihydrogen bis(sulphate)	64969-34-2	718
3,3'-Dichlorobenzidine sulphate	74332-73-3	719
Benzidine based azo dyes		720
4,4'-Bi-o-toluidine	119-93-7	721
4,4'-Bi-o-toluidine dihydrochloride	612-82-8	722
[3,3'-Dimethyl[1,1'-biphenyl]-4,4'-diyl]diammonium bis(hydrogen sulphate)	64969-36-4	723
4,4'-Bi-o-toluidine sulphate	74753-18-7	724
o-Tolidine based dyes		725
Biphenyl-4-ylamine and its salts	92-67-1	726
Azobenzene	103-33-3	727
(Methyl-ONN-azoxy)methyl acetate	592-62-1	728
Cycloheximide	66-81-9	729
2-Methylaziridine	75-55-8	730
Imidazolidine-2-thione	96-45-7	731
Furan	110-00-9	732
Aziridine	151-56-4	733
Captafol	2425-06-1	734
Carbadox	6804-07-5	735
Flumioxazin	103361-09-7	736

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Tridemorph	24602-86-6	737
Vinclozolin	50471-44-8	738
Fluazifop-butyl	69806-50-4	739
Flusilazole	85509-19-9	740
1,3,5-Tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	2451-62-9	741
Thioacetamide	62-55-5	742
N,N-Dimethylformamide	68-12-2	743
Formamide	75-12-7	744
N-Methylacetamide	79-16-3	745
N-Methylformamide	123-39-7	746
N,N-Dimethylacetamide	127-19-5	747
Hexamethylphosphoric-triamide	680-31-9	748
Diethyl sulphate	64-67-5	749
Dimethyl sulphate	77-78-1	750
1,3-Propanesultone	1120-71-4	751
Dimethylsulphamoyl-chloride	13360-57-1	752
Sulfallate	95-06-7	753
A mixture of: 4-[[bis-(4-Fluorophenyl)methylsilyl]methyl]-4H-1,2,4-triazole and 1-[[bis-(4-fluorophenyl)methylsilyl]methyl]-1H-1,2,4-triazole (EC No 403-250-2)		754
(+/-)-Tetrahydrofurfuryl -(R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate	119738-06-6	755
6-Hydroxy-1-(3-Isopropoxypropyl)-4-methyl-2-oxo-5-[4-(phenylazo)phenylazo]-1,2-dihydro-3-pyridinecarbonitrile	85136-74-9	756
(6-(4-Hydroxy-3-(2-methoxyphenylazo)-2-sulfonato-7-naphthylamino)-1,3,5-triazine-2,4-diyl)bis[(amino-1-methylethyl)ammonium] formate	108225-03-2	757
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) (EC No 413-590-3)		758
A mixture of: N-[3-Hydroxy-2-(2-methylacryloylaminomethoxy)propoxymethyl]-2-methylacrylamide and N-2,3-bis-(2-Methylacryloylaminomethoxy)propoxymethyl]-2-methylacrylamide and methacrylamide and 2-methyl-N-(2-		759

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<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
methylacryloylaminomethoxymethyl)- acrylamide and N-(2,3-dihydroxypropoxymethyl)-2-methylacrylamide (EC No 412-790-8)		
1,3,5-tris-[(2S and 2R)-2,3-Epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)- trione	59653-74-6	760
Erionite	12510-42-8	761
Asbestos	12001-28-4	762
Petroleum	8002-05-9	763
Distillates (petroleum), heavy hydrocracked, if they contain > 3 % w/w DMSO extract	64741-76-0	764
Distillates (petroleum), solvent-refined heavy paraffinic, if they contain > 3 % w/w DMSO extract	64741-88-4	765
Distillates (petroleum), solvent-refined light paraffinic, if they contain > 3 % w/w DMSO extract	64741-89- 5	766
Residual oils (petroleum), solvent deasphalted, if they contain > 3 % w/w DMSO extract	64741-95-3	767
Distillates (petroleum), solvent-refined heavy naphthenic, if they contain > 3 % w/w DMSO extract	64741-96-4	768
Distillates (petroleum), solvent-refined light naphthenic, if they contain > 3 % w/w DMSO extract	64741-97-5	769
Residual oils (petroleum), solvent-refined, if they contain > 3 % w/w DMSO extract	64742-01-4	770
Distillates (petroleum), clay-treated heavy paraffinic, if they contain > 3 % w/w DMSO extract	64742-36-5	771
Distillates (petroleum), clay-treated light paraffinic, if they contain > 3 % w/w DMSO extract	64742-37-6	772
Residual oils (petroleum), clay-treated, if they contain > 3 % w/w DMSO extract	64742-41-2	773
Distillates (petroleum), clay-treated heavy naphthenic, if they contain > 3 % w/w DMSO extract	64742-44-5	774
Distillates (petroleum), clay-treated light naphthenic, if they contain > 3 % w/w DMSO extract	64742-45-6	775
Distillates (petroleum), hydrotreated heavy naphthenic, if they contain > 3% w/w DMSO extract	64742-52-5	776
Distillates (petroleum), hydrotreated light naphthenic, if they contain > 3 % w/w DMSO extract	64742-53-6	777
Distillates (petroleum), hydrotreated heavy paraffinic, if they contain > 3 % w/w DMSO extract	64742-54-7	778

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<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Distillates (petroleum), hydrotreated light paraffinic, if they contain > 3 % w/w DMSO extract	64742-55-8	779
Distillates (petroleum), solvent-dewaxed light paraffinic, if they contain > 3 % w/w DMSO extract	64742-56-9	780
Residual oils (petroleum), hydrotreated, if they contain > 3 % w/w DMSO extract	64742-57-0	781
Residual oils (petroleum), solvent-dewaxed, if they contain > 3 % w/w DMSO extract	64742-62-7	782
Distillates (petroleum), solvent-dewaxed heavy naphthenic, if they contain > 3 % w/w DMSO extract	64742-63-8	783
Distillates (petroleum), solvent-dewaxed light naphthenic, if they contain > 3 % w/w DMSO extract	64742-64-9	784
Distillates (petroleum), solvent-dewaxed heavy paraffinic, if they contain > 3 % w/w DMSO extract	64742-65-0	785
Foots oil (petroleum), if it contains > 3 % w/w DMSO extract	64742-67-2	786
Naphthenic oils (petroleum), catalytic dewaxed heavy, if they contain > 3 % w/w DMSO extract	64742-68-3	787
Naphthenic oils (petroleum), catalytic dewaxed light, if they contain > 3 % w/w DMSO extract	64742-69-4	788
Paraffin oils (petroleum), catalytic dewaxed heavy, if they contain > 3 % w/w DMSO extract	64742-70-7	789
Paraffin oils (petroleum), catalytic dewaxed light, if they contain > 3 % w/w DMSO extract	64742-71-8	790
Naphthenic oils (petroleum), complex dewaxed heavy, if they contain > 3 % w/w DMSO extract	64742-75-2	791
Naphthenic oils (petroleum), complex dewaxed light, if they contain > 3 % w/w DMSO extract	64742-76-3	792
Extracts (petroleum), heavy naphthenic distillate solvent, arom. conc., if they contain > 3 % w/w DMSO extract	68783-00-6	793
Extracts (petroleum), solvent-refined heavy paraffinic distillate solvent, if they contain > 3 % w/w DMSO extract	68783-04-0	794
Extracts (petroleum), heavy paraffinic distillates, solvent-deasphalted, if they contain > 3 % w/w DMSO extract	68814-89-1	795
Lubricating oils (petroleum), C20-50, hydrotreated neutral oil-based, high viscosity, if they contain > 3 % w/w DMSO extract	72623-85-9	796
Lubricating oils (petroleum), C15-30, hydrotreated neutral oil-based, if they contain > 3 % w/w DMSO extract	72623- 86-0	797

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<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Lubricating oils (petroleum), C20-50, hydrotreated neutral oil-based, if they contain > 3 % w/w DMSO extract	72623- 87-1	798
Lubricating oils, if they contain > 3 % w/w DMSO extract	74869-22-0	799
Distillates (petroleum), complex dewaxed heavy paraffinic, if they contain > 3 % w/w DMSO extract	90640-91-8	800
Distillates (petroleum), complex dewaxed light paraffinic, if they contain > 3 % w/w DMSO extract	90640-92-9	801
Distillates (petroleum), solvent dewaxed heavy paraffinic, clay-treated, if they contain > 3 % w/w DMSO extract	90640-94-1	802
Hydrocarbons, C20-50, solvent dewaxed heavy paraffinic, hydrotreated, if they contain > 3 % w/w DMSO extract	90640-95-2	803
Distillates (petroleum), solvent dewaxed light paraffinic, clay-treated, if they contain > 3 % w/w DMSO extract	90640-96-3	804
Distillates (petroleum), solvent dewaxed light paraffinic, hydrotreated, if they contain > 3 % w/w DMSO extract	90640-97-4	805
Extracts (petroleum), heavy naphthenic distillate solvent, hydrotreated, if they contain > 3 % w/w DMSO extract	90641-07-9	806
Extracts (petroleum), heavy paraffinic distillate solvent, hydrotreated, if they contain > 3 % w/w DMSO extract	90641-08-0	807
Extracts (petroleum), light paraffinic distillate solvent, hydrotreated, if they contain > 3 % w/w DMSO extract	90641-09-1	808
Residual oils (petroleum), hydrotreated solvent dewaxed , if they contain > 3 % w/w DMSO extract	90669-74-2	809
Residual oils (petroleum), catalytic dewaxed, if they contain > 3 % w/w DMSO extract	91770-57-9	810
Distillates (petroleum), dewaxed heavy paraffinic, hydrotreated if they contain > 3 % w/w DMSO extract	91995-39-0	811
Distillates (petroleum), dewaxed light paraffinic, hydrotreated, if they contain > 3 % w/w DMSO extract	91995-40-3	812
Distillates (petroleum), hydrocracked solvent-refined, dewaxed, if they contain > 3 % w/w DMSO extract	91995-45-8	813
Distillates (petroleum), solvent-refined light naphthenic, hydrotreated, if they contain > 3 % w/w DMSO extract	91995-54-9	814
Extracts (petroleum), hydrotreated light paraffinic distillate solvent, if they contain > 3 % w/w DMSO extract	91995- 73-2	815
Extracts (petroleum), light naphthenic distillate solvent, hydrodesulfurised, if they contain > 3 % w/w DMSO extract	91995-75-4	816

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Extracts (petroleum), light paraffinic distillate solvent, acid-treated, if they contain > 3 % w/w DMSO extract	91995-76-5	817
Extracts (petroleum), light paraffinic distillate solvent, hydrodesulfurised, if they contain > 3 % w/w DMSO extract	91995-77-6	818
Extracts (petroleum), light vacuum gas oil solvent, hydrotreated, if they contain > 3 % w/w DMSO extract	91995-79-8	819
Foots oil (petroleum), hydrotreated, if it contains > 3 % w/w DMSO extract	92045-12-0	820
Lubricating oils (petroleum), C17-35, solvent-extd., dewaxed, hydrotreated, if they contain > 3 % w/w DMSO extract	92045-42-6	821
Lubricating oils (petroleum), hydrocracked nonarom solvent-deparaffined, if they contain > 3 % w/w DMSO extract	92045-43-7	822
Residual oils (petroleum), hydrocracked acid-treated solvent-dewaxed, if they contain > 3 % w/w DMSO extract	92061-86-4	823
Paraffin oils (petroleum), solvent-refined dewaxed heavy, if they contain > 3 % w/w DMSO extract	92129-09-4	824
Extracts (petroleum), heavy paraffinic distillate solvent, clay-treated, if they contain > 3 % w/w DMSO extract	92704- 08-0	825
Lubricating oils (petroleum), base oils, paraffinic, if they contain > 3 % w/w DMSO extract	93572-43-1	826
Extracts (petroleum), heavy naphthenic distillate solvent, hydrodesulfurised, if they contain > 3 % w/w DMSO extract	93763-10-1	827
Extracts (petroleum), solvent-dewaxed heavy paraffinic distillate solvent, hydrodesulfurised, if they contain > 3 % w/w DMSO extract	93763-11-2	828
Hydrocarbons, hydrocracked paraffinic distn. residues, solvent-dewaxed, if they contain > 3 % w/w DMSO extract	93763-38-3	829
Foots oil (petroleum), acid-treated, if it contains > 3 % w/w DMSO extract	93924-31-3	830
Foots oil (petroleum), clay-treated, if it contains > 3 % w/w DMSO extract	93924-32-4	831
Hydrocarbons, C20-50, residual oil hydrogenation vacuum distillate, if they contain > 3 % w/w DMSO extract	93924- 61-9	832
Distillates (petroleum), solvent-refined hydrotreated heavy, hydrogenated, if they contain > 3 % w/w DMSO extract	94733-08-1	833
Distillates (petroleum), solvent-refined hydrocracked light, if they contain > 3 % w/w DMSO extract	94733-09-2	834
Lubricating oils (petroleum), C18-40, solvent-dewaxed hydrocracked distillate-based, if they contain > 3 % w/w DMSO extract	94733-15-0	835



