ASEAN DEFINITION OF COSMETICS AND ILLUSTRATIVE LIST BY CATEGORY OF COSMETIC PRODUCTS

APPENDIX I*

ILLUSTRATIVE LIST OF COSMETIC PRODUCTS BY CATEGORIES

A. 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[1], perfuming them[2] or protect them[3] in order to keep them in good condition[4] change their appearance[5] or correct body odour[6]

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[7], perfuming them[8], changing their appearance[9], and/or correcting body odours[10] and/or protecting[11] or keeping them in good condition[12]

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.

B. ASEAN ILLUSTRATIVE LIST BY CATERGORY 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.)

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* Number of Appendix and Annex is given for easy referred as stated in the ASEAN agreement on cosmetics

ANNEX I

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.

ASEAN COSMETICS LABELING

REQUIREMENTS

APPENDIX II

ASEAN COSMETIC LABELING REQUIREMENTS

A. OBJECTIVE

1. This document provides guidance for labeling requirements requirements of cosmetic products to which Article 5 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 or other form of packaging immediately in contact with the cosmetic product

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

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

   Registration holder means the holder of the authorization for the cosmetic products

B. LABELLING 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 products and its function, unless it is clear from the presentation of the product;

   b) Instructions on the use of the cosmetic products, unless it is clear from the product name or presentation;

   c) Full ingredient listing. The ingredients shall be specified by 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 product;
      - 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 in metric and imperials system;

g) The manufacturer's batch number;

h) The manufacturing date or expiry date of the product in clear terms (e.g. month/year);

i) Special precautions to be observed in use, especially those listed in the column "Conditions or 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 e.g. declaration of ingredients from animal origin. In this case:

(i) There must be statement (of any format) on the product label that presence of ingredients from animal origin

(ii) For ingtedients from bovine and porcine origin, the exact animal must be declared.

(iii) Ingredients from human placenta must be declared specifically on the product label.

j) Registration number from the country of origin (manufacture) of the country of registration.

2. In cases where the size, shape or nature of the container or package does not permit the particulars laid down in para 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 products;

(b) the manufacturer's batch number

3. The particulars referred in para 1 and para 2 shall be easily legible, clearly comprehensible and indelible.

4. The particulars listed in para 1 shall appear in English and/or National Language and/or language understood by the consumer where the product is marketed.

Appendix A

Listed of Standard References to be use for Cosmetic Ingredient Nomenclature

1. International Cosmetic Ingredient Dictionary
2. British Pharmacopeia
3. United States Pharmacopeia
4. Chemical Abstract Services
5. Japanese Standard Cosmetic Ingredient
6. Japanese Cosmetic Ingredients Codex

ASEAN COSMETIC CLAIM GUIDELINES

APPENDIX III

ASEAN COSMETIC CLAIM GUIDELINES

This document provides guidance in relation to cosmetic/drug interface in respect of product claims.

Products are determined to be either “cosmetic” or “drug” based on two factors:

- Composition of the product, and
- The proposed use (++) of the product

Compositon – The compostion of a product does not necessarily determine its classification. However it is quite possible that an ingredient, or the concentration of an ingredient, may make the product unsuitable for classification of a cosmetic.

Proposed use – According to the definition of the term “drug” and “cosmetic” in respective legislation, the key consideration for the classification of a drug is its proposed use. The claims made in package inserts, in advertisements, and especially in product labels, indicate to the consumers the intended use of the product.

As a general rule, cosmetic products must only make cosmetic claimed benefits; and not medicinal or therapeutic claimed benefits. Any cosmetic claimed benefits made shall be aligned with what is accepted internationally and shall be justified either by technical data and/or cosmetic formulation or preparation itself. Manufacturers / product owners will be allowed to use their own scientifically accepted protocols / design in generating the technical data provided there is justification why such protocol / design is used.

ASEAN COSMETIC PRODUCT REGISTRATION REQUIREMENTS

APPENDIX IV

ASEAN COSMETIC PRODUCT REGISTRATION REQUIREMENTS

Technical Documents

A. INTRODUCTION

The ASEAN Product Registration Requirements/Procedures shall be reduced to their simplest form. This scheme shall be reviewed to evaluate if it can already be replaced by the ASEAN Cosmetic Directve scheme for all cosmetic products with focus on post-marketing surveillance system.

B. COVERAGE

The following shall apply to all cosmetic products that are currently required to be registered in the respective ASEAN countries. Registration is defined as the submission of information on the product and undergoing an evaluation and approval process prior to marketing the product. The ASEAN member countries, based on their existing laws, shall designate the cosmetic products that need to undergo the requirements of registration. The ASEAN member countries shall, within their own competence, may accept product regisration approvals of any of the ASEAN member countries, which regulate cosmetic products. This process of mutual acceptance of each others product registration approvals mean that, where an ASEAN member country product registration approval that complies with this ASEAN Cosmetic Product Registration Requirements is obtained, the other ASEAN member countries may agree to such approval and may allow the corresponding cosmetic products to be marketed in their respective countries.

The above shall also apply to imported products from non-ASEAN countries and marketed within the ASEAN region. However, the country issuing the product registration shall take necessary steps to ensure that the imported product being registered complies with the ASEAN Harmonized Cosmetic Regulatory Scheme Technical Documents.

C. REGISTRATION LEAD TIME

Registration leadtime is preferably 30 working days maximum.

D. VALIDITY OF PRODUCT REGISTRATION

The Product Registration shall be valid for 5 years subject to renewal. Any change in the formulation which affect the function of the product and any change in the product claims shall require a new product registration.

E. REGISTRATION REQUIREMENTS

1. Language Requirements : English and/or the most common language used in each of the countries where the product is to be marketed.

2. Technical Requirements :

2.1 Qualitative composition of the product with INCI nomenclature of ingredients or any approved nomenclature as given in any standard references that may be approved from time to time. Quantitative composition is required for substances with restrictions for use. The master formula of the product shall be made available to the cosmetic regulatory agency when requested or necessary.

2.2 Finished Product Description. Finished Product Specifications as required by the country.

2.3 Test Methods as required by the country.

2.4 (i) Certificate of Free Sale and License to Operate / Manufacturer[1]; or

(ii) Certificate of Free Sale and Certificate of Good Manufacturing Practice; or

(iii) Certificate of Origin[1] ; or

(iv) Certificate issued by the Board of Health or competent authority stating that the manufacturing plant meets the national requirements in terms of hygiene, safety and quality.

Certificate of Free Sale shall be issued by the Board of Health or any competent authority of the country where the product is marketed starting the country of manufacture.

License to Operate/Manufacture shall be issued by the Board of Health or cosmetic regulatory agencies from the country of manufacture.

Certificate of Good Manufacturing Practice shall be issued by the Board of Health or cosmetic regulatory agencies from the country of manufacture.

[1] The License to Operate/Manufacture or Certificate of Origin shall indicate that the manufacturing plant have met the national requirements in terms of hygiene, safety and quality. This statement is made with the end view that the ASEAN Cosmetic GMP shall be reference guideline for manufacturing standards in ASEAN within the agreed implementation timing of the Member States.

Certificate of Origin shall be issued by the Board of Health or cosmetic regulatory agencies from the country where the finished cosmetic product has been manufactured (i.e. cream, gel, pencil, stick).

In the event that there is no issuing regulatory agency in all cases, the document may be issued recognized associations. Qualification of these associations rests with the industry or any country agency and a list shall be made available to all ASEAN Member Countries.

2.5 Technical data or clinical data (when appropriate) to support special product claims.

2.6 Information sheet containing the product description/use, methods of administration, necessary precautions to be observed during use of the product, declaration of shelf life and method of decoding batch reference, pack sizes available, information on the product owner, manufacturer or assembler.

2.7 Company's declaration of absence of prohibited substances and compliance with the content limits of restricted substances.