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<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Lubricating oils (petroleum), C18-40, solvent-dewaxed hydrogenated raffinate-based, if they contain > 3 % w/w DMSO extract	94733-16-1	836
Hydrocarbons, C13-30, arom.-rich, solvent-extd. naphthenic distillate, if they contain > 3 % w/w DMSO extract	95371-04-3	837
Hydrocarbons, C16-32, arom. rich, solvent-extd. naphthenic distillate, if they contain > 3 % w/w DMSO extract	95371-05-4	838
Hydrocarbons, C37-68, dewaxed deasphalted hydrotreated vacuum distn. residues, if they contain > 3 % w/w DMSO extract	95371-07-6	839
Hydrocarbons, C37-65, hydrotreated deasphalted vacuum distn. residues, if they contain > 3 % w/w DMSO extract	95371-08-7	840
Distillates (petroleum), hydrocracked solvent-refined light, if they contain > 3 % w/w DMSO extract	97488-73-8	841
Distillates (petroleum), solvent-refined hydrogenated heavy, if they contain > 3 % w/w DMSO extract	97488-74-9	842
Lubricating oils (petroleum), C18-27, hydrocracked solvent-dewaxed, if they contain > 3 % w/w DMSO extract	97488-95-4	843
Hydrocarbons, C17-30, hydrotreated solvent-deasphalted atm. distn. residue, distn. lights, if they contain > 3 % w/w DMSO extract	97675-87-1	844
Hydrocarbons, C17-40, hydrotreated solvent-deasphalted distn. residue, vacuum distn. lights, if they contain > 3 % w/w DMSO extract	97722-06-0	845
Hydrocarbons, C13-27, solvent-extd. light naphthenic, if they contain > 3 % w/w DMSO extract	97722-09-3	846
Hydrocarbons, C14-29, solvent-extd. light naphthenic, if they contain > 3 % w/w DMSO extract	97722-10-6	847
Foots oil (petroleum), carbon-treated, if it contains > 3 % w/w DMSO extract	97862-76-5	848
Foots oil (petroleum), silicic acid-treated, if it contains > 3 % w/w DMSO extract	97862-77-6	849
Hydrocarbons, C27-42, dearomatised, if they contain > 3 % w/w DMSO extract	97862-81-2	850
Hydrocarbons, C17-30, hydrotreated distillates, distn. lights, if they contain > 3 % w/w DMSO extract	97862-82-3	851
Hydrocarbons, C27-45, naphthenic vacuum distn., if they contain > 3 % w/w DMSO extract	97862-83-4	852
Hydrocarbons, C27-45, dearomatised, if they contain > 3 % w/w DMSO extract	97926-68-6	853
Hydrocarbons, C20-58, hydrotreated, if they contain > 3 % w/w	97926-70-0	854

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<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
DMSO extract		
Hydrocarbons, C27-42, naphthenic, if they contain > 3 % w/w DMSO extract	97926-71-1	855
Extracts (petroleum), light paraffinic distillate solvent, carbon-treated, if they contain > 3 % w/w DMSO extract	100684-02-4	856
Extracts (petroleum), light paraffinic distillate solvent, clay-treated, if they contain > 3 % w/w DMSO extract	100684-03-5	857
Extracts (petroleum), light vacuum, gas oil solvent, carbon-treated, if they contain > 3 % w/w DMSO extract	100684-04-6	858
Extracts (petroleum), light vacuum gas oil solvent, clay-treated, if they contain > 3 % w/w DMSO extract	100684-05-7	859
Residual oils (petroleum), carbon-treated solvent-dewaxed, if they contain > 3 % w/w DMSO extract	100684-37-5	860
Residual oils (petroleum), clay-treated solvent-dewaxed, if they contain > 3 % w/w DMSO extract	100684-38-6	861
Lubricating oils (petroleum), C>25, solvent-extd., deasphalted, dewaxed, hydrogenated, if they contain > 3 % w/w DMSO extract	101316-69-2	862
Lubricating oils (petroleum), C17-32, solvent-extd., dewaxed, hydrogenated, if they contain > 3 % w/w DMSO extract	101316-70-5	863
Lubricating oils (petroleum), C20-35, solvent-extd., dewaxed, hydrogenated, if they contain > 3 % w/w DMSO extract	101316-71-6	864
Lubricating oils (petroleum), C24-50, solvent-extd., dewaxed, hydrogenated, if they contain > 3 % w/w DMSO extract	101316-72-7	865
Distillates (petroleum), sweetened middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64741-86-2	866
Gas oils (petroleum), solvent-refined, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64741-90-8	867
Distillates (petroleum), solvent-refined middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64741-91-9	868
Gas oils (petroleum), acid-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-12-7	869
Distillates (petroleum), acid-treated middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-13-8	870
Distillates (petroleum), acid-treated light, except if the full refining history is known and it can be shown that the substance from which	64742-14-9	871

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
it is produced is not a carcinogen		
Gas oils (petroleum), chemically neutralised, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-29-6	872
Distillates (petroleum), chemically neutralised middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-30-9	873
Distillates (petroleum), clay-treated middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-38-7	874
Distillates (petroleum), hydrotreated middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-46-7	875
Gas oils (petroleum), hydrodesulfurised, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-79-6	876
Distillates (petroleum), hydrodesulfurised middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-80-9	877
Distillates (petroleum), catalytic reformer fractionator residue, high-boiling, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	68477-29-2	878
Distillates (petroleum), catalytic reformer fractionator residue, intermediate-boiling, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	68477-30-5	879
Distillates (petroleum), catalytic reformer fractionator residue, low-boiling, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	68477-31-6	880
Alkanes, C12-26-branched and linear, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	90622-53-0	881
Distillates (petroleum), highly refined middle, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	90640-93-0	882
Distillates (petroleum), catalytic reformer, heavy arom. conc, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	91995-34-5	883
Gas oils, paraffinic, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	93924-33-5	884

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Naphtha (petroleum), solvent-refined hydrodesulfurised heavy, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97488-96-5	885
Hydrocarbons, C16-20, hydrotreated middle distillate, distn. lights, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97675- 85-9	886
Hydrocarbons, C12-20, hydrotreated paraffinic, distn. lights, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97675-86-0	887
Hydrocarbons, C11-17, solvent-extd. light naphthenic, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97722-08-2	888
Gas oils, hydrotreated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97862-78-7	889
Distillates (petroleum), carbon-treated light paraffinic, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	100683-97-4	890
Distillates (petroleum), intermediate paraffinic, carbon-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	100683-98-5	891
Distillates (petroleum), intermediate paraffinic, clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	100683-99-6	892
Lubricating greases, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	74869-21-9	893
Slack wax (petroleum), except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64742-61-6	894
Slack wax (petroleum), acid-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	90669-77-5	895
Slack wax (petroleum), clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	90669-78-6	896
Slack wax (petroleum), hydrotreated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	92062-09-4	897
Slack wax (petroleum), low-melting, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	92062-10-7	898

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Slack wax (petroleum), low-melting, hydrotreated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	92062-11-8	899
Slack wax (petroleum), low-melting, carbon-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97863-04-2	900
Slack wax (petroleum), low-melting, clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97863-05-3	901
Slack wax (petroleum), low-melting, silicic acid-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97863- 06-4	902
Slack wax (petroleum), carbon-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	100684-49-9	903
Petrolatum, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	8009-03-8	904
Petrolatum (petroleum), oxidised, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	64743-01-7	905
Petrolatum (petroleum), alumina-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	85029-74-9	906
Petrolatum (petroleum), hydrotreated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	92045-77-7	907
Petrolatum (petroleum), carbon-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97862-97-0	908
Petrolatum (petroleum), silicic acid-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	97862-98-1	909
Petrolatum (petroleum), clay-treated, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	100684-33-1	910
Distillates (petroleum), light catalytic cracked	64741-59-9	911
Distillates (petroleum), intermediate catalytic cracked	64741-60-2	912
Distillates (petroleum), light thermal cracked	64741-82-8	913
Distillates (petroleum), hydrodesulfurised light catalytic cracked	68333-25-5	914

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Distillates (petroleum), light steam-cracked naphtha	68475-80-9	915
Distillates (petroleum), cracked steam-cracked petroleum distillates	68477-38-3	916
Gas oils (petroleum), steam-cracked	68527-18-4	917
Distillates (petroleum), hydrodesulfurised thermal cracked middle	85116-53-6	918
Gas oils (petroleum), thermal-cracked, hydrodesulfurised	92045-29-9	919
Residues (petroleum), hydrogenated steam-cracked naphtha	92062-00-5	920
Residues (petroleum), steam-cracked naphtha distn.	92062-04-9	921
Distillates (petroleum), light catalytic cracked, thermally degraded	92201-60-0	922
Residues (petroleum), steam-cracked heat-soaked naphtha	93763-85-0	923
Gas oils (petroleum), light vacuum, thermal-cracked hydrodesulfurised	97926-59-5	924
Distillates (petroleum), hydrodesulfurised middle coker	101316-59-0	925
Distillates (petroleum), heavy steam-cracked	101631-14-5	926
Residues (petroleum), atm. Tower	64741-45-3	927
Gas oils (petroleum), heavy vacuum	64741-57-7	928
Distillates (petroleum), heavy catalytic cracked	64741-61-3	929
Clarified oils (petroleum), catalytic cracked	64741-62-4	930
Residues (petroleum), catalytic reformer fractionator	64741-67-9	931
Residues (petroleum), hydrocracked	64741-75-9	932
Residues (petroleum), thermal cracked	64741-80-6	933
Distillates (petroleum), heavy thermal cracked	64741-81-7	934
Gas oils (petroleum), hydrotreated vacuum	64742-59-2	935
Residues (petroleum), hydrodesulfurised atmospheric tower	64742-78-5	936
Gas oils (petroleum), hydrodesulfurised heavy vacuum	64742-86-5	937
Residues (petroleum), steam-cracked	64742-90-1	938
Residues (petroleum), atmospheric	68333-22-2	939
Clarified oils (petroleum), hydrodesulfurised catalytic cracked	68333-26-6	940
Distillates (petroleum), hydrodesulfurised intermediate catalytic cracked	68333-27-7	941

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<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Distillates (petroleum), hydrodesulfurised heavy catalytic cracked	68333-28-8	942
Fuel oil, residues-straight-run gas oils, high-sulfur	68476-32-4	943
Fuel oil, residual	68476-33-5	944
Residues (petroleum), catalytic reformer fractionator residue distn.	68478-13-7	945
Residues (petroleum), heavy coker gas oil and vacuum gas oil	68478-17-1	946
Residues (petroleum), heavy coker and light vacuum	68512-61-8	947
Residues (petroleum), light vacuum	68512-62-9	948
Residues (petroleum), steam-cracked light	68513-69-9	949
Fuel oil, No 6	68553-00-4	950
Residues (petroleum), topping plant, low-sulfur	68607-30-7	951
Gas oils (petroleum), heavy atmospheric	68783-08-4	952
Residues (petroleum), coker scrubber, condensed-ring-arom.-contg	68783-13-1	953
Distillates (petroleum), petroleum residues vacuum	68955-27-1	954
Residues (petroleum), steam-cracked, resinous	68955-36-2	955
Distillates (petroleum), intermediate vacuum	70592-76-6	956
Distillates (petroleum), light vacuum	70592-77-7	957
Distillates (petroleum), vacuum	70592-78-8	958
Gas oils (petroleum), hydrodesulfurised coker heavy vacuum	85117-03-9	959
Residues (petroleum), steam-cracked, distillates	90669-75-3	960
Residues (petroleum), vacuum, light	90669-76-4	961
Fuel oil, heavy, high-sulfur	92045-14-2	962
Residues (petroleum), catalytic cracking	92061-97-7	963
Distillates (petroleum), intermediate catalytic cracked, thermally degraded	92201-59-7	964
Residual oils (petroleum)	93821-66-0	965
Residues, steam cracked, thermally treated	98219-64-8	966
Distillates (petroleum), hydrodesulfurised full-range middle	101316-57-8	967
Distillates (petroleum), light paraffinic	64741-50-0	968

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Distillates (petroleum), heavy paraffinic	64741-51-1	969
Distillates (petroleum), light naphthenic	64741-52-2	970
Distillates (petroleum), heavy naphthenic	64741-53-3	971
Distillates (petroleum), acid-treated heavy naphthenic	64742-18-3	972
Distillates (petroleum), acid-treated light naphthenic	64742-19-4	973
Distillates (petroleum), acid-treated heavy paraffinic	64742-20-7	974
Distillates (petroleum), acid-treated light paraffinic	64742-21-8	975
Distillates (petroleum), chemically neutralised heavy paraffinic	64742-27-4	976
Distillates (petroleum), chemically neutralised light paraffinic	64742-28-5	977
Distillates (petroleum), chemically neutralised heavy naphthenic	64742-34-3	978
Distillates (petroleum), chemically neutralised light naphthenic	64742-35-4	979
Extracts (petroleum), light naphthenic distillate solvent	64742-03-6	980
Extracts (petroleum), heavy paraffinic distillate solvent	64742-04-7	981
Extracts (petroleum), light paraffinic distillate solvent	64742-05-8	982
Extracts (petroleum), heavy naphthenic distillate solvent	64742-11-6	983
Extracts (petroleum), light vacuum gas oil solvent	91995-78-7	984
Hydrocarbons, C26-55, arom. Rich	97722-04-8	985
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)] bis(4-aminonaphthalene-1- sulphonate)	573-58-0	986
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo] [1,1'-biphenyl]-4-yl] azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate	1937- 37-7	987
Tetrasodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxynaphthalene-2,7-disulphonate]	2602-46-2	988
4-o-Tolylazo-o-toluidine	97-56-3	989
4-Aminoazobenzene	60-09-3	990
Disodium[5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulphophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]salicylate(4-))cuprate(2-)	16071-86-6	991
Resorcinol diglycidyl ether	101-90-6	992
1,3-Diphenylguanidine	102-06-7	993



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<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Heptachlor-epoxide	1024-57-3	994
4-Nitrosophenol	104-91-6	995
Carbendazim	10605-21-7	996
Allyl glycidyl ether	106-92-3	997
Chloroacetaldehyde	107-20-0	998
Hexane	110-54-3	999
2-(2-Methoxyethoxy)ethanol	111-77-3	1000
(+/-)-2-(2,4-Dichlorophenyl)-3-(1H-1,2,4-triazol-1-yl)propyl-1,1,2,2-tetrafluoroethylether	112281-77-3	1001
4-[4-(1,3-Dihydroxyprop-2-yl)phenylamino]-1,8-dihydroxy-5-nitroanthraquinone	114565-66-1	1002
5,6,12,13-Tetrachloroanthra(2,1,9-def:6,5,10-d'e'f')diisoquinoline-1,3,8,10 (2H,9H)-tetrone	115662-06-1	1003
Tris(2-Chloroethyl) phosphate	115-96-8	1004
4'-Ethoxy-2-benzimidazoleanilide	120187-29-3	1005
Nickel dihydroxide	12054-48-7	1006
N,N-Dimethylaniline	121-69-7	1007
Simazine	122-34-9	1008
Bis(cyclopentadienyl)-bis(2,6-difluoro-3-(pyrrol-1-yl)-phenyl)titanium	125051-32-3	1009
N,N,N',N'-Tetraglycidyl-4,4'-diamino-3,3'-diethyldiphenylmethane	130728-76-6	1010
Divanadium pentaoxide	1314-62-1	1011
Alkali salts of pentachlorophenol	131-52-2 & 7778-73-6	1012
Phosphamidon	13171-21-6	1013
N-(Trichloromethylthio)phthalimide	133-07-3	1014
N-2-Naphthylaniline	135-88-6	1015
Ziram	137-30-4	1016
1-Bromo-3,4,5-trifluorobenzene	138526-69-9	1017
Propazine	139-40-2	1018
3-(4-Chlorophenyl)-1,1-dimethyluronium trichloroacetate; monuron-	140-41-0	1019

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<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
TCA		
Isoxaflutole	141112-29-0	1020
Kresoxim-methyl	143390-89-0	1021
Chlordecone	143-50-0	1022
9-Vinylcarbazole	1484-13-5	1023
2-Ethylhexanoic acid	149-57-5	1024
Monuron	150-68-5	1025
Morpholine-4-carbonyl chloride	15159-40-7	1026
Daminozide	1596-84-5	1027
Alachlor	15972-60-8	1028
UVCB condensation product of: tetrakis-hydroxymethylphosphonium chloride, urea and distilled hydrogenated C16-18 tallow alkylamine	166242-53-1	1029
Ioxynil	1689-83-4	1030
3,5-Dibromo-4-hydroxybenzonitrile	1689-84-5	1031
2,6-Dibromo-4-cyanophenyl octanoate	1689-99-2	1032
[4-[[4-(Dimethylamino)phenyl][4-[ethyl(3-sulphonatobenzyl)amino]phenyl]methylene]cyclohexa-2,5-dien-1-ylidene](ethyl)(3-sulphonatobenzyl)ammonium, sodium salt	1694-09-3	1033
5-Chloro-1,3-dihydro-2H-indol-2-one	17630-75-0	1034
Benomyl	17804-35-2	1035
Chlorothalonil	1897-45-6	1036
N'-(4-Chloro-o-tolyl)-N,N-dimethylformamidinium monohydrochloride	19750-95-9	1037
4,4'-Methylenebis(2-ethylaniline)	19900-65-3	1038
Valinamide	20108-78-5	1039
[(p-Tolyloxy)methyl]oxirane	2186-24-5	1040
[(m-Tolyloxy)methyl]oxirane	2186-25-6	1041
2,3-Epoxypropyl o-tolyl ether	2210-79-9	1042
[(Tolyloxy)methyl]oxirane, cresyl glycidyl ether	26447-14-3	1043
Di-allate	2303-16-4	1044
Benzyl 2,4-dibromobutanoate	23085-60-1	1045

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<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Trifluoriodomethane	2314-97-8	1046
Thiophanate-methyl	23564-05-8	1047
Dodecachloropentacyclo[5.2.1.02,6.03,9.05,8]decane	2385-85-5	1048
Propyzamide	23950-58-5	1049
Butyl glycidyl ether	2426-08-6	1050
2,3,4-Trichlorobut-1-ene	2431-50-7	1051
Chinomethionate	2439-01-2	1052
(R)-a-Phenylethylammonium (-)-(1R,2S)-(1,2-epoxypropyl)phosphonate monohydrate	25383-07-7	1053
5-Ethoxy-3-trichloromethyl-1,2,4-thiadiazole	2593-15-9	1054
Disperse Yellow 3	2832-40-8	1055
1,2,4-Triazole	288-88-0	1056
Aldrin	309-00-2	1057
Diuron	330-54-1	1058
Linuron	330-55-2	1059
Nickel carbonate	3333-67-3	1060
3-(4-Isopropylphenyl)-1,1-dimethylurea	34123-59-6	1061
Iprodione	36734-19-7	1062
4-Cyano-2,6-diiodophenyl octanoate	3861-47-0	1063
5-(2,4-Dioxo-1,2,3,4-tetrahydropyrimidine)-3-fluoro-2-hydroxymethylterahydrofuran	41107-56-6	1064
Crotonaldehyde	4170-30-3	1065
Hexahydrocyclopenta(c)pyrrole-1-(1H)-ammonium N-ethoxycarbonyl-N-(p-olylsulfonyl)azanide	EC No 418-350-1	1066
4,4'-Carbonimidoylbis[N,N-dimethylaniline]	492-80-8	1067
DNOC	534-52-1	1068
Toluidinium chloride	540-23-8	1069
Toluidine sulphate (1:1)	540-25-0	1070
2-(4-tert-Butylphenyl)ethanol	5406-86-0	1071

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Substance	CAS Number	Ref. No
Fenthion	55-38-9	1072
Chlordane, pur	57-74-9	1073
Hexan-2-one	591-78-6	1074
Fenarimol	60168-88-9	1075
Acetamide	60-35-5	1076
N-cyclohexyl-N-methoxy-2,5-dimethyl-3-furamide	60568-05-0	1077
Dieldrin	60-57-1	1078
4,4'- Isobutylethylidenediphenol	6807-17-6	1079
Chlordimeform	6164-98-3	1080
Amitrole	61-82-5	1081
Carbaryl	63-25-2	1082
Distillates (petroleum), light hydrocracked .	64741-77-1	1083
1-Ethyl-1-methylmorpholinium bromide	65756-41-4	1084
(3-Chlorophenyl)-(4-methoxy-3-nitrophenyl)methanone	66938-41-8	1085
Fuels, diesel, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen	68334-30-5	1086
Fuel oil, no. 2	68476-30-2	1087
Fuel oil, no. 4	68476-31-3	1088
Fuels, diesel, no. 2	68476-34-6	1089
2,2-Dibromo-2-nitroethanol	69094-18-4	1090
1-Ethyl-1-methylpyrrolidinium bromide	69227-51-6	1091
Monocrotophos	6923-22-4	1092
Nickel	7440-02-0	1093
Bromomethane	74-83-9	1094
Chloromethane	74-87-3	1095
Iodomethane	74-88-4	1096
Bromoethane	74-96-4	1097
Heptachlor	76-44-8	1098

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<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
Fentin hydroxide	76-87-9	1099
Nickel sulphate	7786-81-4	1100
3,5,5-Trimethylcyclohex-2-enone	78-59-1	1101
2,3-Dichloropropene	78-88-6	1102
Fluazifop-P-butyl	79241-46-6	1103
(S)-2,3-Dihydro-1H-indole-carboxylic acid	79815-20-6	1104
Toxaphene	8001-35-2	1105
(4-Hydrazinophenyl)-N-methylmethanesulfonamide hydrochloride	81880-96-8	1106
CI Solvent yellow 14.	842-07-9	1107
Chlozolate	84332-86-5	1108
Alkanes, C10-13, chloro	85535-84-8	1109
Pentachlorophenol	87-86-5	1110
2,4,6-Trichlorophenol	88-06-2	1111
Diethylcarbamoil-chloride	88-10-8	1112
1-Vinyl-2-pyrrolidone	88-12-0	1113
Myclobutanil; 2-(4-chlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)hexanenitrile	88671-89-0	1114
Fentin acetate	900-95-8	1115
Biphenyl-2-ylamine	90-41-5	1116
Trans-4-cyclohexyl-L-proline monohydro-chloride	90657-55-9	1117
2-Methyl-m-phenylene diisocyanate	91-08-7	1118
4-Methyl-m-phenylene diisocyanate	584-84-9	1119
m-Tolylidene diisocyanate	26471-62-5	1120
Fuels, jet aircraft, coal solvent extrn., hydrocracked hydrogenated	94114-58-6	1121
Fuels, diesel, coal solvent extrn., hydrocracked hydrogenated	94114-59-7	1122
Pitch, if it contains > 0,005 % w/w benzo[a]pyrene	61789-60-4	1123
2-Butanone oxime	96-29-7	1124
Hydrocarbons, C16-20, solvent-dewaxed hydrocracked paraffinic distn. residue	97675-88-2	1125

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Substance	CAS Number	Ref. No
$\alpha$ , $\alpha$ -Dichlorotoluene	98-87-3	1126
Mineral wool, with the exception of those specified elsewhere in this Annex; [Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na <sub>2</sub> O + K <sub>2</sub> O + CaO + MgO + BaO) content greater than 18 % by weight] .		1127
Reaction product of acetophenone, formaldehyde, cyclohexylamine, methanol and acetic acid	EC No 406-230-1	1128
Salts of 4,4'-carbonimidoylbis[N,N-dimethylaniline]		1129
1,2,3,4,5,6-Hexachlorocyclohexanes with the exception of those specified elsewhere in this Annex		1130
Trisodium bis(7-acetamido-2-(4-nitro-2-oxidophenylazo)-3-sulfonato-1-naphtholato)chromate(1-)	EC No 400-810-8	1131
A mixture of: 4-allyl-2,6-bis(2,3-epoxypropyl)phenol, 4-allyl-6-(3-(6-(3-(6-(3-(4-allyl-2,6-bis(2,3-epoxypropyl)-phenoxy)2-hydroxypropyl)-4-allyl-2-(2,3-epoxypropyl)phenoxy)-2-hydroxypropyl)-4-allyl-2-(2,3-epoxypropyl)-phenoxy-2-hydroxypropyl-2-(2,3-epoxypropyl)phenol, 4-allyl-6-(3-(4-allyl-2,6-bis(2,3-epoxypropyl)phenoxy)-2-hydroxypropyl)-2-(2,3-epoxypropyl)phenoxy)phenol and 4-allyl-6-(3-(6-(3-(4-allyl-2,6-bis(2,3-epoxypropyl)-phenoxy)-2-hydroxypropyl)-4-allyl-2-(2,3-epoxypropyl) phenoxy)2-hydroxypropyl)-2-(2,3-epoxypropyl)phenol	EC No 417-470-1	1132
Costus root oil ( <i>Saussurea lappa</i> Clarke), when used as a fragrance ingredient	8023-88-9	1133
7-Ethoxy-4-methylcoumarin, when used as a fragrance ingredient	87-05-8	1134
Hexahydrocoumarin, when used as a fragrance ingredient	700-82-3	1135
Peru balsam (INCI name: <i>Myroxylon pereirae</i> , when used as a fragrance ingredient'	8007-00-9	1136
Isobutyl nitrite	542-56-3	1137
Isoprene (stabilized) (2-methyl-1,3-butadiene)	78-79-5	1138
1-bromopropane n-propyl bromide	106-94-5	1139
chloroprene (stabilized) (2-chlorobuta-1,3-diene)	126-99-8	1140
1,2,3-trichloropropane	96-18-4	1141
Ethylene glycol dimethyl ether (EGDME)	110-71-4	1142
Dinocap (ISO)	39300-45-3	1143
Diaminotoluene, technical product -mixture of [4-methyl-m-phenylene diamine] <sup>(1)</sup> and [2-methyl-m-phenylene diamine] <sup>(2)</sup> methyl-phenylenediamine	25376-45-8	1144