2.8 Business License of the registrant or the company / person responsible for placing the product in the market.

2.9 Label copy

2.10 Samples as required by the country

3. For a product that has an existing product registration approval issued by any ASEAN member country, the following shall be submitted to the cosmetic regulatory agency in the other country / ies where the product is to be marketed:

3.1 Notification Letter advising the cosmetic regulatory agency that the product will be marketed in the country. The Notification shall consist the following information:

i. Name of Product
ii. Product Brand
iii. Product Description
(*Describe the form of Cosmetics such as cream, gel, powder, pencil, stick etc)*
iv. Purpose of Cosmetic (intended use)
(Describe the purpose of the cosmetic such as baby product, deodorant, eye lotion, hai dye, hair shampoo, skin moisturizer, etc.)
v. Product Formula
(Shall consist of full ingredients listing and indicate percentage of restricted ingredients)
vi. Packaging particulars
(Describe the packaging and their pack sizes, e.g. glass, 10ml, 30ml & 100ml)

vii. Name and address of person responsible for putting the product on the market
viii. Name and address of manufacturer or contract manufacturer
ix. Name and address of importer
x. A copy of the product label

3.2 Certificate of Product Registration certified true copy by the issuing agency.

COMMON REQUIREMENTS FOR IMPORT / EXPORT OF COSMETIC PRODUCTS

APPENDIX V

COMMON REQUIREMENTS FOR IMPORT / EXPORT

OF COSMETIC PRODUCTS

A. SCOPE

Only regulatory requirements imposed by health authorities are considered in this document. The requirements are applicable to Phase 1 of the harmonized scheme only.

B. IMPORT REQUIREMENTS

1. Registration of registrants or companies/persons responsible for placing the product in the market

This will facilitate investigation and follow up by regulatory authorities in the event of product problems. Registration of registrant or company/person responsible for placing the product in the market should be based on the requirements of individual countries.

2. Product Registration

Only countries which wish to register cosmetic products will be involved. The requirements in the approved Technical Document on Product Registration procedures should be followed.

3. Product Labelling

To ensure informed choice by consumers, to facilitate the work of healthcare professionals and to allow effective control by the regulatory authorities, cosmetic products in the market should conform with designated labeling requirements. The requirements in the approved Technical Document on Product Labelling requirements should be followed.

4. Compliance With Allowed, Prohibited and Restricted Ingredient Lists

To ensure that only safe ingredients are used in cosmetic products sold in ASEAN countries, lists of cosmetic ingredients and prohibited substances must be laid down for the cosmetic industries in ASEAN. The requirements in the approved Technical Document on Common Ingredient Listings should be followed.

5. Record Keeping By Registrant or Company/person Responsible for Placing the Product in the Markets

The registrant or company/person responsible for placing the product in the market must keep records of the primary distribution of their products, for the purpose of product recall according to the respective country's procedures.

C. IMPORTATION FOR DIRECT RE-EXPORTATION OUT OF ASEAN

Importation for direct re-export of cosmetic products can be exempted from cosmetic product import requirements as they will not impact the safety of local consumers, but the registrant or company / person responsible for placing the product in the market should maintain proper records and documents. These records should be open to inspection by the authorities at any time when required.

"Import for direct re-export" refers to importation by an ASEAN trader of cosmetic products which are subsequently exported out of ASEAN by the same ASEAN trader. The cosmetic products involved do not enter into the ASEAN market.

D. EXPORT REQUIREMENTS

Requirements for the export of cosmetic products will be based on the requirements of individual countries, if any. If the products meant for the export market are also sold locally and hence comply with the relevant regulatory requirements, free sale certificates may be issued by the health authorities upon request. The list of health authorities in ASEAN member countries issuing Certificate of Free Sale can be complied later by ACCSQ CPWG and distributed to all ASEAN member countries.

E. SUMMARY

In summary, cosmetic products will be allowed for importation provided they comply with local registration and licensing requirements, labeling requirements and requirements on restriction of ingredients. The registrant or company / person responsible for placing the product in the market will be required to maintain records of primary distribution for the purpose of product recall. Requirements for the export of cosmetic products will be based on the requirements of individual countries, if any.

ASEAN GUIDELINES FOR COSMETIC GOOD MANUFACTURING PRACTICE

APPENDIX VI

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 high 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 al 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.

2.5 Defined areas should be provided for, wherever possible and applicable:

3.5.1 Materials receiving.

1.5.2 Materials Sampling

1.5.3 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 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 practiced 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 pratise 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 authorized 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 sanitizing 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 sanitizing 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 labeled. 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 shall 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 labeled 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 used 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 shall 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, whether they remain unchanged or become altered.

(d) List of raw materials used

(e) List of equipment used.

(f) 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
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 labeled 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

A 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 audits may also be extended to suppliers and contractors, if necessary. A report should be made at the completion of each quality 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 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 authorized 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 wether 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.

12.5 All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.

12.6 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.

12.7 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 isssues.

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, 1st 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, 1st Edition, 1999

A COSMETIC INGREDIENT LISTING AND ASEAN HANDBOOK OF COSMETIC INGREDIENT

LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF THE COMPOSITION OF COSMETIC PRODUCTS

ANNEX II – Part 1

LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF THE COMPOSITION OF COSMETIC PRODUCTS

Reference Number	Substance
1	N-5 Chlorobenzoxazol-2-ylacetamide
2	ß-Acetoxyethy trimethylammonium hydroxide (acetylcholine and its salts)
3	DEANOL ACEGLUMATE
4	Spironolactone
5	[4-(4-HYDROXY-3-IODOPHENOXY)-3,5-DIODOPHENYL] ACETIC ACID AND ITS SALTS
6	Methotrexate
7	Aminocaproic acid and its salts
8	Cinchophen,its salts,derivatives and salts of these derivatives
9	Thyropropic acid and its salts
10	Trichloroacetic acid
11	*Aconitum napellus* L. (leaves,roots and galenical preparations)
12	Aconitine (principal alkaloid of *Aconitum napellus* L.) and its salts
13	*Adonis vernalis* L. and its preparations
14	Epinephrine
15	*Rauwolfia serpentina* alkaloids and their salts
16	Alkyne alcohols,their esters,ethers and salts
17	Isoprenaline
18	Allyl isothiocyanate
19	Alloclamide and its salts
20	Nalorphine,its salts and ethers
21	Sympathomimetic amines acting on the central nervous system: any substance contained in the first list of medicaments w/c are subject to medical Prescription and are referred to in resolution AP(69) 2 of the Council of Europe
22	Aniline,its salts and its halogenated and sulphonated derivatives
23	Betoxycaine and its salts
24	Zoxazolamine
25	Procainamide,its salts and derivatives
26	Benzidine
27	Tuaminoheptane,its isomers and salts
28	Octodrine and its salts
29	2-Amino-1,2-bis (4-methoxyphenyl) ethanol and its salts

Reference Number	Substance
30	1,3-dimethylpentylamine and its salts
31	4-Aminosalicylic acid and its salts
32	TOLUIDINES, THEIR ISOMERS, SALTS AND HALOGENATED AND SULPHONATED DERIVATIVES
33	Xylidines, their isomers, salts and halogenated and sulphonated derivatives
34	Imperatorin [9-(3-methylbut-2-enyloxy) furo(3,2-g)chromen-7-one]
35	*Ammi majus* and its galenical preparations
36	2,3-Dichloro-2-methylbutane
37	Subtances w/ androgenic effect
38	Anthrancene oil
39	Antibiotics
40	Antimony and its compounds
41	*Apocynum cannabinum* L. and its preparations
42	Apomorphine (5,6,6a,7-tetrahydro-6-methyl-4H-dibenzo (de, g)- quinoline-10,11- dyhydric alcohol) and its salts
43	Arsenic and its compounds
44	*Atropa belladonna* L. and its preparations
45	Atropine, its salts and derivatives
46	Barium salts with the exception of barrium sulfhate, baruim 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
47	Benzene
48	Benzimidazol-2(3H)-one
49	Benzazepines and benzadiazepines
50	1-Dimethylaminomethyl-1-methylpropyl benzoate (amylocaine) and its salts
51	2,2,6-Trimethyl-4-piperidyl benzoate (benzamine) and its salts
52	Isocarboxazide
53	Bendroflumethiazide and its derivatives
54	Beryllium and its compounds
55	Bromine, elemental
56	Bretylium tosilate
57	Carbromal
58	Bromisoval
59	Brompheniramine and its salts
60	Benzilonium bromide
61	Tetrylammonium bromide
62	Brucine
63	Tetracaine and its salts