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<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
p-chlorobenzotrichloride	5216-25-1	1145
Diphenylether; octabromo derivate	32536-52-0	1146
1,2-bis(2-methoxyethoxy)ethane triethylene glycol dimethyl ether (TEGDME)	112-49-2	1147
Tetrahydrothiopyran-3-carboxaldehyde	61571-06-0	1148
4,4'-bis(dimethylamino)benzophenone (Michler's ketone)	90-94-8	1149
Oxiranemethanol, 4-methylbenzene-sulfonate, (S)	70987-78-9	1150
1,2-benzenedicarboxylic acid, dipentylester, branched and linear [1] n-pentyl-isopentylphthalate [2] di-n-pentyl phthalate [3] diisopentylphthalate [4]	84777-06-0 [1] - [2] 131-18-0 [3] 605-50-5 [4]	1151
Benzyl butyl phthalate (BBP)	85-68-7	1152
1,2-benzenedicarboxylic acid di-C 7-11, branched and linear alkylesters	68515-42-4	1153
A mixture of: disodium 4-(3-ethoxycarbonyl-4-(5-(3-ethoxycarbonyl-5-hydroxy-1-(4-sulfonatophenyl) pyrazol-4-yl) penta-2,4-dienylidene)-4,5-dihydro-5-oxopyrazol-1-yl)benzenesulfonate and trisodium 4-(3-ethoxycarbonyl-4-(5-(3ethoxycarbonyl-5-oxido-1-(4-sulfonatophenyl)pyrazol-4-yl) penta-2,4-dienylidene)-4,5-dihydro-5-oxopyrazol-1-yl)benzenesulfonate	EC No 402-660-9	1154
(methylenebis(4,1-phenylenazo(1-(3-(dimethylamino) propyl)-1,2-dihydro-6-hydroxy-4-methyl-2-oxopyridine-5,3diyl)))-1,1'-dipyridinium dichloride dihydrochloride	EC No 401-500-5	1155
2-[2-hydroxy-3-(2-chlorophenyl) carbamoyl-1-naphthylazo]7-[2-hydroxy-3-(3-methylphenyl)-2-[2-hydroxy-3-(3-methylphenyl)-carbamoyl-1-naphthylazo]-7-[2-hydroxy-3-(3methylphenyl)carbamoyl-1-naphthylazo]fluoren-9-one	EC No 420-580-2	1156
azafenidin	68049-83-2	1157
2,4,5-trimethylaniline [1] 2,4,5-trimethylaniline hydrochloride [2]	137-17-7 [1] 21436-97-5 [2]	1158
4,4'-thiodianiline and its salts	139-65-1	1159
4,4'-oxydianiline (p-aminophenyl ether) and its salts	101-80-4	1160
N,N,N',N'-tetramethyl-4,4'-methylenedianiline	101-61-1	1161
6-methoxy-m-toluidine (p-cresidine)	120-71-8	1162
3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	1163

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
A mixture of: 1,3,5-tris(3-aminomethylphenyl)-1,3,5-(1H,3H,5H)-triazine-2,4,6-trione and a mixture of oligomers of 3,5-bis(3-aminomethylphenyl)-1-poly[3,5-bis(3-aminomethylphenyl)-2,4,6-trioxo-1,3,5-(1H,3H,5H)-triazin-1-yl]1,3,5-(1H,3H,5H)-triazine-2,4,6-trione	EC No 421-550-1	1164
2-nitrotoluene	88-72-2	1165
tributyl phosphate	126-73-8	1166
naphthalene	91-20-3	1167
nonylphenol [1] 4-nonylphenol, branched [2]	25154-52-3 [1] 84852-15-3 [2]	1168
1,1,2-trichloroethane	79-00-5	1169
pentachloroethane	76-01-7	1170
vinylidene chloride (1,1-dichloroethylene)	75-35-4	1171
allyl chloride (3-chloropropene)	107-05-1	1172
1,4-dichlorobenzene (p-dichlorobenzene)	106-46-7	1173
bis(2-chloroethyl) ether	111-44-4	1174
phenol and it's alkali salts	108-95-2	1175
bisphenol A (4,4'-isopropylidenediphenol)	80-05-7	1176
trioxymethylene (1,3,5-trioxan)	110-88-3	1177
propargite (ISO)	2312-35-8	1178
1-chloro-4-nitrobenzene	100-00-5	1179
molinate (ISO)	2212-67-1	1180
fenpropimorph	67564-91-4	1181
Epoxiconazole		1182
methyl isocyanate	624-83-9	1183
N,N-dimethylanilinium tetrakis(pentafluorophenyl)borate	118612-00-3	1184
O,O'-(ethenylmethylsilylene) di[(4-methylpentan-2-one) oxime]	EC No 421-870-1	1185
A 2:1 mixture of: 4-(7-hydroxy-2,4,4-trimethyl-2-chromanyl) resorcinol-4-yl-tris(6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate) and 4-(7-hydroxy-2,4,4-trimethyl-2-chromanyl) resorcinol bis(6-diazo-5,6-dihydro-5-oxonaphthalen-1-sulfonate)	140698-96-0	1186



**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
a mixture of: reaction product of 4,4'-methylenebis[2-(4-hydroxybenzyl)-3,6-dimethylphenol] and 6-diazo-5,6-dihydro-5-oxo-naphthalenesulfonate (1:2) and reaction product of 4,4'-methylenebis[2-(4-hydroxybenzyl)-3,6-dimethylphenol] and 6-diazo-5,6-dihydro-5-oxonaphthalenesulfonate (1:3)	EC No 417-980-4	1187
Malachite green hydrochloride [1] malachite green oxalate [2]	569-64-2 [1] 18015-76-4 [2]	1188
1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl) pentan-3-ol	107534-96-3	1189
5-(3-butyryl-2,4,6-trimethylphenyl)-2-[1-(ethoxyimino) propyl]-3-hydroxycyclohex-2-en-1-one	138164-12-2	1190
trans-4-phenyl-L-proline	96314-26-0	1191
bromoxynil heptanoate (ISO)	56634-95-8	1192
A mixture of: 5-[(4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl) azo]-2,5-diethoxyphenyl)azo]-2-[(3-phosphonophenyl)azo] benzoic acid and 5-[(4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl) azo]-2,5-diethoxyphenyl)azo]-3-[(3-phosphonophenyl) azo]benzoic acid	163879-69-4	1193
2-[4-(2-ammoniopropylamino)-6-[4-hydroxy-3-(5-methyl-2methoxy-4- sulfamoylphenylazo)-2-sulfonatophenylamino]- 1,3,5-triazin-2-ylamino]-2-aminopropyl formate	EC No 424-260-3	1194
5-nitro-o-toluidine [1] 5-nitro-o-toluidine hydrochloride [2]	99-55-8 [1] 51085-52-0 [2]	1195
1-(1-naphthylmethyl)quinolinium	65322-65-8	1196
(R)-5-bromo-3-(1-methyl-2-pyrrolidinyl methyl)-1H-indole	143322-57-0	1197
pymetrozine (ISO)	123312-89-0	1198
oxadiargyl (ISO)	39807-15-3	1199
chlorotoluron (3-(3-chloro-p-tolyl)-1,1-dimethylurea)	15545-48-9	1200
N-[2-(3-acetyl-5-nitrothiophen-2-ylazo)-5-diethylaminophenyl] acetamide	EC No 416-860-9	1201
1,3-bis(vinylsulfonylacetamido)-propane	93629-90-4	1202
p-phenetidine (4-ethoxyaniline)	156-43-4	1203
m-phenylenediamine and its salts	108-45-2	1204

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
residues (coal tar), creosote oil distn., if it contains > 0,005 % w/w benzo[a]pyrene	92061-93-3	1205
creosote oil, acenaphthene fraction, wash oil, if it contains > 0,005 %w/w benzo[a]pyrene	90640-84-9	1206
creosote oil, if it contains > 0,005 %w/w benzo[a]pyrene	61789-28-4	1207
creosote, if it contains > 0,005 % w/w benzo[a]pyrene	8001-58-9	1208
creosote oil, high-boiling distillate, wash oil, if it contains > 0,005 %w/w benzo[a]pyrene	70321-79-8	1209
extract residues (coal), creosote oil acid, wash oil extract residue, if it contains > 0,005 % w/w benzo[a]pyrene	122384-77-4	1210
creosote oil, low-boiling distillate, wash oil, if it contains > 0,005 %w/w benzo[a]pyrene	70321-80-1	1211
6-Methoxy-2,3-Pyridinediamine and its HCl salt, when used as a substance in hair dye products	94166-62-8	1212
2,3-Naphthalenediol, when used as a substance in hair dye products	92-44-4	1213
2,4-Diaminodiphenylamine, when used as a substance in hair dye products	136-17-4	1214
2,6-Bis(2-Hydroxyethoxy)-3,5-Pyridinediamine and its HCl salt, when used as a substance in hair dye products	117907-42-3	1215
2-Methoxymethyl-p-Aminophenol and its HCl salt, when used as a substance in hair dye products	29785-47-5	1216
4,5-Diamino-1-Methylpyrazole and its HCl salt, when used as a substance in hair dye products	20055-01-0	1217
4,5-Diamino-1-((4-Chlorophenyl)methyl)-1H-Pyrazole Sulfate, when used as a substance in hair dye products	163183-00-4	1218
4-Chloro-2-Aminophenol, when used as a substance in hair dye products	95-85-2	1219
4-Hydroxyindole, when used as a substance in hair dye products	2380-94-1	1220
4-Methoxytoluene-2,5-Diamine and its HCl salt, when used as a substance in hair dye products	56496-88-9	1221
5-Amino-4-Fluoro-2-Methylphenol Sulfate, when used as a	163183-01-5	1222

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
substance in hair dye products		
N,N-Diethyl-m-Aminophenol, when used as a substance in hair dye products	91-68-9	1223
N,N-Dimethyl-2,6-Pyridinediamine and its HCl salt, when used as a substance in hair dye products		1224
N-Cyclopentyl-m-Aminophenol, when used as a substance in hair dye products	104903-49-3	1225
N-(2-Methoxyethyl)-p-phenylenediamine and its HCl salt, when used as a substance in hair dye products	72584-59-9	1226
2,4-Diamino-5-methylphenetol and its HCl salt, when used as a substance in hair dye products	113715-25-6	1227
1,7-Naphthalenediol, when used as a substance in hair dye products	575-38-2	1228
3,4-Diaminobenzoic acid, when used as a substance in hair dye products	619-05-6	1229
2-Aminomethyl-p-aminophenol and its HCl salt, when used as a substance in hair dye products	79352-72-0	1230
Solvent Red 1 (CI 12150), when used as a substance in hair dye products	1229-55-6	1231
Acid Orange 24 (CI 20170), when used as a substance in hair dye products	1320-07-6	1232
Acid Red 73 (CI 27290), when used as a substance in hair dye products	5413-75-2	1233
PEG-3,2',2'-di-p-Phenylenediamine	144644-13-3	1234
6-Nitro-o-Toluidine	570-24-1	1235
HC Yellow No 11	73388-54-2	1236
HC Orange No 3	81612-54-6	1237
HC Green No 1	52136-25-1	1238
HC Red No 8 and its salts	97404-14-3 & 13556-29-1	1239
Tetrahydro-6-nitroquinoxaline and its salts	158006-54-3 & 41959-35-7	1240
Disperse Red 15, except as impurity in Disperse Violet 1	116-85-8	1241

**Annexe II Part 1 – List of substances which must not form part of the composition of cosmetic products**

<b>Substance</b>	<b>CAS Number</b>	<b>Ref. No</b>
4-amino-3-fluorophenol	399-95-1	1242
N,N'-dihexadecyl-N,N'-bis(2-hydroxyethyl)propanediamide Bishydroxyethyl Biscetyl Malonamide	149591-38-8	1243

(1) for the individual ingredient see reference number 364 in Annex II.

(2) for the individual ingredient see reference number 413 in Annex II.

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

**ANNEX III, PART 1**

***LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO RESTRICTIONS AND CONDITIONS LAID DOWN***

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
1a	Boric acid, borates and tetraborates with the exception of substance No 1184 in Annex II	<p>(a) Talc</p> <p>(b) Products for oral hygiene</p> <p>(c) Other products (excluding bath products and hair waving products)</p>	<p>(a) 5% (by mass/mass as boric acid)</p> <p>(b) 0.1% (by mass/mass as boric acid)</p> <p>(c) 3% (by mass/mass as boric acid)</p>	<p>(a) 1. Not to be used in products for children under 3 years of age</p> <p>2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5% (by mass/mass as boric acid)</p> <p>(b) Not to be used in products for children under 3 years of age</p> <p>(c) 1. Not to be used in products for children under 3 years of age</p> <p>2. Not to be used on peeling or irritated skin if the concentration of free soluble borates exceeds 1.5% (by mass/mass as boric acid)</p>	<p>(a) 1. Not to be used for children under 3 years of age</p> <p>2. Not to be used on peeling or irritated skin</p> <p>(b) 1. Not to be swallowed</p> <p>2. Not to be used for children under 3 years of age</p> <p>(c) 1. Not to be used for children under 3 years of age</p> <p>2. Not to be used on peeling or irritated skin</p>

### Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
1b	Tetraborates	(a) Bath products  (b) Hair waving products	(a) 18% (by mass/mass as boric acid)  (b) 8% (by mass/mass as boric acid)	(a) Not to be used in products for children under 3 years of age	(a) Not to be used for bathing children under 3 years of age  (b) Rinse well
2a	Thioglycolic acid and its salts	(a) Hair waving or straightening products: - General use  - Professional use  (b) Depilatories (c) Other hair care products which are removed after application	- 8% ready for use pH 7-9.5  - 11% ready for use pH 7-9.5  - 5% ready for use pH 7-12.7 - 2% ready for use pH 7-9.5  Percentages calculated as thioglycollic acid.	a) b) c)  The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences:  - Avoid contact with eyes.  - In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice.  - Wear suitable gloves (a) and c) only	a) - Contains thioglycolate. - Follow the instructions - Keep out of reach of children.  - For professional use only.  b) and c) - Contains thioglycolate. - Follow the instruction. - Keep out of reach of children.

### Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
2b	Thioglycolic acid esters	Hair waving or straightening products: - General use  - Professional use	- 8% ready for use pH 6-9.5  - 11% ready for use pH 6-9.5  Percentages calculated as thioglycolic acid.	The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: ▪ May cause sensitisation in the event of skin contact. ▪ Avoid contact with eyes. ▪ In the event of contact with eyes, rinse off with plenty of water and seek medical advice. ▪ Wear suitable gloves.	- Contains thioglycollate. - Follow the instructions. - Keep out of reach of children.  - For professional use only.
3	Oxalic acid, its esters and alkaline salts	Hair care products	5%		- For professional use only
4	Ammonia		6% calculated as NH <sub>3</sub>		- Above 2%: contains ammonia
5	Tosylchloramide sodium		0.2%		
6	Chlorates of alkali metals	(a) Toothpaste (b) Other uses	(a) 5% (b) 3%		



**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
8	p-Phenylenediamine, its N-substituted derivatives and its salts; N-substituted derivatives of o-Phenylenediamine <sup>(5)</sup> , with exception of those derivatives listed elsewhere in this Annex	Oxidizing colouring agents for hair dyeing  (a) General use    (b) Professional use	6% calculated as free base		(a)- Can cause an allergic reaction  - Contains phenylenediamines  - Do not use to dye eyelashes or eyebrows   (b) - For professional use only.  - Contains phenylenediamines  - Can cause an allergic reaction.  - Wear suitable gloves

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
9	Methylphenylenediamines, their N-substituted derivatives and their salts <sup>(1)</sup> with the exception of substance N°364 and 413 in Annex II.	Oxidizing colouring agents for hair dyeing  (a) general use  (b) professional use	10% calculated as free base		(a) - Can cause an allergic reaction . - Contains phenylenediamines - Do not use to dye eyelashes or eyebrows.  (b) - For professional use only. - Contains phenylenediamines - Can cause an allergic reaction. - Wear suitable gloves.
10	Diaminophenols <sup>(1)</sup>	Oxidizing colouring agents for hair dyeing  (a) general use  (b) professional use	10% calculated as free base		(a) - Can cause an allergic reaction. - Contains diaminophenols. - Do not use to dye eyelashes or eyebrows.  (b) For professional use only. - Contains diaminophenols. - Can cause an allergic reaction. - Wear suitable gloves.
11	Dichlorophen		0.5%		– Contains dichlorophen

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
12	Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	(a) Hair-care preparations (b) Skin-care preparations  (c) Nail hardening preparations (d) Oral hygiene products	(a) 12% H <sub>2</sub> O <sub>2</sub> (40 volumes) present or released (b) 4% of H <sub>2</sub> O <sub>2</sub> present or released (c) 2% of H <sub>2</sub> O <sub>2</sub> present or released (d) 0.1% of H <sub>2</sub> O <sub>2</sub> present or released		(a) (b) (c) - Contains hydrogen peroxide. - Avoid contact with eyes. - Rinse eyes immediately if product comes into contact with them.  (a) Wear suitable gloves.
13	Formaldehyde	Nail hardeners	5% calculated as formaldehyde		Protect cuticles with grease or oil. Contains formaldehyde <sup>(2)</sup>

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
14	Hydroquinone (3)	<p>a) Oxidizing colouring agent for hair-dyeing</p> <p>1. General use</p> <p>2 Professional use</p> <p>b) Artificial nail systems</p>	<p>(a) 0.3%</p> <p>(b) 0.02% after mixing for use</p>	Professional use only	<p>(a) 1.</p> <ul style="list-style-type: none"> <li>- Do not use to dye eyelashes or eye brows</li> <li>- Rinse the eyes immediately if the product comes into contact with them</li> <li>- Contains hydroquinone</li> </ul> <p>2. For professional use only</p> <ul style="list-style-type: none"> <li>- Contains hydroquinone</li> <li>- Rinse the eyes immediately if the product comes into contact with them</li> </ul> <p>(b)</p> <ul style="list-style-type: none"> <li>- For professional use only</li> <li>- Avoid skin contact</li> <li>- Read directions for use carefully</li> </ul>

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
15a	Potassium or sodium hydroxide	(a) Nail cuticle solvent  (b) Hair straightener 1. General use  2. Professional use  (c) pH adjuster – depilatories  (d) Other uses as pH adjuster	(a) 5% by weight (4)  (b) 1. 2% by weight (4)  2. 4.5% by weight (4)  (c) up to pH 12.7  (d) up to pH 11		(a) - Contains alkali - Avoid contact with eyes - Can cause blindness - Keep out of reach of children  (b) 1. - Contains alkali - Avoid contact with eyes - Can cause blindness - Keep out of reach of children 2. - For professional use only - Avoid contact with eyes - Can cause blindness  (c) – Keep out of reach of children. – Avoid contact with eyes

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
15b	Lithium hydroxide	(a) Hair straightener 1. General use  2. Professional use <u>(b) pH adjuster – for depilatories</u> <u>(c) Other uses – as pH adjuster (for rinse-off products only)</u>	(a) 1. 2% by weight <sup>(6)</sup>  2. 4.5% by weight <sup>(6)</sup>	(b) pH value not to exceed pH 12,7  (c) pH value not to exceed pH 11	(a) 1. –Contains alkali - Avoid contact with eyes - Can cause blindness - Keep out of reach of children 2. - For professional use only - Avoid contact with eyes - Can cause blindness
15c	Calcium hydroxide	(a) Hair straighteners containing two components: calcium hydroxide and a guanidine salt <u>(b) pH adjuster – for depilatories</u> <u>(c) Other uses (e.g. pH adjuster, processing aid)</u>	(a) 7% by weight calcium hydroxide	(b) pH value not to exceed pH 12.7 (c) pH value not to exceed pH 11	(a) - Contains alkali - Avoid contact with eyes - Can cause blindness - Keep out of reach of children (b) - Contains alkali - Keep out of reach of children - Avoid contact with eyes
16	1-Naphthol (CAS No. 90-15-3) and its salts	Oxidizing colouring agents for hair dyeing	2%	In combination with hydrogen peroxide the maximum use concentration upon application is 1.0%.	- Can cause allergic reaction.

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
17	Sodium nitrite	Rust inhibitor	0.2%	Do not use with secondary and/or tertiary amines or other substances forming nitrosamines	
18	Nitromethane	Rust inhibitor	0.3%		
21	Quinine and its salts	(a) Shampoos  (b) Hair lotions	(a) 0.5% calculated as quinine base  (b) 0.2% calculated as quinine base		

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
22	Resorcinol ( <sup>3</sup> )	(a) Oxidizing colouring agent for hair dyeing 1. General use 2. Professional use  (b) Hair lotions and shampoos	(a) 5%  (b) 0.5%		(a) 1. - Contains resorcinol - Rinse hair well after application - Do not use to dye eyelashes or eyebrows - Rinse eyes immediately if product comes into contact with them 2. - For professional use only - Contains resorcinol - Rinse eyes immediately if product comes into contact with them  (b) - Contains resorcinol
23	(a) Alkali sulphides  (b) Alkaline earth sulphides	(a) Depilatories  (b) Depilatories	(a) 2% calculated as sulphur pH up to 12.7 (b) 6% calculated as sulphur pH up to 12.7		(a) - Keep out of reach of children - Avoid contact with eyes (b) - Keep out of reach of children - Avoid contact with the eyes



**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
24	Water-soluble zinc salts with the exception of zinc-4-hydroxybenzenesulphonate and zinc pyrithione		1% calculated as zinc		
25	Zinc 4-hydroxybenzene sulphonate	Deodorants, antiperspirants and astringent lotions	6% calculated as % of anhydrous substance		- Avoid contact with eyes
26	Ammonium monofluorophosphate	Oral hygiene products	0.15% calculated as F when mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.15%.	<b>Thailand only</b> 0.11% calculated as F when mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.11%.	- Contains ammonium monofluorophosphate
27	Sodium monofluorophosphate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains sodium monofluorophosphate
28	Potassium monofluorophosphate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains potassium monofluorophosphate
29	Calcium monofluorophosphate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains calcium monofluorophosphate
30	Calcium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains calcium fluoride

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
31	Sodium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains sodium fluoride
32	Potassium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains potassium fluoride
33	Ammonium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains ammonium fluoride
34	Aluminium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains aluminium fluoride
35	Stannous fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains stannous fluoride
36	Hexadecyl ammonium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains hexadecyl ammonium fluoride
37	3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium difluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains 3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium difluoride
38	NN'N'-Tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains NN'N'-Tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride
39	Octadecenyl-ammonium fluoride	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains octadecyl-ammonium fluoride

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
40	Sodium fluorosilicate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains sodium fluorosilicate
41	Potassium fluorosilicate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains potassium fluorosilicate
42	Ammonium fluorosilicate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains ammonium fluorosilicate
43	Magnesium fluorosilicate	Ditto	0.15% Ditto	Thailand 0.11% ditto	- Contains magnesium fluorosilicate
44	1,3-Bis(hydroxymethyl) imidazolidine-2-thione	a) Hair care preparations  b) Nail care preparations	a) Up to 2%  b) Up to 2%	a) Prohibited in aerosols dispensers (sprays)  b) The pH of the product as applied must be less than 4	- Contains 1, 3-bis (hydroxymethyl) imidazolidine-2- thione
45	Benzyl alcohol	Solvents, perfumes and flavouring			
46	6-Methylcoumarin	Oral hygiene products	0.003%		
47	Nicomethanol hydrofluoride	Oral hygiene products	0.15% calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.15%	<b>Thailand only</b> 0.11% calculated as F when mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.11%.	- Contains nicomethanol hydrofluoride

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
48	Silver nitrate	Solely for products intended for colouring eyelashes and eyebrows	4%		<ul style="list-style-type: none"> <li>- Contains silver nitrate</li> <li>- Rinse the eyes immediately if product comes into contact with them</li> </ul>
49	Selenium disulphide	Anti-dandruff shampoo	1%		<ul style="list-style-type: none"> <li>- Contains selenium disulphide</li> <li>- Avoid contact with eyes or damaged skin</li> </ul>
50	Aluminium zirconium chloride hydroxide complexes $Al_xZr(OH)_yCl_z$ and the aluminium zirconium chloride hydroxide glycine complexes	Anti-perspirants	<ul style="list-style-type: none"> <li>▪ 20% as anhydrous aluminium zirconium chloride hydroxide</li> <li>▪ 5.4% as zirconium</li> </ul>	<ol style="list-style-type: none"> <li>1. The ratio of the number of aluminium atoms to that of zirconium atoms must be between 2 and 10</li> <li>2. The ratio of the number of (Al + Zr) atoms to that of chlorine atoms must be between 0.9 and 2.1</li> <li>3. Prohibited in aerosol dispensers (sprays)</li> </ol>	Do not apply to irritated or damaged skin