Reference Number	Substance
64	Mofebutazone
65	Tolbutamide
66	Carbutamide
67	Phenylbutazone
68	Cadmium and its compounds
69	Cantharides, *Cantharis vesicatoria*
70	(1R,2S)-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride (cantharidin)
71	Phenprobamate
72	Nitroderivatives of carbozol
73	Carbon disulphide
74	Catalase
75	Cephaeline and its salts
76	*Chenopodium ambrosioides* (essential oil)
77	2,2,2-Trichloroethane-1,1-diol
78	Chlorine
79	Chlorpropamide
80	Diphenoxylate hydrochloride
81	4-Phenylazophenyiene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)
82	Chlorzoxazone
83	2-Chloro-6-methylpyrimidin-4-yldimethylamine (crimidine-ISO)
84	Chlorprothixene and its salts
85	Clofenamide
86	N,N-bis (2-chloroethyl) methylamine N-oxide and its salts
87	Chlormethine and its salts
88	CYCLOPHOSPHAMIDE AND ITS SALTS
89	Mannomustine and its salts
90	Butanilicaine and its salts
91	Chlormezanone
92	Triparanol
93	2-[2-(4-Chlorophenyl)-2-phenylacetyl] indan 1,3-dione (chlorophacinone-ISO)
94	Chlorphenoxamine
95	PHENAGLYCODOL
96	Chloroethane
97	Chromium; chromic acid and its salts
98	*Claviceps purpurea Tul*., its alkaloids and galenical preparations
99	*Conium maculatum* L.(fruit,powder,galenical preparations)
100	Glycyclamide

Reference Number	Substance
101	Cobalt benzenesulphonate
102	Colchicine, its salts and derivatives
103	Colchicoside and its derivatives
104	*Colchicum autumnale* L. and its galenical preparations
105	Convallatoxin
106	*Anamirta cocculus* L.(fruit)
107	Croton tiglium (oil)
108	1-Butyl-3-(N-crotonoylsulphanilyl) urea
109	Curare and curarine
110	Synthetic curarizants
111	Hydrogen cyanide and its salts
112	2-α-Cyclohexylbenz,yl (N,N,N',N'-tetraethyl) trimethylenediamine (phenetamine)
113	Cyclomenol and its salts
114	Sodium hexacyclonate
115	Hexapropymate
116	Dextropropoxyphene
117	O,O'-Diacetyl-N-allyl-N-normorphine
118	Pipazetate and its salts
119	5-(α-ß- Dibromophenethyl)-5- methylhydantoin
120	N,N'-Pentamethylenebis (trimethylammonium) salts,e.g. Pentamethonium bromide
121	N,N'-[(Methylimino)diethylene]bis(ethyldimethylammonium) salts,e.g. azamethonium bromide
122	Cyclarbamate
123	Clofenotane; DDT (ISO)
124	Hexamethylenebis (trimethylammonium) salts e.g. hexamethonium bromide*
125	Dichloroethanes (ethylene chlorides)
126	Dichloroethylenes (acetylene chlorides)
127	Lysergide and its salts
128	2-Diethylaminoethyl 3-hydroxy-4-phenylbenzoate and its salts
129	Cinchocaine and its salts
130	3-Diethylaminopropyl cinnamate
131	O,O'-Diethyl O-4-nitrophenyl phosphorothioate (parathion-ISO)
132	(Oxalylbisiminoethylene) bis [(O-chlorobenzyl) diethylammonium] salts, e.g. ambenomium chloride
133	Methyprylon and its salts
134	Digitaline and all heterosides of *Digitalis purpurea* L.
135	7-[2-Hydroxy-3-(2-hydroxyethyl)-N-methylamino) propyl]theophylline (xanthinol)

Reference Number	Substance
136	Dioxethedrin and its salts
137	Piprocurarium
138	Propyphenazone
139	Tetrabenazine and its salts
140	Captodiame
141	Mefeclorazine and its salts
142	Dimethylamine
143	1,1-Bis(dimethylaminomethyl) propyl benzoate (amydricaine,alypine) and its salts
144	Methapyrilene and its salts
145	Metamfepramone and its salts
146	Amitriptyline and its salts
147	Metformin and its salts
148	Isosorbide dinitrate
149	Malononitrile
150	Succinonitrile
151	Dinitrophenol isomers
152	Inproquone
153	Dimevamide and its salts
154	Diphenylpyraline and its salts
155	Sulfinpyrazone
156	N-(3-Carbamoyl-3,3-diphenylpropyl)-N,N-diisopropylmethylammonium salts, e.g. isopropamide iodide
157	Benactyzine
158	Benzatropine and its salts
159	Cyclizine and its salts
160	5,5-Diphenyl-4-imidazolidone
161	Probenecid
162	Disulfiram; thiram (ISO)
163	Emetine, its salts and derivatives
164	Ephedrine and its salts
165	Oxanamide and its derivatives
166	Eserine or physostigmine and its salts
167	Esters of 4-aminobenzoic acid, with the free amino group,with the exception of That given in Annex VII, Part 2
168	Choline salts and their esters, e.g.choline chloride
169	Caramiphen and its salts
170	Diethyl 4-nitrophenyl phosphate

Reference Number	Substance
171	Metethoheptazine and its salts
172	Oxpheneridine and its salts
173	Ethoheptazine and its salts
174	Metheptazine and its salts
175	Methylphenidate and its salts
176	Doxylamine and its salts
177	Tolboxane
178	4-Benzyloxyphenol,4-methoxyphenol and 4-ethoxyphenol
179	Parethoxycaine and its salts
180	Fenozolone
181	Glutethimide and its salts
182	Ethylene oxide
183	Bemegride and its salts
184	Valnoctamide
185	Haloperidol
186	Paramethasone
187	Fluanisone
188	Trifluperidol
189	Fluoresone
190	Fluorouracil
191	Hydroflouric acid,its normal salts,its complexes and hydrofluorides with the EXCEPTION OF THOSE GIVEN IN ANNEX III, PART1
192	FURFURYLTRIMETHYLAMMONIUM SALTS, E.G. FURTRETHONIUM IODIDE*
193	Galantamine
194	Progestogens
195	1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO) (lindane)
196	(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- dimethanonaphtalene (endrin-ISO)
197	Hexachloroethane
198	(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)
199	Hydrastine, hydrastanine and their salts
200	Hydrazides and their salts
201	Hydrazine, its derivatives and their salts
202	Octamoxin and its salts
203	Warfarin and its salts
204	Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and its salts of the acid
205	Methocarbamol
206	Propatylnitrate

Reference Number	Substance
207	4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin
208	Fenadiazole
209	Nitroxoline and its salts
210	Hyoscyamine,its salts and derivative
211	Hycoscyamus niger L. (leaves,seeds,powder and galenical preparations)
212	Pemoline and its salts
213	Iodine
214	Decamethylenebis (trimethylammonium) salts,e.g. decamethonium bromide
215	Ipecacuanha (*Cephaelis ipecacuanha* Brot. And related species) (roots,powder & galenical preparations
216	(2-Isopropylpent-4-enoyl) urea (apronalide)
217	α-Santonin ((3S,5aR,9bS)-3,3a,4,5,5a,9b-hexahydro-3,5a,9-trimethyl-naphto(1,2-b)furan-2,8-dione
218	*Lobelia inflata* L. and its galenical preparations
219	Lobeline and its salts
220	Barbiturates
221	Mercury and its compounds except those special cases included in Annex VI, Part 1
222	3,4,5-Trimethoxyphenethylamine and its salts
223	Metaldehyde
224	2-(4-Allyl-2-methoxyphenoxy)-N,N-dietthylacetamide and its salts
225	Coumetarol
226	Dextromethrophan and its salts
227	2-Methylheptylamine and its salts
228	Isometheptene and its salts
229	Mecamylamine
230	Guaifenesin
231	Dicoumarol
232	Phenmetrazine,its derivatives and salts
233	Thiamazole
234	3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2H,5H,pyrano(3,2-c)-(1)benzopyran-5-one(cyclocoumarol)
235	Carisoprodol
236	Meprobamate
237	Tefazoline and its salts
238	Arecoline
239	Poldine methylsulfate
240	Hydroxyzine
241	2-NAPHTHOL

Reference Number	Substance
242	1-and- 2-Naphthylamines and their salts
243	3-(1-Naphthyl)-4-hydroxycoumarin
244	Naphazoline and its salts
245	Neostigmine and its salts (e.g. neostigmine bromide)
246	Nicotine and its salts
247	Amyl nitrites
248	Inorganic nitrites, with the exception of sodium nitrite
249	Nitrobenzene
250	Nitrocresols and their alkali metals salts
251	Nitrofurantoin
252	Furazolidone
253	Propane-1,2,3-triyl trinitrate
254	Acenocoumarol
255	Alkali pentacyanonitrosylferrate (2-)
256	Nitrostilbenes, their homologues and their derivatives
257	Noradrenaline and its salts
258	Noscapine and its salts
259	Guanethidine and its salts
260	Oestrogens,with the exception of thosed listed in Annex V
261	Oleandrin
262	Chlortalidone
263	Pelletierine and its salts
264	Pentachloroethane
265	Pentaerithrityl tetranitrate
266	Petrichloral
267	Octamylamine and its salts
268	Picric acid
269	Phenacemide
270	Difencloxazine
271	2-Phenylindan-1,3-dione (phenindione)
272	Ethylphenacemide
273	Phenprocoumon
274	Fenyramidol
275	Triamterence and its salts
276	Tetraethyl pyrophosphate; TEPP (ISO)
277	Tritolyl phosphate
278	Psilocybine
279	Phosphorus and metal phosphides