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
51	Quinolin-8-ol and bis (8-hydroxyquinolinium) sulphate	<ul style="list-style-type: none"> <li>▪ Stabilizer for hydrogen peroxide in rinse-off hair care preparations.</li> <li>▪ Stabilizer for hydrogen peroxide in non-rinse-off hair-care preparations.</li> </ul>	<ul style="list-style-type: none"> <li>▪ 0.3% calculated as base</li> <li>▪ 0.03% calculated as base</li> </ul>		
52	Methanol	Denaturant for ethanol and isopropyl alcohol	5% calculated as a % of ethanol and isopropyl alcohol		
53	Etidronic acid and its salts (1-hydroxy-ethylidene-diphosphonic acid and its salts)	a) Hair-care b) Soap	(a) 1.5% expressed as etidronic acid (b) 0.2% expressed as etidronic acid		
54	1-Phenoxypropan-2-ol	<ul style="list-style-type: none"> <li>- Rinse-off products only</li> <li>- Prohibited in oral hygiene products</li> </ul>	2%	As a preservative, see Annex VI, Part 1, N° 43	-
55	Entry deleted				

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
56	Magnesium fluoride	Dental hygiene products	0.15% calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.15%	<b>Thailand only</b> 0.11% calculated as F when mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.11%.	- Contains magnesium fluoride

## **Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

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**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
58	Strontium acetate hemihydrate	Toothpaste	3.5% calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3.5%		<ul style="list-style-type: none"> <li>- Contains strontium acetate</li> <li>- Frequent use by children is not advisable</li> </ul>
59	Talc: Hydrated magnesium silicate	a) Powdery products intended to be used by children b) Other products			<ul style="list-style-type: none"> <li>- a) – Keep powder away from children's nose and mouth</li> </ul>
60	Fatty acid dialkylamides and dialkanolamides		Maximum secondary amine content: 0.5%	<ul style="list-style-type: none"> <li>- Do not use with nitrosating systems</li> <li>- Maximum secondary amine content : 5% (applies to raw materials)</li> <li>- Maximum nitrosamine content : 50 µg/kg</li> <li>- Keep in nitrite-free containers</li> </ul>	



**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
61	Monoalkylamines, monoalkanolamines and their salts		Maximum secondary amine content: 0.5%	<ul style="list-style-type: none"> <li>- Do not use with nitrosating systems</li> <li>- Minimum purity: 99%</li> <li>- Maximum secondary amine content: 0.5% (concerns raw materials)</li> <li>- Maximum nitrosamine content: 50 µg/kg</li> <li>- Keep in nitrite-free containers</li> </ul>	
62	Trialkylamines, trialkanolamines and their salts	(a) non-rinse-off products  (b) other products	(a) 2.5%	(a) (b): <ul style="list-style-type: none"> <li>- Do not use with nitrosating systems</li> <li>- Minimum purity: 99%</li> <li>- Maximum secondary amine content: 0.5% (concerns raw materials)</li> <li>- Maximum nitrosamine content: 50 µg/kg</li> <li>- Keep in nitrite-free containers</li> </ul>	

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
63	Strontium hydroxide	pH-regulator in depilatory products	3.5% calculated as strontium, max pH of 12.7		<ul style="list-style-type: none"> <li>- Keep out of reach of children</li> <li>- Avoid contact with the eyes</li> </ul>
64	Strontium peroxide	Rinse-off hair care preparations professional use	4.5% calculated as strontium in the ready-for-use preparation	All products must meet the hydrogen peroxide release requirements	<ul style="list-style-type: none"> <li>- Avoid contact with eyes</li> <li>- Rinse eyes immediately if product comes into contact with them</li> <li>- For professional use only</li> <li>- Wear suitable gloves</li> </ul>
65	Benzalkonium chloride, bromide and saccharinate	(a) Rinse-off hair (head) care products  (b) Other products	(a) 3% (as benzalkonium chloride)  (b) 0.1% (as benzalkonium chloride)	(a) In the final products the concentrations of benzalkonium chloride, bromide and saccharinate with an alkyl chain of C <sub>14</sub> , or less must not exceed 0.1% (as benzalkonium chloride)	(a) Avoid contact with the eyes  (b) Avoid contact with the eyes
66	Polyacrylamides	(a) Body-care leave-on products (b) Other cosmetic products		(a) Maximum residual acrylamide content; 0.1 mg/kg (b) Maximum residual acrylamide content; 0.5 mg/kg	
				-	
				-	

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
93	2,4-Diamino-pyrimidine-3-oxide (CAS No 74638-76-9)	Hair care formulations	1.5 %		
94	Benzoyl peroxide	Artificial nail systems	0.7 % (After mixing for use)	Professional use only	- For professional use only - Avoid skin contact - Read directions for use carefully
95	Hydroquinone methylether	Artificial nail systems	0.02 % (After mixing for use)	Professional use only	- For professional use only - Contains hydroquinone, do not use on children under the age of 12 years - Avoid skin contact - Read directions for use carefully
96	Musk xylene (CAS No 81-15-2)	All cosmetic products, with the exception of oral care products	(a) 1.0 % in fine fragrance (b) 0.4 % in eau de toilette (c) 0.03 % in other products		
97	Musk ketone (CAS No 81-14-1)	All cosmetic products, with the exception of oral care products	(a) 1.4 % in fine fragrance (b) 0.56 % in eau de toilette (c) 0.042 % in other products		

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
98	Salicylic acid ( <sup>7</sup> ) (CAS No 69-72-7)	a) Rinse-off hair products  b) Other products	a) 3.0 %  b) 2.0 %	Not to be used in preparations for children under three years of age, except for shampoo  For purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product	Not to be used for children under three years of age <sup>8</sup>
99	Inorganic sulphites and bisulphites ( <sup>9</sup> )	a) Oxidative hair dye products  b) Hair straightening products  c) Self tanning products for the face  d) Other self tanning products	a) 0.67 % expressed as free SO <sub>2</sub>  b) 6.7 % expressed as free SO <sub>2</sub>  c) 0.45 % expressed as free SO <sub>2</sub>  d) 0.40 % expressed as free SO <sub>2</sub>	For purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product	

**Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down**

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
100	Triclocarban <sup>(10)</sup> (CAS No 101-20-2)	Rinse-off products	1.5 %	Purity criteria:  3,3',4,4'-Tetrachloroazobenzene ≤1 ppm 3,3',4,4'-Tetrachloroazoxybenzene ≤1 ppm  For purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product	
101	Zinc pyrithione <sup>(11)</sup> (CAS No 13463-41-7)	Leave-on hair products	0.1 %	For purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product	
A1	Camphor	Body powder		Not for use in products for children under the age of 3 years	Contains camphor - Not for use in products for children under the age of 3 years
A2	Menthol	Leave on products		Not for use in leave-on products for children under the age of 3 years	Contains menthol - Not for use in products for children under the age of 3 years

### Annex III – Part 1 – List of substances that cosmetic products must not contain except subject to restrictions and conditions laid down

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
A3	Deleted				
A4	Persulphates of ammonium, potassium or sodium	Hair bleaching products	45 % Persulphate before mixing with hydrogen peroxide. Not to exceed 20% after mixing.		Avoid contact with eyes. Test for allergic reaction before use. Stop using and rinse with water if irritation, burning or rash occurs at contact area. Do not use if there is scratch on scalp or dermatitis. Do not scratch heavily during hair wash. Keep out of reach of children and in a cool place.

- (1) These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed 1.
- (2) Only if the concentration exceeds 0,05 %.
- (3) These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorized for each of them does not exceed 2.
- (4) The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In cases of mixtures, the sum should not exceed the limits given in column d.
- (5) These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorised for each of them does not exceed 1.
- (6) The concentration of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In case of mixtures, the sum should not exceed the limits given in column d.
- (7) As a preservative, see Annexe VI, Part 1, No 3
- (8) Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin
- (9) As a preservative, see Annexe VI, Part 1, No 9
- (10) As a preservative, see Annexe VI, Part 1, No 23
- (11) As a preservative, see Annexe VI, Part 1, No 8

## Annexe III - Part 2– List of substances provisionally allowed

### ANNEX III – PART 2

#### LIST OF SUBSTANCES PROVISIONALLY ALLOWED

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
1	Basic blue 7 (CAS No 2390-60-5)	Non-oxidising colouring agents for hair dyeing	0.2 %		Can cause allergic reaction	30/06/2008
2	2-Amino-3-nitrophenol (CAS No 603-85-0) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	(a) (b) Can cause allergic reaction	30/06/2008
3	4-Amino-3-nitrophenol (CAS No 610-81-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	(a) (b) Can cause allergic reaction	30/06/2008
4	2,7-Naphthalenediol (CAS No 582-17-2) and its salts	Oxidising colouring agents for hair dyeing	1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.5 %		30/06/2008
5	m-Aminophenol (CAS No 591-27-5) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	Can cause allergic reaction	30/06/2008

### Annexe III - Part 2– List of substances provisionally allowed

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
6	2,6-Dihydroxy-3,4-dimethyl-pyridine (CAS No 84540-47-6) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	Can cause allergic reaction	30/06/2008
7	4-Hydroxypropylamino-3-nitrophenol (CAS No 92952-81-3) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 5.2 % (b) 2.6 %	In combination with hydrogen peroxide the maximum concentration upon application is 2.6 %	(a) (b) Can cause allergic reaction	30/06/2008
8	6-Nitro-2,5-pyridinediamine (CAS No 69825-83-8) and its salts	Non- oxidising colouring agents for hair dyeing	3.0 %		Can cause allergic reaction	30/06/2008
9	HC Blue No 11 (CAS No 23920-15-2) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	(a) (b) Can cause allergic reaction	30/06/2008
10	Hydroxyethyl-2-nitro-p-toluidine (CAS No 100418-33-5) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	(a) (b) Can cause allergic reaction	30/06/2008
11	2-Hydroxyethyl-picramic acid (CAS No 99610-72-2) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	(a) (b) Can cause allergic reaction	30/06/2008



### Annexe III - Part 2– List of substances provisionally allowed

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
12	p-Methylaminophenol (CAS No 150-75-4) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	Can cause allergic reaction	30/06/2008
13	2,4-Diamino-5-methylphenoxyethanol (CAS No 141614-05-3) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	Can cause allergic reaction	30/06/2008
14	HC Violet No 2 (CAS No 104226-19-9) and its salts	Non- oxidising colouring agents for hair dyeing	2.0 %			30/06/2008
15	Hydroxyethyl-2,6-dinitro-p-anisidine (CAS No 122252-11-3) and its salts	Non- oxidising colouring agents for hair dyeing	3.0 %		Can cause allergic reaction	30/06/2008
16	HC Blue No 12 (CAS No 104516-93-0) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 1.5 % (b) 1.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.75 %	(a) (b) Can cause allergic reaction	30/06/2008
-						
18	1,3-Bis-(2,4-diaminophenoxy)propane (CAS No 81892-72-0) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	Can cause allergic reaction	30/06/2008

### Annexe III - Part 2– List of substances provisionally allowed

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
19	3-Amino-2,4-dichlorophenol (CAS No 61693-43-4) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	Can cause allergic reaction	30/06/2008
20	Phenyl methyl pyrazolone (CAS No 89-25-8) and its salts	Oxidising colouring agents for hair dyeing	0.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.25 %	Can cause allergic reaction	30/06/2008
21	2-Methyl-5-hydroxyethylaminophenol (CAS No 55302-96-0) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	Can cause allergic reaction	30/06/2008
22	Hydroxybenzomorphaline (CAS No 26021-57-8) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %	Can cause allergic reaction	30/06/2008
-						
24	HC Yellow No 10 (CAS No 109023-83-8) and its salts	Non- oxidising colouring agents for hair dyeing	0.2 %			30/06/2008
25	2,6-Dimethoxy-3,5-pyridine-diamine (CAS No 85679-78-3) and its salts	Oxidising colouring agents for hair dyeing	0.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.25 %	Can cause allergic reaction	30/06/2008
26	HC Orange No 2 (CAS No 85765-48-6) and its salts	Non- oxidising colouring agents for hair dyeing	1.0 %			30/06/2008

### Annexe III - Part 2– List of substances provisionally allowed

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
27	HC Violet No 1 (CAS No 82576-75-8) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 0.5 % (b) 0.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.25 %		30/06/2008
28	3-Methylamino-4-nitro-phenoxyethanol (CAS No 59820-63-2) and its salts	Non- oxidising colouring agents for hair dyeing	1.0 %			30/06/2008
29	2-Hydroxy-ethylamino-5-nitro-anisole (CAS No 66095-81-6) and its salts	Non- oxidising colouring agents for hair dyeing	1.0 %			30/06/2008
30	2-Chloro-5-nitro-N-hydroxyethyl-p-phenylenediamine (CAS No 50610-28-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
31	HC Red No 13 (CAS No 94158-13-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 2.5 % (b) 2.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.25 %		30/06/2008
32	1,5-Naphthalenediol (CAS No 83-56-7) and its salts	Oxidising colouring agents for hair dyeing	1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.5 %		30/06/2008
33	Hydroxypropyl bis (N-hydroxyethyl-p-phenylenediamine) (CAS No 128729-30-6) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %	Can cause allergic reaction	30/06/2008