Reference Number	Substance
280	Thalidomide and its salts
281	*Physostigma venenosum* Balf
282	Picrotoxin
283	Pilocarpine and its salts
284	α-Piperidin-2-yl benzyl acetate laevorotatory thereoform (Levophacetoperane and its salt)
285	Pipradrol and its salts
286	Azacyclonol and its salts
287	Bietamiverine
288	Butopiprine and its salts
289	Lead and its compounds,with the exception of that mentioned in ANNEX III,
	N° 55 under the condition stated
290	Coniine
291	*PRUNUS LAUROCERASUS* L. (CHERRY LAUREL WATER)
292	Metyrapone
293	Radioactive substances (1)
294	*Juniperus sabina* L.(leaves,esential oil & galenical preparations)
295	Hyoscine, its salts and derivatives
296	Gold salts
297	Selenium and its compounds with the exception of selenium disulphide under the conditions set out under the reference n° 49 in ANNEX III, Part 1
298	*Solanum nigrum* L. and its galenical preparations
299	Sparteine and its salts
300	Glucocorticoids
301	*Datura stramonium* L. and its galenical preparatipns
302	Strophantines, their aglucones & their respective derivatives
303	*Strophantus* species and their galenical preparations
304	Strychnine and its salts
305	*Strychnos* species and their galenical preparations
306	Narcotics, natural and synthetic: All substances listed in Table I and II of the Single Convension on narcotic drugs signed in New York on 30 March 1961.
307	Sulphonamides (sulphanilamide & its derivatives obtained by substitution of one
	or more H-atoms of the -NH2 groups) and their salts
308	Sultiame
309	Neodymium and its salts
310	Thiotepa
311	*Pilocarpus jaborandi Holmes* and its galenical preparations
312	Tellurium and its compounds

Reference Number	Substance
313	Xylometazoline and its salts
314	Tetrachloroethylene
315	Carbon Tetrachloride
316	Hexaethyl tetraphosphate
317	Thallium and its compounds
318	*Thevetia neriifolia Juss*. Glycoside extract
319	ETHIONAMIDE
320	Phenothiazine and its compounds
321	Thiourea and its derivatives, with exception of the one listed in Annex III,Part 1
322	Mephenesin and its esters
323	Vaccine, toxins or serums listed in the Annex to the Second Counsil Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (O J N L 147,9.6.1975,p.13)
324	Tranylcypromine and its salts
325	Trichloronitromethane (chloropicrine)
326	2,2,2-Tribromoethanol (tribromoethyl alcohol)
327	Trichlormethine and its salts
328	Tretamine
329	Gallamine triethiodide
330	*Urginea scilla Stern*. And its galenical preparations
331	Veratrine, its salts and galenical preparations
332	*Schoenoocaulon officinale Lind*.(seeds and galenical preparations)
333	*Veratrum Spp*. And their preparations
334	Vinyl chloride monomer
335	Ergocalciferol and cholecalciferol (vitamins D2 and D3)
336	Salts of O-alkyldithiocarbonic acids
337	Yohimbine and its salts
338	Dimethyl sulfoxide
339	Diphenhydramine and its salts
340	4-tert-Butylphenol
341	4-tert-Butylpyrocatechol
342	Dihydrotachysterol
343	Dioxane
344	Morpholine and its salts
345	*Pyrethrum album* L. and its galenical preparations
346	2-(4-Methoxybenzyl-N-(2-pyridyl)amino)ethyldimethylamine maleate
347	Tripelennamine

Reference Number	Substance
348	Tetrachlorosalicylanilides
349	Dichlorosalicylanilides
350	TETRABROMOSALICYLANILIDES
351	Dibromosalicylanilides
352	Bithionol
353	Thiuram monosulphides
354	Thiuram disulphides
355	Dimethylformamide
356	4-Phenylbut-3-en-2-one
357	Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol except for normal content in natural essences used
358	Furocoumarines (e.g. trioxysalan,8-methoxypsoralen, 5-methoxypsoralen), except for normal content in natural essences used. In Sun protection and in Bronzing products, urocoumarins shall be below 1 mg/kg
359	Oil from the seeds of *Laurus nobilis* L.
360	Safrole except for normal content in the natural essences used and provided the concentration does not exceed: ▪ 100 ppm in the finished product ▪ 50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children
361	5,5'-Di-isopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihypoiodite
362	3'-ethyl-5',6',7,8'-tetrahydro-5',5',8',8',-tetramethyl-2'-acetonaphthone or 7-acetyl-6-ethyl-1,1,4,4- tetrametyl-1, 2,3,4-tetrahydronaphtalen
363	o-phenylenediamine and its salts
364	4-Methyl-m-phenylenediamine and its salts
365	Aristolochic acid and its salts/;Aristolochia spp. and their preparations
366	Chloroform
367	2,3,7,8,-Tetra chlorodibenzo-p-dioxin
368	2,6-Dimethyl-1,3-dioxan-4-yl acetate (Dimethoxane)
369	Pyrithione sodium (INNM)
370	N-(Trichloromethylthio)-4-cyclohexene-1,2-dicarboximide (Captan)
371	2,2'-Dihydroxy-3,3'5,5',6,6'-hexachlorodiphenylmethane (Hexachlorophene)
372	6-(Piperidinyl)-2,4-pyrimidinediamine-3-oxide (Minoxidil) and its salts
373	3,4',5-Tribromosalicylanilide
374	*Phytolacca Spp*. And their preparations
375	Tretinoin (retinoic acid and its salts)
376	1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole-CI 76050) & their salts
377	1-Methoxy-2,4-diamenobenzene (2,5-diaminoanisole) and their salts
378	Colouring agent CI 12140

Reference Number	Substance
379	Colouring agent CI 26105
380	Colouring agent CI 42555 Colouring agent CI 42555-1 Colouring agent CI 42555-2
381	Amyl 4-dimethylaminobenzoate,mixed isomers (Padimate A (INN)
382	Benzoyl peroxide
383	2-Amino-4-nitrophenol
384	2-Amino-5-nitrophenol
385	11α-Hydroxypregn-4-ene-3,20-dione and its esters
386	Colouring agent CI 42640
387	Colouring agent CI 13065
388	Colouring agent CI 42535
389	Colouring agent CI 61554
390	Anti-androgens with steroid structure
391	Zirconium and its compounds, with the exception of the subtances listed under reference number 50 in ANNEX III,Part One, and the zirconium lakes, pigments or salts of colouring agents listed in ANNEX IV, Part One, with reference number 3
392	Thyrothricine
393	Acetonitrile
394	Tetrahydrozoline and its salts
395	Hydroxy-8-quinoline and its sulphate, except for the uses provided for in n° 51 in Annex III, Part 1
396	Dithio-2,2'-bispyridine-dioxide 1,1' (additive w/ trihydrated magnesium sulphate)-(pyrithione disulphide + magnesium sulphate)
397	Colouring agent CI 12075 and its lakes, pigments and salts
398	Colouring agent CI 45170 and CI 45170:1
399	Lidocaine
400	1,2-Epoxybutane
401	Colouring agent CI 15585
402	STRONTIUM LACTATE
403	Strontium nitrate
404	Strontium polycarboxylate
405	Pramocaine
406	4-Ethoxy-m-phenylenediamine and its salts
407	2,4-Diaminophenylethanol and its salts
408	Cathechol
409	Pyrogallol
410	Nitrosamines
411	Secondary dialkanolamines

Reference Number	Substance
412	4-Amino-2-nitrophenol
413	2-Methyl-m-phenylenediamine
414	4-tert-Butyl-3-methoxy-2,6-dinitrotoluene (Musk ambrette)
416	Cells,tissues or products of human origin
417	3,3- Bis (4-hydroxyphenyl)phthalide (Phenolphthalein)
418	3-Imidazol-4-ylacrylic acid and its ethyl ester (urocanic acid)
419	(a) the skull, including the brain and eyes, tonsil and spinal cord of: -bovine animals aged 12 month -ovine and caprine animals which are aged over 12 months or have a Permanent incisor tooth erupted through the gum; (b) The spleens of ovine and caprine animals and ingredients derived therefrom. However, tallow derivatives may be used provided that the following methods have been used and strictly certified by the producer - transesterification or hydrolysis at at least 200ºC and at appropriate corresponding pressure, for 20 minutes (glycerol and fatty acids and esters); - saponification with NaOH 12M (glycerol and soap): - batch process: 95ºC for 3 hours or - continuous process: at 140ºC, 2 bars (2000 hPa) for 8 minutes or equivalent
420	Crude and refined coal tars
421	1,1,3,3,5-Pentamethyl-4,6-dinitroindane (moskene)
422	5-tert-Butyl-1,2,3-trimethyl-4,6-dinitrobenzene (musk tibetene)

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

ANNEX III – PART 1

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

EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
1a	Boric Acid, borates and tetraborates	(a) Talc	(a) 5% (by Mass/mass as boric acid)	(a) 1. Not to be used in products for children under 3 years of age 2. Not to be use on peeling or irritated skin the concentration of free soluble borate exceeds 1.5% (by mass/mass as boric acid)	(a) 1. Not to be used for children under 3 years old of age 2. Not to be used on peeling or irritated skin
		(b) Products for oral hygiene	(b) 0.1% (by mass/mass as boric acid)	(b) 1. Not to be used in products for children under 3 years of age	(b) 1. Not to be swallowed 2. Not to be used for children under 3 years of of age
		(c) Other products (excluding bath products and hair waving products)	(c) 3% (by mass/mass as boric acid)	(c) 1. Not to be used in products for children under 3 years of age 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)	(c) 1. Not to be used for children under 3 years of age 2. Not to be used on peeling or irritated skin
1b	Tetraborates	(a) Bath products	(a) 18% (by mass/mass as boric acid)	(a) 1. Not to be used in products for children under 3 years of age	(a) Not to be used of bathing children under 3 years of age
		(b) Hair waving products	(b) 8% (by mass/mass as boric acid)		(b) Rinse well

(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.

EU Ref #	Substance	Restrictions			Conditions of Use and Warnings Which msut be Printed on the Label
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & 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) 1. Not to be used in products for children under 3 years of age	(a) Not to be used of bathing children under 3 years of age (b) Rinse well
2a	Thioglycollic acid and its salts	(a) Hair waving or straightening products: (1) General use (2) 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 (b) 5% ready for use pH 7-12.7 (c) 2% ready for use pH 7-9,5 Percentage calculated as Thioglycollic acid	a) b) c) The directions for use drawn up in the national or official languages(s) must obligatorily incorporate the following sentences: ▪ Avoid contact with eyes. ▪ In the event of contact with eyes, rinse immediately with plenty of medical water and seek advice. ▪ Wear suitable gloves (a) and c) only	a) ▪ Contains thioglycollate ▪ Follow the instructions ▪ Keep out of reach children. ▪ For professional use only b) and c) ▪ Contains Thioglycollate. ▪ Follow the instruction. ▪ Keep out of reach children.

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EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
2b	Thioglycollic acid esters	Hair waving or straightening products: (a) General use (b) Professional use	 (a) 8% ready for use pH 6-9,5 (b) 11% ready for use pH 6-9,5 Percentage calculated as thioglycollic acid	The directions for use drawn up in the national or official language(s) must obligatorily incorporate the followimg sentences: ▪ May cause sensitisation in the event of skin contact. ▪ Avoid contact with eyes, rinse off with plenty of water and seek medical advice. ▪ Wear suitable gloves	▪ Contains thioglycollates. ▪ Follow the instructions. ▪ Keep out of reach 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_3		▪Above 2%: contains ammonia
5	Tosylchloramide sodium (*)		0.2%		
6	Chlorates of Alkali metals	(a) Toothpaste (b) Other uses	(a) 5% (b) 3%		
7	Dichloromethane		35% (when mixed with 1,1,1 -trichloroethane, total concentration must Not exceed 35%)	0.2% as maximum impurity content	

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EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Lables
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
8	m-and p- Phenylenediamines, their N- substituted derivatives and their salts; N- substituted derivatives of o-phenylenediamines (1)	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 dye eyelashes eyebrows (b) ▪ For professional use only ▪ Contains phenylenediamines ▪ Can cause an allergic reaction ▪ Wear suitable gloves
9	Methylphenylenediamines, their N-substituted derivatives and their salts (1) with The of substance N°364 and 413 in Annex II	Oxidizing colouring agents for hair dyeing (a) General use (b) Professional	10% calculated as free base		(a) ▪ Can cause an allergic reaction ▪ Contains phenylenediamines ▪ Do not use to dye eyelashes eyebrows. (b) ▪ For professional use only ▪ Contains phenylenediamines ▪ Can cause an allergic reaction ▪ Wear suitable gloves
10	Diaminophenols (1)	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 of eyebrows (b) ▪ For professional use only. ▪ Contains diamonophenols. ▪ Can cause an allergic reaction ▪ wear suitable gloves

(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.

EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
11	Dichlorophen (*)		0.50%		Contains dichlorophen
12	Hydrogen peroxide, and other compounds or mixture that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	(a) Hair-care preparations	12% H_2O_2 (40 volumes) present or released		(a) (b) (c) ▪ Contains hydrogen peroxide ▪ Avoid contact with eyes rinse eyes immediately ▪ if product comes into contact with them.
		(b) Skin-Care preparations	4% of H_2O_2 present or released		
		(c) Nail hardening preparations	2% of H_20_2 present or released		
		(d) Oral hygiene products	0.1% of H_20_2 present or released		(a) Wear suitable gloves
13	Formaldehyde	Nail hardeners	5% calculated as formaldehyde		▪ Protect cuticles with grease or oil ▪ Contains formaldehyde (2)

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(2) Only if the concentration exceeds 0.05%.
(3) 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 maximum allowab;e concentrationns

EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
14	Hydroquinone (1)	Oxidizing colouring agent for hair dyeing (a) General use (b) Professional use	0.30%		(a) 1. ▪ Do not use to dye eyelashes or eyebrows ▪ Rinse the eyes immediately if the product comes into contact with eyes ▪ Contains hydroquinone 2. ▪ For Professional use only ▪ Contains hydroquinone ▪ Rinse the eyes immedeately if the product comes ▪ into contact with the eyes
					(b) ▪ Contains hydroquinone ▪ Avoid contact with the eyes ▪ If irritation develops discontinue use areas ▪ Do not use on children under the age of 12

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(2) Only if the concentration exceeds 0.05%.
(3) 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 maximum allowable concentrations.

EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
15a	Potassium or sodium hydroxide	(a) Nail cuticle solvent	(a) 5% by weight (3)		(a) ▪ Contains alkali ▪ Avoid contact with eyes ▪ Can cause blindness ▪ Keep out of reach children
		(b) Hair straightener	(b)		(b) (1) ▪ Contains alkali
		(1) General use	(1) 2% by weight (3)		▪ Avoid contact with eyes ▪ Can cause blindness ▪ Keep out of reach children
		(2) Professional use	(2) 4.5% by weight		(2) ▪ For Professional use only ▪ Avoid contact with eyes ▪ Can cause blindness
		(c) pH adjuster - depilatories	(c) up to pH 12.7		(c) ▪ Keep out of reach of children ▪ Avoid contact with eyes
		(d) Other uses as pH adjuster	(d) up to pH 11		
15b	Lithium hydroxide	(a) Hair straightener (1) General use	(a) (1) 2% by weight (1)		(a) (1) ▪ Contains alkali ▪ Avoid contact with eyes ▪ Can cause blindness ▪ Keep out of reach children

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(2) Only if the concentration exceeds 0.05%.
(3) 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 maximum allowable concentrations.

EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
		(2) Professional use (b) Other uses	(2) 4.5% by weight (1)		(2) ▪ For professional use only ▪ Avoid contact with eyes ▪ Can cause blindness
15c	Calcium hydroxide	(a) Hair straighteners containing two componets: calcium hydroxide and a guanidine salts (b) Other uses	(a) 7% by weight calcium hydroxide		(a) ▪ Contains alkali ▪ Avoid contact with eyes ▪ Can cause blindness ▪ Keep out of reach of children
16	Alpha-naphthol	Colouring agent for hair dyeing	0.50%		Contains alpha-naphthol
17	Sodium nitrite	0.20%	Do not use with secondary and/ or Tertiary amines or other substances Forming nitrosamines		
18	Nitromethane	Rust inhibitor	0.30%		
19	Phenol and its alkali salts	Soaps and /shampoos	1% calculated as phenol		▪ Contains phenol
21	Quinine and its salts	(a) Shampoos (b) Hair lotions	(a) 0.5% calculated as quinine base (b) 0.2% calculated as quinine base		

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(2) Only if the concentration exceeds 0.05%.
(3) 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 maximum allowable concentrations.

EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
22	Resorcinol (1)	(a) Oxidizing colouring agent for hair dyeing (1) General use	(a) 5%		(a) (1) ▪ Contains resorcinol ▪ Rinse hair well after application ▪ Do not use to dye eyelashes or eyebrows ▪ Rinse eye immediately if product comes into contact with them
		(2) Professional use			(2) ▪ For professional use only ▪ Contains resorsinol ▪ Rinse eyes immediately if product comes into contact with them
		(b) Hair lotions and shampoos	(b) Hair lotions and shampoos		(b) ▪ Contains resorcinol
23	(a) Alkali sulphides	(a) Depilatories	(a) 2% calculated as sulphur pH to 12.7		(a) ▪ Keep out of reach of children ▪ Avoid contact with eyes
	(b) Alkaline earth sulphides	(b) Depilatories	(b) 6% calculated as sulphur pH up to 12.7		(b) ▪ Keep out of reach of children
24	Water Soluble zinc salts with exception of zinc-4-hydrobenzenesulphonate and zinc pyrithione		1% calculated as zinc		

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EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
25	Zinc 4-hydroxyybenzene sulphonate	Deodorants, antiperspirant and astringent lotions	6% calculated as 5 of anhydrous substance		Avoid contact with eyes
26	Amomonium 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%.		Contains ammonium monofluorophosphste
27	Sodium monoflourophosphate	Ditto	0.15% Ditto		Contains sodium monoflourophosphate
28	Potassium monofluorophosphate	Ditto	0.50% Ditto		Contains potassium monoflourophosphate
29	Calcium monofluorophosphate	Ditto	0.50% Ditto		Contains monoflourophosphate
30	Calcium fluoride	Ditto	0.15% Ditto		Contains calcium flouride
31	Soduim fluoride	Ditto	0.15% Ditto		Contains Soduim flouride
32	Potassium fluoride	Ditto	0.15%		Contains potassiun flouride

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EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
33	Ammonium fluoride	Ditto	0.50% Ditto		Contains ammonium fluoride
34	Aluminum fluoride	Ditto	0.15% Ditto		Contains ammonium fluoride
35	Stannous fluoride	Ditto	0.15% Ditto		Contains Stannous fluoride
36	Hexadecyl ammonium fluoride	Ditto	0.15% Ditto		Contains hexadecyl ammonium fluoride
37	3-(N-Hexadecyl-N-2 hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium dihy-Droflouride	Ditto	0.15% Ditto		Contains3-(N-Hexadecyl-N-2 hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium dihydrofluoride
38	NN'N-Tris(polyoxyethylene)-N- hexadedecylpropy-lenediamine dihydrofluoride	Ditto	0.15% Ditto		Contains NN'N-Tris(polyoxyethylene)-N- hexadedecylpropylenediamine dihydrofluoride
39	Octadecynyl-ammonium fluoride	Ditto	0.15% Ditto		Conatains octadecyl-ammonium fluoride
40	Sodium fluorosilicate	Ditto	0.15% Ditto		Contains Sodium fluorosilicate
41	Potassium fluorosilicate	Ditto	0.15% Ditto		Contains potassium fluorosilicate
42	Ammonium fluorosilicate	Ditto	0.15% Ditto		Contains ammonium fluorosilicate

EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
43	Magnesium fluorosilicate	Ditto	0.15% 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 aerosol dispensers (spray) (b) The pH of the product as applied must be less than 4	Contains 1,3-bis (hydroxymethyl) imidazolidin-2-thione
45	Benzyl alcohol	Solvents, perfumes and flavouring			
46	6-Methylcoumarin	Oral hygiene products	0.00%		
47	Nicomethanol hydrofluoride	Oral hygiene products	0.15% calculated as F. When mixed other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.15%		Contains nicomethanol hydroflouride
48	Silver Nitrate	Solely for products intended for colouring eyelashes and eyebrows	4%		▪ Contains silver nitrate ▪ Rinse the eyes immediately if ▪ Products comes into contact with them
49	Selenium disulphide	Anti-dandruff shampoo	1%		▪ Contains selenium disulphide ▪ Avoid contact with eyes or damaged skin

EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
50	Aluminium zirconium chloride hydroxide complexes alxZR (OH)yCLz and the Aluminium zirconium chloride hydroxide glycine complexes	Antiperspirant	20% as anhydrous aluminum zirconium chloride hydroxide	(1) The ratio of the number of aluminum atoms to that of zirconium atoms must be between 2 and 10 (2) The ratio of the number of (Al + Zr) atoms to that chlorine atoms must be Between 0.9 and 2.1 (3) Prohibited in aerosol dispensers (sprays)	Do not apply to irritated or damaged
51	Quinolin-8-ol and bis (8-hydroxyquinolinium) sulphate	▪ stabilizer for hydrogen peroxide in rinse-off hair care preparations ▪ stabilizer for hydrogen peroxide in non-rinse	▪ 0.3% calculated as base ▪ 0.03% calculated as base		
52	Methanol	Denaturant for ethanol and isopropyl alcohol	5% calculated as a % of ethanol and isopropyl alcohol		
53	Etidronic acids 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-2ol	Rinse of products only Prohibited in oral hygiene products	2%	As a preservative, see Annex VI, Part 1, Nº43	

EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
55	Lead Acetate	Only for hair dyeing	0.6% calculated in lead		▪ Keep away from children. ▪ Avoid contact with the eyes ▪ Wash hands after use ▪ Contains lead acetate ▪ Do not use to dye eyelashes, eyes or moustaches ▪ If irritation develops, discontinue
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%		Contains magnesium fluoride
57	Strontium chloride hexahydrate	(a) Toothpaste	(a) 3.5% calculated as strontium. When mixed with other permitted Strontium products the total Strontium content must not Exceed 3.5%		▪ Contains strontium chloride ▪ Frequent use by children is not advisable
		(b) Shampoo and face care products	(b) 2.1% calculated as strontium compounds, the total strontium content must not exceed 2.10%		

EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & 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%		▪ Contains strontium acetate ▪ Frequent use by children is not advisable
59	Talc: hydrated magnesium silicate	(a) Powdery products intended to be used by children (b) Other products			(a) Keep powder away from children's nose & mouth
60	Fatty acid dialkanolamides		Maximum dialkanolamine content: 0.5%	▪ Do not use withnitrosating systems ▪ Maximum dialkanolamine content : 50 ug/kg ▪ Keep in nitrate-free containers	
61	Monoalkanolamines		Maximum dialkanolamine content: 0.5%	▪ Do not use with nitrosating system ▪ Minimum purity : 99% ▪ Maximum secondary alkanolamine content: ▪ 0.5% (concerns raw materials) ▪ Maximum N- Nitroso- dialkanolamine content: 50 ug/kg ▪ Keep in nitrate-free containers	

EU Ref #	Substance	Restrictions			Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application And/or Use	Maximum Allowable Concentration In the Finished Cosmetic Product	Other Limitations & Requirements	
a	b	c	d	e	f
62	Trialkanolamines	(a) Non rinse-off products (b) Other products	(a) 2.5%	(a) (b): ▪ Do not use with nitrosating system ▪ Minimum purity: 99% ▪ Maximum secondary alkanolamine content: ▪ 0.5% (concerns raw materials) ▪ Maximum N-nitroso-dialkanolamine content: 50ug/kg ▪ Keep in nitrite-free containers	
63	Strontium hydroxide	pH-regulator in depilatory products	3.5% calculated as strontium, max pH of 12.7		▪ Keep out of reach of children ▪ Avoid contact with the eyes
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	▪ Avoid contact with eyes ▪ Rinse eyes immediately if products comes into contact with them ▪ For professional use only ▪ Wear suitable gloves
65	Benzalkonium choloride, 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 Sacchinate with an alkyl chain of C14, or Less must not exceed 0.1% (as benzalkoinium chloride)	(a) Avoid contact with the eyes (b) Avoid contact with the eyes

LIST OF SUBSTANCES PROVISIONALLY ALLOWED

ANNEX III – PART 2

LIST OF SUBSTANCES PROVISIONALLY ALLOWED

EU Ref #	Substance		Restriction authorized		Conditions of Use and Warning Which Must be Printed on the Labels
		Field of Application and/or use	Maximum authorized concentration In the Finished Cosmetic Product	Other Limitations and Requirements	
a	b	c	d	e	f

LIST OF COLORING AGENTS ALLOWED

FOR USE IN COSMETIC PRODUCTS (1)

ANNEX IV – PART 1

LIST OF COLOURING AGENTS 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 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 (2)
		1	2	3	4	
10006	Green				X	
10020	Green			X		
10316(3)	Yellow		X			
11680	Yellow			X		
11710	Yellow			X		
11725	Orange				X	
11920	Orange	X				
12010	Red			X		

(1) Lakes or salts of these colouring agents using substances not prohibited under Annex II or not excluded under Anne 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 fulfill 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.