### Annexe III - Part 2– List of substances provisionally allowed

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
34	o-Aminophenol (CAS No 95-55-6) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
35	4-Amino-2-hydroxytoluene (CAS No 2835-95-2) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008
36	2,4-Diaminophenoxyethanol (CAS No 66422-95-5) and its salts	Oxidising colouring agents for hair dyeing	4.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 2.0 %		30/06/2008
37	2-Methylresorcinol (CAS No 608-25-3) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
38	4-Amino-m-cresol (CAS No 2835-99-6) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008
39	2-Amino-4-hydroxyethylaminoanisole (CAS No 83763-47-7) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008
-						

### Annexe III - Part 2– List of substances provisionally allowed

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
41	6-Amino-o-cresol (CAS No 17672-22-9) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008
-						
43	Hydroxyethylamino-methyl-p-aminophenol (CAS No 110952-46-0) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008
44	Hydroxyethyl-3,4-methylenedioxyaniline (CAS No 81329-90-0) and its salts	Oxidising colouring agents for hair dyeing	3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008
45	Acid Black 52 (CAS No 3618-58-4) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
46	2-Nitro-p-phenylenediamine (CAS No 5307-14-2) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 0.3 % (b) 0.3 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.15 %		30/06/2008
47	HC Blue No 2 (CAS No 33229-34-4) and its salts	Non- oxidising colouring agents for hair dyeing	2.8 %			30/06/2008

### Annexe III - Part 2– List of substances provisionally allowed

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
48	3-Nitro-p-hydroxyethylaminophenol (CAS No 65235-31-6) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 6.0 % (b) 6.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 3.0 %		30/06/2008
49	4-Nitrophenyl aminoethylurea (CAS No 27080-42-8) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 0.5 % (b) 0.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.25 %		30/06/2008
50	HC Red No 10 + HC Red No 11 (CAS No 95576-89-9 + 95576-92-4) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
51	Yellow No 6 (CAS No 10433-00-8) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
52	HC Yellow No 12 (CAS No 59320-13-7) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 1.0 % (b) 0.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.5 %		30/06/2008
53	HC Blue No 10 (CAS No 102767-27-1) and its salts	Oxidising colouring agents for hair dyeing	2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008

### Annexe III - Part 2– List of substances provisionally allowed

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels	Allowed Until
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g
54	HC Blue No 9 (CAS No 114087-47-1) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 1.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
55	2-Chloro-6-ethylamino-4-nitrophenol (CAS No 131657-78-8) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 3.0 % (b) 3.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.5 %		30/06/2008
56	2-Amino-6-chloro-4-nitrophenol (CAS No 6358-09-4) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 2.0 % (b) 2.0 %	In combination with hydrogen peroxide the maximum concentration upon application is 1.0 %		30/06/2008
57	Basic Blue 26 (CAS No 2580-56-5) (CI 44045) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 0.5 % (b) 0.5 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.25 %		30/06/2008
58	Acid Red 33 (CAS No 3567-66-6) (CI 17200) and its salts	Non- oxidising colouring agents for hair dyeing	2.0 %			30/06/2008
59	Ponceau SX (CAS No 4548-53-2) (CI 14700) and its salts	Non- oxidising colouring agents for hair dyeing	2.0 %			30/06/2008
60	Basic Violet 14 (CAS No 632-99-5) (CI 42510) and its salts	(a) Oxidising colouring agents for hair dyeing (b) Non- oxidising colouring agents for hair dyeing	(a) 0.3 % (b) 0.3 %	In combination with hydrogen peroxide the maximum concentration upon application is 0.15 %		30/06/2008

**ANNEX IV – PART 1**

**LIST OF COLOURING AGENTS ALLOWED FOR USE IN  
COSMETIC PRODUCTS**

Field of application

- Column 1: Colouring agents allowed in all cosmetic products
- Column 2: Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of eyes, in particular eye make-up and eye make-up remover.
- Column 3: Colouring agents allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes
- Column 4: Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
10006	Green				X	
10020	Green			X		
10316 <sup>(2)</sup>	Yellow		X			
11680	Yellow			X		
11710	Yellow			X		
11725	Orange				X	
11920	Orange	X				
12010	Red			X		
12085 <sup>(2)</sup>	Red	X				3% max. concentration in the finished products
12120	Red				X	
12370	Red				X	
12420	Red				X	
12480	Brown				X	
12490	Red	X				
12700	Yellow				X	
13015	Yellow	X				
14270	Orange	X				
14700	Red	X				
14720	Red	X				
14815	Red	X				



**ANNEX IV Part 1 – List of colouring agents allowed for use in cosmetic products**

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
15510 <sup>(2)</sup>	Orange		X			
15525	Red	X				
15580	Red	X				
15620	Red				X	
15630 <sup>(2)</sup>	Red	X				3% max. concentration in the finished products
15800	Red			X		
15850 <sup>(2)</sup>	Red	X				
15865 <sup>(2)</sup>	Red	X				
15880	Red	X				
15980	Orange	X				
15985 <sup>(2)</sup>	Yellow	X				
16035	Red	X				
16185	Red	X				
16230	Orange			X		
16255 <sup>(2)</sup>	Red	X				
16290	Red	X				
17200 <sup>(2)</sup>	Red	X				
18050	Red			X		
18130	Red				X	
18690	Yellow				X	
18736	Red				X	
18820	Yellow				X	
18965	Yellow	X				
19140 <sup>(2)</sup>	Yellow	X				
20040	Yellow				X	Maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
20470	Black				X	
21100	Yellow				X	Maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 ppm
21108	Yellow				X	Ditto
21230	Yellow			X		
24790	Red				X	

**ANNEX IV Part 1 – List of colouring agents allowed for use in cosmetic products**

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
26100	Red			X		Purity criteria: aniline ≤ 0.2% 2-naphtol ≤ 0.2% 4-aminoazobenzene ≤ 0.1% 1-(phenylazo)-2-naphtol ≤ 3% 1-[2-(phenylazo)phenylazo]-2-naphtalenol ≤ 2%
27755	Black	X				
28440	Black	X				
40215	Orange				X	
40800	Orange	X				
40820	Orange	X				
40825	Orange	X				
40850	Orange	X				
42045	Blue			X		
42051 <sup>(2)</sup>	Blue	X				
42053	Green	X				
42080	Blue				X	
42090	Blue	X				
42100	Green				X	
42170	Green				X	
42510	Violet			X		
42520	Violet				X	5 ppm max. concentration in the finished product
42735	Blue			X		
44045	Blue			X		
44090	Green	X				
45100	Red				X	
45190	Violet				X	
45220	Red				X	
45350	Yellow	X				6% max. concentration in the finished product
45370 <sup>(2)</sup>	Orange	X				Not more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid and 2% 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid
45380 <sup>(2)</sup>	Red	X				Ditto

**ANNEX IV Part 1 – List of colouring agents allowed for use in cosmetic products**

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
45396	Orange	X				When used in lipstick, the colouring agent is allowed only in free acid form and in a maximum concentration of 1%
45405	Red		X			Not more than 1% 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid and 2% 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid
45410 <sup>(2)</sup>	Red	X				ditto
45430 <sup>(2)</sup>	Red	X				ditto
47000	Yellow			X		
47005	Yellow	X				
50325	Violet				X	
50420	Black			X		
51319	Violet				X	
58000	Red	X				
59040	Green			X		
60724	Violet				X	
60725	Violet	X				
60730	Violet			X		
61565	Green	X				
61570	Green	X				
61585	Blue				X	
62045	Blue				X	
69800	Blue	X				
69825	Blue	X				
71105	Orange			X		
73000	Blue	X				
73015	Blue	X				
73360	Red	X				
73385	Violet	X				
73900	Violet				X	
73915	Red				X	
74100	Blue				X	
74160	Blue	X				
74180	Blue				X	
74260	Green		X			

**ANNEX IV Part 1 – List of colouring agents allowed for use in cosmetic products**

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
75100	Yellow	X				
75120	Orange	X				
75125	Yellow	X				
75130	Orange	X				
75135	Yellow	X				
75170	White	X				
75300	Yellow	X				
75470	Red	X				
75810	Green	X				
77000	White	X				
77002	White	X				
77004	White	X				
77007	Blue	X				
77015	Red	X				
77120	White	X				
77163	White	X				
77220	White	X				
77231	White	X				
77266	Black	X				
77267	Black	X				
77268:1	Black	X				
77288	Green	X				Free from chromate ion
77289	Green	X				Free from chromate ion
77346	Green	X				
77400	Brown	X				
77480	Brown	X				
77489	Orange	X				
77491	Red	X				
77492	Yellow	X				
77499	Black	X				
77510	Blue	X				Free from cyanide ion
77713	White	X				
77742	Violet	X				
77745	Red	X				

# ANNEX IV Part 1 – List of colouring agents allowed for use in cosmetic products

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
77820	White	X				
77891	White	X				
77947	White	X				
Lactoflavin	Yellow	X				
Caramel	Brown	X				
Capsanthin, Capsorubin	Orange	X				
Beetroot red	Red	X				
Anthocyanins	Red	X				
Aluminium, zinc, magnesium and calcium stearates	White	X				
Bromothymol blue	Blue				X	
Bromocresol green	Green				X	
Acid Red 195	Red			X		
Guiazulene <sup>(3)</sup>	Blue		X			

- 
- (1) Lakes or salts of these colouring agents using substances not prohibited under Annex II or not excluded under Annex V from the scope of this Directive are equally allowed.
- (2) The insoluble barium, strontium and zirconium lakes, salts and pigments of these colouring agents shall also be permitted. They must pass the test for insolubility which will be determined by the procedure laid down in Article 9.
- (3) Adopted during the Fifth ASEAN Cosmetic Committee Meeting

**ANNEX IV – PART 2**

**LIST OF COLOURING AGENTS PROVISIONALLY ALLOWED  
FOR USE IN COSMETIC PRODUCTS**

Field of application

- Column 1: Colouring agents allowed in all cosmetic products
- Column 2: Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of eyes, in particular eye make-up and eye make-up remover.
- Column 3: Colouring agents allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes
- Column 4: Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

<b>Colour Index Number or Denomination</b>	<b>Colour</b>	<b>Field of application</b>	<b>Other limitations and requirements</b>
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**Note: no colorant is listed in this section at the present time.**

## **ANNEX IV – PART 2**

### **LIST OF COLOURING AGENTS PROVISIONALLY ALLOWED FOR USE IN COSMETIC PRODUCTS (1)**

#### Field of application

- Column 1: Colouring agents allowed in all cosmetic products
- Column 2: Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of eyes, in particular eye make-up and ey make-up remover.
- Column 3: Colouring agents allowed exclusively in cosmetic products intended no to come into contact with the mucous membranes
- Column 4: Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

<b>Colour Index Number or Denomination</b>	<b>Colour</b>	<b>Field of application</b>	<b>Other limitations and requirements (2)</b>
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**Note: no colorant is listed in this section for the present time.**

- (1) Lakes or salts of these colouring agents using substances not prohibited under Annex II or not excluded under Annex V from the scope of this Directive are equally allowed.
- (2) Colouring agents whose number is preceded by the letter “E” in accordance with the EEC Directive of 1962 concerning foodstuffs and colouring matters must fulfil the purity requirements laid down in those Directives. They continue to be subject to the general criteria set out in Annex III to the 1962 Directive concerning colouring matters where the letter “E” has been deleted therefrom.

**ANNEX VI**

**LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS  
MAY CONTAIN**

**Preamble**

1. Preservatives are substances which may be added to cosmetic products for the primary purpose of inhibiting the development of micro-organisms in such products.
2. The substances marked with the symbol (+) may also be added to cosmetic products in concentration other than those laid down in this ANNEX for other purposes apparent from the presentation of the products, e.g. as deodorants in soaps or as anti-dandruff agents in shampoos.
3. Other substances used in the formulation of cosmetic products may also have anti-microbial properties and thus help in the preservation of the products, as, for instance, many essential oils and some alcohols. These substances are not included in the ANNEX.
4. For the purposes of this list
  - "Salts" is taken to mean: salts of the cations sodium, potassium, calcium, magnesium, ammonium, and ethanolamines; salts of the anions chloride, bromide, sulphate, acetate.
  - "Esters" is taken to mean: esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl, phenyl.
5. All finished products containing formaldehyde or substances in this ANNEX and which release formaldehyde must be labelled with the warning "contains formaldehyde" where the concentration of formaldehyde in the finished product exceeds 0.05%.