(3) 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 8.

Colour Index Number or Denomination	Colour	Field of Application				Other Limitation And Requirements (2)
		1	2	3	4	
12085(3)	Red	X				3% max, concentration in the finished products
12120	Red				X	
12150	Red	X				
12370	Red				X	
12420	Red				X	
12480	Brown				X	
12490	Red	X				
12700	Yellow				X	
13015	Yellow	X				E 105
14270	Orange	X				E 103
14700	Red	X				
14720	Red	X				E 122
14815	Red	X				E125
15510 (3)	Orange		X			
15525	Red	X				
15580	Red	X				
15620	Red				X	
15630 (3)	Red	X				3% max, concentration in the finished products
15800	Red			X		
15850 (3)	Red	X				
15865 (3)	Red	X				
15880	Red	X				
15980	Orange	X				E111
15985 (3)	Yellow	X				E110
16035	Red	X				
16185	Red	X				E123
16230	Orange			X		
16255 (3)	Red	X				E 124
16290	Red	X				E 126
17200 (3)	Red	X				
18050	Red			X		
18130	Red				X	
18690	Yellow				X	

Colour Index Number or Denomination	Colour	Field of Application				Other Limitation And Requirement (2)
		1	2	3	4	
18736	Red				X	
18820	Yellow				X	
18965	Yellow	X				
19140 (3)	Yellow	X				E 102
20040	Yellow				X	Maximum 3,3'- dimethylbenzidine concentration in the colouring agent: 5 ppm
20170	Orange			X		
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	
26100	Red			X		Purity criteria aniline ≤ 0.2% 2-naphtol ≤ 0.2% 4-aminoazobenzene ≤ 0.1% 1-(phenylazo)-2-naphtol ≤ 0.3% 1-[2-(phenylazo)phenylazo]-2-naphtalenol ≤ 2%
27290 (3)	Red				X	
27755	Black	X				E 152
28440	Black	X				E 151
40215	Orange				X	
40800	Orange	X				
40820	Orange	X				E 160 e
40825	Orange	X				E 160 f
40850	Orange	X				E 161 g
42045	Blue			X		
42051 (3)	Blue	X				E 131
42053	Green	X				
42080	Blue			X		
42090	Blue	X				
42100	Green				X	
42170	Green				X	

Colour Index Number or Denomination	Colour	Field of Application				Other Limitation And Requirement (2)
		1	2	3	4	
42510	Violet			X		
42520	Violet				X	5 ppm max, concentration in the finished product
42735	Blue			X		
44045	Blue			X		
44090	Green	X				E142
45100	Red			X		
45190	Violet			X		
45220	Red			X		
45350	Yellow	X				6% max, concentration in the finished product
45370 (3)	Orange	X				Not more than 1% 2-(6-hydroxy-3 oxo-3H-xanthen-9yl) benzoic acid and 2% 2-(bromo-6-hydroxy-3-oxo 3H-xanthen-9-yl) benzoic acid
45380 (3)	Red	X				Ditto
45396	Orange	X				When used in lipstick, the colouring agent is allowed only in free acid form in a maximum concentration of 1%
45405	Red		X			Not more than 1% 2-(6-hydroxy-3 oxo-3H-xanthen-9yl) benzoic acid and 2% 2-(bromo-6-hydroxy-3-oxo 3H-xanthen-9-yl) benzoic acid
45410 (3)	Red	X				Ditto
45425	Red	X				Not more than 1% 2-(6-hydroxy-3 oxo-3H-xanthen-9yl) benzoic acid and 2% 2-(bromo-6-hydroxy-3-oxo 3H-xanthen-9-yl) benzoic acid
45430 (3)	Red	X				E 127,ditto
47000	Yellow			X		
47005	Yellow	X				E 104
50325	Violet				X	
50420	Black			X		
51319	Violet				X	
58000	Red	X				
59040	Green			X		
60724	Violet				X	
60725	Violet	X				
60730	Violet			X		

Colour Index Number or Denomination	Colour	Field of Application				Other Limitation And Requirement (2)
		1	2	3	4	
61565	Green	X				
61570	Green					
61585	Blue	X				
62045	Blue				X	
69800	Blue				X	E130
69825	Blue	X				
71105	Orange			X		
73000	Blue	X				
73015	Blue	X				
73360	Red	X				
73385	Voiolet	X				
73900	Violet				X	
73915	Red				X	
74100	Blue				X	
74160	Blue	X				
74180	Blue				X	
74260	Green		X			
75100	Yellow	X				
75120	Orange	X				E 160 b
75125	Yellow	X				E 160 d
75130	Orange	x				E 160 a
75135	Yellow	X				E 160 d
75170	White	X				
75300	Yellow	X				E 100
75470	Red	X				E 120
75810	Green	X				E 140 and E 141
77000	White	X				E 173
77002	White	X				
77004	White	X				
77007	White	X				
77015	Red	X				
77120	White	X				
77163	White	X				
77220	White	X				E 170
77231	White	X				

Colour Index Number or Denomination	Colour	Field of Application				Other Limitation And Requirements (2)
		1	2	3	4	
77266	Black	X				
77267	Black	X				
77268:1	Black	X				E 153
77288	Green	X				Free from chromate ion
77289	Green	X				Free from chromate ion
77346	Green	X				
77400	Brown	X				
77480	Brown	X				E 175
77489	Orange	X				E 172
77491	Red	X				E 172
77492	Yellow	X				E 172
77499	Black	X				E 172
77510	Blue	X				Free from cyanide ion
77713	White	X				
77742	Violet	X				
77745	Red	X				
77820	White	X				E 174
77891	White	X				E 171
77947	White	X				
Lactoflavin	Yellow	X				E 101
Caramel	Brown	X				E 150
Capsanthin,Capsorubin	Orange	X				E 160 c
Beetroot red	Red	X				E 162
Anthocyanins	Red	X				E 163
Aluminium,zinc, magnesium and calcium stearates	White	X				
Bromthymol blue	Blue				X	
Bromcresol green	Green				X	
Acid Red 195	Red	X				

LIST OF COLORING AGENTS PROVISIONALLY ALLOWED FOR USE IN COSMETIC PRODUCTS (1)

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 except those intended to be applied in the vicinity of eyes, in particular aye make-up and eye 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.

Colour Index Number or Denomination	Colour	Field of Application	Other limitations and requirements (2)

Note: no colorant id 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 fulfill 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.