**ANNEX VI List of preservatives allowed for use in cosmetic products**

**ANNEX VI – PART 1**

**LIST OF PRESERVATIVES ALLOWED**

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	Benzoic acid (CAS No. 65-85-0), and its sodium salt (CAS No 532-32-1)	Rinse off products, except oral care products; 2.5 % (acid)  Oral care products; 1.7 % (acid)  Leave on products; 0.5 % (acid)		
1a	Salts of benzoic acid other than those listed under reference number 1 and esters of benzoic acid	0.5 % (acid)		
2	Propionic acid and its salts	2% (acid)		
3	Salicylic acid and its salts (+) <sup>(1)</sup>	0.5% (acid)	Not to be used in preparations for children under 3 years of age, except for shampoos	- Not to be used for children under 3 years of age <sup>(2)</sup>
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts	0.6% (acid)		
5	Formaldehyde and paraformaldehyde (+)	0.2% (except for products for oral hygiene)  0.1% (products for oral hygiene)  expressed as free formaldehyde	Prohibited in aerosol dispensers (sprays)	

**ANNEX VI List of preservatives allowed for use in cosmetic products**

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
7	Biphenyl-2-ol (o-phenylphenol) and its salts	0.2% expressed as phenol		
8	Zinc pyrithione (+) <sup>(3)</sup>	Hair products; 1.0 % Other products; 0.5%	Rinse off products only. Not for use in products for oral care	
9	Inorganic sulphites and hydrogensulphites (+) <sup>(4)</sup>	0.2% expressed as free SO <sub>2</sub>		
10	Entry deleted			
11	Chlorobutanol (INN)	0.5%	Prohibited in aerosol dispensers (sprays)	- Contains chlorobutanol
12	4-Hydroxybenzoic acid its salts and esters	0.4% (acid) for 1 ester; 0.8% (acid) for mixtures of esters		
13	3-Acetyl-6-methylpyran-2,4 (3H)-dione (Dehydroacetic acid) and its salts	0.6% (acid)	Prohibited in aerosol dispensers (sprays)	
14	Formic acid and its sodium salt	0.5% (expressed as acid)		
15	3,3'-Dibromo-4,4'-hexamethylene-dioxydibenzamidine (Dibromohexamidine) and its salts ( including isethionate)	0.1%		
16	Thiomersal (INN)	0.007% (of Hg) If mixed with other mercurial compounds authorized by this Directive, the maximum concentration of Hg remains fixed at 0.007%	For eye make-up and eye make-up remover only	- Contains thiomersal

**ANNEX VI List of preservatives allowed for use in cosmetic products**

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
17	Phenylmercuric salts (including borate)	Ditto	Ditto	- Contains phenylmercuric compounds
18	Undec-10-enoic acid and salts (+)	0.2% (acid)		
19	Hexetidine (INN)	0.1%		
20	5-Bromo-5-nitro-1,3 dioxane	0.1%	Rinse-off products only Avoid formation of nitrosamines	
21	Bronopol (INN)	0.1%	Avoid formation of nitrosamines	
22	2,4-Dichlorobenzyl alcohol	0.15%		
23	Triclocarban (INN) (+) <sup>(5)</sup>	0.2%	Purity criteria: 3,3',4,4'-Tetrachloroazobenzene less than 1 ppm; 3,3',4,4'-Tetrachloroazoxybenzene less than 1 ppm	
24	4-Chloro-m-cresol	0.2%	Prohibited in products intended to come into contact with mucous membranes	
25	Triclosan (INN) (+)	0.3%		
26	4-Chloro-3,5-xlenol	0.5%		

**ANNEX VI List of preservatives allowed for use in cosmetic products**

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
27	3,3'-Bis(1-hydroxymethyl-2,5-dioximidazolidin-4-yl)-1,1'-methyleneurea ("Imidazolidinyl urea")	0.6%		
28	Poly(1-hexamethylenebiguanide hydrochloride)	0.3%		
29	2-Phenoxyethanol	1.0%		
30	Hexamethylenetetramine (methenamine) (INN)	0.15%		
31	Methenamine 3-chloroallylochloride (INN)	0.2%		
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl) 3,3-dimethylbutan-2-one (+)	0.5%		
33	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione	0.6%		
34	Benzyl alcohol (+)	1%		
35	1-Hydroxy-4-methyl-6(2,4,4-trimethylpentyl)-2-pyridon and its monoethanolamine salt (+)	1% 0.5%	Products rinsed-off For other products	
36	Entry deleted			
37	6,6-Dibromo-4,4-dichloro-2,2'-methylene-diphenol:Bromochlorophen	0.1%		
38	4-Isopropyl-m-cresol	0.1%		
39	Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate	0.0015% (of a mixture in the ratio 3:1 of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one)		
40	2-Benzyl-4-chlorophenol (Chlorophene)	0.2%		

**ANNEX VI List of preservatives allowed for use in cosmetic products**

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
41	2-Chloroacetamide	0.3%		- Contains chloroacetamide
42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+)	0.3% expressed as chlorhexidine		
43	1-Phenoxypropan-2-ol (+)	1.0%	Only for rinse-off products	
44	Alkyl (C12-C22) trimethyl ammonium, bromide and chloride (+)	0.1%		
45	4,4-Dimethyl-1,3-oxazolidine	0.1%	The pH of the finished product must not be lower than 6	
46	N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolinidyl-4)-N'-(hydroxymethyl) urea	0.5%		
47	1,6-Di(4-amidinophenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxy- benzoate (+)	0.1%		
48	Glutaraldehyde (Pentane-1,5-dial)	0.1%	Prohibited in aerosols (sprays)	- Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0.05%)
49	5-Ethyl-3,7-dioxa-1-azabicyclo [3.3.0] octane	0.3%	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes	
50	3-(p-Chlorophenoxy)-propane-1,2-diol (chlorphenesin)	0.3%		

**ANNEX VI List of preservatives allowed for use in cosmetic products**

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
51	Sodium hydroxymethylamino acetate (Sodium hydroxymethylglycinate)	0.5%		
52	Silver chloride deposited on Titanium dioxide	0.004% calculated as AgCl	20% AgCl (w/w) on TiO <sub>2</sub> Prohibited in products for children under three years of age, in oral hygiene products and in products intended for application around the eyes and on the lips	
53	Benzethonium chloride (INCI)	0.1%	(a) Rinse-off products only  (b) Leave on products other than for oral care use.	
54	Benzalkonium chloride, bromide and saccharinate*	0.1% calculated as Benzalkonium chloride		- Avoid contact with the eyes
55	Benzylhemiformal	0.15%	Only for products to be removed by rinsing	

# ANNEX VI List of preservatives allowed for use in cosmetic products

Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
56	iodopropynyl butyl-carbamate (IPBC) 3-iodo-2-propynylbutylcarbamate	(a) rinse-off products: 0.02 %  (b) leave-on products: 0.01 % except in deodorants & antiperspirants: 0.0075 %	Not to be used in oral hygiene and lip care products  (a) Not to be used in preparations for children under three years of age, except in bath products/shower gels and shampoo.  (b) Not to be used in body lotion and body cream (*)  Not to be used in preparations for children under three years of age.	(a) Not to be used for children under three years of age (**)  (b) Not to be used for children under three years of age (***)
57	Methylisothiazolinone (INCI)	0.01 %		

1. For non-preservative usage see Annex III. Part 1, entry 98
2. Solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin
3. For non-preservative usage see Annex III. Part 1, entry 101
4. For non-preservative usage see Annex III. Part 1, entry 99
5. For non-preservative usage see Annex III. Part 1, entry 100

(\*) Concerns any products aimed to be applied on a large part of the body

(\*\*) Solely for products, other than bath products/shower gels and shampoo, which might be used for children under three years of age.

(\*\*\*) Solely for products which might be used for children under three years of age.

**ANNEX VI List of preservatives allowed for use in cosmetic products**

**ANNEX VI – PART 2**

**LIST OF PRESERVATIVES PROVISIONALLY ALLOWED**

Colipa Number	Reference Number	Substance	Maximum authorized concentration	Limitations and requirements	Conditions of use and warnings which must be printed on the label
	a	b	c	d	e

Note: no preservative is listed in this section for the present time.



## ANNEX VII – List of UV filters which cosmetic products may contain

### ANNEX VII

#### LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MAY CONTAIN

For the purpose of this Directive, UV filters are substances which, contained in cosmetic sunscreen products, are specifically intended to filter certain UV rays in order to protect the skin from certain harmful effects of these rays.

These UV filters may be added to other cosmetic products within the limits and under the conditions laid down in this Annex.

Other UV filters used in cosmetic products solely for the purpose of protecting the product against UV rays are not included in this list.

### ANNEX VII - PART 1

#### LIST OF PERMITTED UV FILTERS WHICH COSMETIC PRODUCTS MAY CONTAIN

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	d	e
1	4-Aminobenzoic acid	5%		
2	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidene methyl) anilinium methyl sulphate	6%		
3	Homosalate (INN)	10%		
4	Oxybenzone (INN)	10%		Contains oxybenzone <sup>1</sup>
6	2-Phenylbenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts	8% expressed as acid		

**ANNEX VII – List of UV filters which cosmetic products may contain**

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
7	3,3'-(1,4-Phenylenedimethylene)bis(7,7-dimethyl-2-oxo-bicyclo-[2,2,1]hept-1-yl methanesulphonic acid) and its salts	10% (expressed as acid)		
8	1-(4-Tert-butylphenyl)-3-(4-methoxyphenyl)propane-1,3-dione	5%		
9	alpha-(2-Oxoborn-3-ylidene) toluene-4-sulphonic acid and its salts	6% (expressed as acid)		
10	2-Cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester (Octocrylene)	10% (expressed as acid)		
11	Polymer of N-[(2 and 4)-[(2-oxoborn-3-ylidene) methyl] benzyl] acrylamide	6%		
12	Octyl methoxycinnamate	10%		
13	Ethoxylated-ethyl-4-aminobenzoate (PEG-25 PABA )	10%		
14	Isopentyl-4-methoxycinnamate (Isoamyl p-methoxycinnamate)	10%		
15	2,4,6-Trianiilino-(p-carbo-2'-ethylhexyl-1'-oxy)-1,3,5-triazine (Octyl triazone)	5%		
16	Phenol,2-(2H-benzotriazol-2-yl)-4-methyl-6-(2-methyl-3-(1,3,3,3-tetramethyl-1-(trimethylsilyl)oxy)-disiloxanyl)propyl (Drometrizole Trisiloxane)	15%		
17	Benzoic acid, 4,4-(((1,1-dimethylethyl)amino)carbonyl)phenyl)amino)-1,3,5-triazine-2,4-diyl)diimino)bis-,bis-(2-ethylhexyl)ester)	10%		

**ANNEX VII – List of UV filters which cosmetic products may contain**

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
18	3-(4'-Methylbenzylidene)-d-1 camphor (4-Methylbenzylidene Camphor)	4%		
19	3-Benzylidene camphor (3-Benzylidene camphor)	2%		
20	2-Ethylhexyl salicylate (Octyl Salicylate)	5%		
21	4-Dimethyl-amino-benzoate of ethyl-2-hexyl (octyl dimethyl PABA)	8%		
22	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid (Benzophenone-5) and its sodium salt	5% (of acid)		
23	2,2'-Methylene-bis-6-(2H-benzotriazol-2yl)-4-(tetramethyl-butyl)-1,1,3,3-phenol	10%		
24	Monosodium salt of 2-2'-bis-(1,4-phenylene)1H-benzimidazole-4,6-disulphonic acid	10% (of acid)		
25	(1,3,5)-Triazine-2,4-bis((4-(2-ethyl-hexyloxy)-2-hydroxy)-phenyl)-6-(4-methoxyphenyl)	10%		
26	Dimethicodiethyltbenzalmalonate (CAS No 207574-74-1) INCI Polysilicone - 15	10 %		
27	Titanium dioxide	25 %		
28	Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-, hexylester (INCI Name; Diethylamino Hydroxybenzoyl Hexyl Benzoate; CAS No 302776-68-7)	10 % in sunscreen products		
A28	Methyl anthranilate	5 %		

**ANNEX VII – List of UV filters which cosmetic products may contain**

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
A29	Zinc oxide	25 % in sunscreen products		

1. Not required if concentration is 0.5 % or less and when it is used only for product protection purposes

**ANNEX VII – List of UV filters which cosmetic products may contain**

**ANNEX VII - PART 2**

**LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MAY PROVISIONALLY CONTAIN**

Colipa number	Referenc e number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
	<b>a</b>	<b>b</b>	<b>c</b>	<b>d</b>	<b>e</b>

**Note: no UV filter is listed in this section for the present time.**

## **ANNEX V**

### **LIST OF EXCLUDED FROM THE SCOPE OF THE DIRECTIVE**

5. Strontium and its compounds, with the exception of strontium lactate, strontium nitrate and strontium polycarboxylate listed in Annex II, strontium sulphide, strontium chloride, strontium acetate, strontium hydroxide, strontium peroxide, under the conditions laid down in Annex III, Part 1, and of strontium lakes, pigments and salts of the colouring agents listed with the reference (3) in Annex IV, Part 1.