LIST OF EXCLUDED FROM THE SCOPE

OF THE DIRECTIVE

ANNEX V

LIST OF EXCLUDED FROM THE SCOPE OF THE DIRECTIVE

5. Strontium and its compound, 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, Part 1.

LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS MAY CONTAIN

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 purpose 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 labeled with the warning "contains formaldehyde" where the concentration of formaldehyde in the finished product exceeds 0.05%

LIST OF PRESERVATIVES ALLOWED

ANNEX VI – PART 1

LIST OF PRESERVATIVES 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
P2	1	Benzoic acid, its salts and esters(+)	0.5% (acid)		
P13	2	Propionic acids and salts (+)	2% (acid)		
P14	3	Salicylic acid and its salts (+)	0.5% (acid)		
P15	4	Sorbic acid (hexa-2-4-dienoic acid) and its salts (+)	0.6% (acid)	Not to be use in preparation in children under 3 years of age, excepts for shampoos	Not to be use for children under 3 years of age (1)
P39	5	Formaldehyde and paraformaldehyde (+)	0.2% (except for products for oral hygiene) 0.1%(products for oral hygiene) express as free formaldehyde	Prohibited in aerosol dispensers(spray)	
P47	7	Biphenyl-2-ol (o-phenylpenol) and its salts (+)	0.2% express as phenol		
P81	8	Pyrithione zinc (NN) (+)	0.50%	Authorized in products rinsed off, forbidden in products for oral hygiene	
P51	9	Inorganic sulphites and hydrogensulphites(+)	0.2% expressed as free SO_2		
P 66	10	Sodim iodate	0.1%	Rinse-off products	

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
P68	11	Chlorobutanol (INN)	0.50%	Prohibited in aerosol dispensers spray	Contains chlorobutanol
P82	12	4-hydroxybenzoic acids its salts and esters (+)	0.4%(acid) for ester; 0.8% (acid) for mixtures of esters		
P5	13	3-Acetyl-6-methylperan-2,4(3H)-dione (Dehydroacetic acid) and its salts	0.6% (acid)	Prohibited in aerosol dispensers (spray)	
P6	14	Formic acid and its sodium salts (+)	0.5% (expressed as acid)		
P9	15	3,3'-Dibromo-4,4'-hexamethylene-dioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate)	0.10%		
P12	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
P48	17	Phenylmercuric salts (including borate)	Ditto	Ditto	Contains phenylmercuric compounds
P16	18	Undec-10-enoic acid and salts (+)	0.2% (acid)		
P20	19	Hexetidine (INN) (+)	0.10%		

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
P23	20	5-Bromo-5-nitro-1,3 dioxane	0.10%	-Rinse-off products only -Avoid formation of nitrosamines	
P24	21	Bronopol (INN) (+)	0.10%	Avoid formation of nitrosamines	
P74	22	2,4-Dichlorobenzyl alcohol (+)	0.15%		
P29	23	Triclocarban (INN) (+)	0.20%	Purity criteria: 3,3',4,4' Tetrachloroazobenzene less than 1 ppm;3,3',4,4'-Tetrachloroazoxybenzene less than 1 ppm	
P30	24	4-Chloro-m-cresol	0.20%	Prohibited in products intended to come into contact with mucous membranes	
P32	25	Triclosan(INN) (+)	0.30%		
P37	26	4-Chloro-3,5-xylenol (+)	0.50%		
P43	27	3,3'-Bis91-hydroxymethyl-2,5-dioxoimidazolidin 4-yl)-1,1'-methylenediurea ("Imidazolidinyl urea") (+)	0.60%		
P52	28	Poly(1-hexamethylenebiguanide hydrochloride (+)	0.30%		
P53	29	2-Phenoxyethanol (+)	1.00%		

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
P55	30	Hexamethylenetetramine (+) Methenamine (INN)	0.15%		
P63	31	Methenamine 3-chloroallylochloride (INNM)	0.20%		
P64	32	1-(4_chlorophenoxy)-1-(imidazol-1yl)3,3-dimethylbutan-2-0n2 (+)	0.50%		
P65	33	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazoli- dine-2,4-dione (+)	0.60%		
P67	34	Benzyl alcohol (+)	1%		
P59	35	1-Hydroxy-4-methyl-6(2,4,4-trimethylpentyl)2- pyridon ans its monoenatholamine salt(+)	1% 0.50%	Products rinsed -off For other products	
P77	36	1,2-Dibromo-2,4-dicyanobutane	0.10%	Not to be used in cosmetic sunscreen products at a concentration exceeding 0.03%	
P25	37	6,6 dibromo-4,4-dichloro-2,2'-methylene-diphenol:Bromochlorophen) (+)	0.10%		
P44	38	4-Isopropyl-m-cresol	0.10%		
P56	39	Mixture of 5-Chloro-2methyl-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-ethyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-0ne)		
P22	40	2-Benzyl-4-chlorophenol (Chlorophene)	0.20%		

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
P27	41	2-Chloroacetamide	0.30%		Contains chloroacetamide
P35	42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+)	0.3% expressed as chlorxidine		
P54	43	1-Phenoxypropanpropan-2-ol	1.00%	Only for rinse-off products	
P72	44	Alkyl (C12-C22) trimethyl ammonium, bromide	0.10%		
P75	45	4,4-Dimethyl-1,3-oxazolidine	0.10%	The pH of the finished product must not be lower than 6	
P79	46	N-(hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolinidyl-4)-N'-(hydroxymethyl)urea	0.50%		
P8	47	1,6-Di(4-amidinophenoxy)-n-hexane (Hexamidine) and its salts (including isethionate and p-hydroxy-benzoate (+)	0.10%		
P76	48	Glutaraldehyde (Pentane-1,5-dial	0.10%	Prohibited aerosols (sprays)	Contains glutaraldehyde (where glutaraldehyde concentration in the finished products exceeds 0.05%
P90	49	5-Ethyl-3,7-dioxa-1-azabicyclo [3.3.0] octane	0.30%	Prohibited in oral hygiene products and in products intended to come into	

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
					contact with mucous membranes
P4	50	3-(p-Chlorophenoxy)-propane-1,2-diol (chlorphenesin)	0.30%		
P84	51	Sodium hydroxymethylamino Acetate (Sodium hydroxymethylglycinate)	0.50%		
P93	52	Silver chloride deposited Titanium dioxide	0.004% calculated as AgCl	20%AgCl (w/w) on TiO_2	prohibited in products for children under 3 years of a age, in oral hygiene products intended for application around the eyes and on the Lips
P70	53	Benzenthonium chloride	0.10%		Rinse-off products only
P71	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 removed by rinsing
	56	3-Iodo-2-propynylbutylcarbamate	0.05%		1. Not to be use for oral hygiene and lip care products 2. If the concentration in pro-ducts intended to remain on the skin exceeds 0.02% add the phrase: contains iodine

LIST OF PRESERVATIVES

PROVISIONALLY ALLOWED

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.

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 substance which, contained in cosmetic sunscreen products, are specially 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.

LIST OF PERMITTED UV FILTERS

WHICH COSMETIC PRODUCTS MAY CONTAIN

ANNEX VII – PART 1

LIST OF PERMITTED UV FILTERS WHICH COSMETIC

Colipa Number	Reference Number	Substance	Maximum Authorized Concentration	Other Limitations And Requirements	Conditions of use and Warnings which must be Printed on the Label
S1	1	4-Aminobenzoic acid	5%		
S57	2	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidenemethyl) anilium metyl sulphate	6%		
S12	3	Homosalate (INN)	10%		
S38	4	Oxybenzone (INN)	10%		Contains oxybenzone (1)
S 45	6	2-phenylbenzimidazole-5-sulfonic 2-phenylbenzimidazole-5-sulfonic and triethanolamine salts	8% (expressed as acid)		
S71	7	3,3'-(1,4-Phenylenedimethylene) bis(7,7-dimethyl-2-oxo-bicyclo-[2,2,1] heptylmethanesulfonic acid) and its salts	10% (expressed as acid)		
S66	8	1-4--Tert-butylphenyl)-3-(-4-me-Thoxyphenyl)propane-1,3-dione	5% (expressed as acid)		
S59	9	Alpha-(2-Oxoborn-3-ylidene) toluene-4-sulphonic acid and its salts			

Colipa Number	Reference Number	Substance	Maximum Authorized concentration	Other limitations And requirements	Conditions of use and Warnings which must be Printed on the label
S 32	10	2-Cyano-3,3-diphenylacrylic acid,2	10%		
		etylhexyl ester (Octocrylene)	(expressed as acid)		
S 72	11	Polymer of N-{(2 and 4)-[(2-oxoborn 3-ylidene0) methyl] bemzyl] acryla mide	6%		
S 28	12	Octyl methoxycinnamate	10%		
S 3	13	Ethoxylated-ethyl-1 aminoben-zoate (PEG-25 PABA)	10%		
S 27	14	Isopentyl-4-methoxycinnamate (Isoamyl p-methoxycinnamate)	10%		
S 69	15	2,4,6-Trianilino-p-carbo-2'-ethylhexyl -1'-oxy)-1,3,5-triazine Octyl triazone)	5%		
S 73	16	Phenol,2-2(2H-benzotriazol-2-yl)-4-methyl-6-(2-methyl-3-(1,3,3,3-tetra methyl-1-(trimethylsilyl)oxy)-disiloxanyl)propyl (Drometriazole Trisiloxane)	15%		
S 78	17	Benzoic acid, 4,4-((6-(((1,1-dime-thylethyl(amino)carbonyl)phenyl) amino)1,3,5-triazine-2-4-diyl)diimi-no)bis-,bis(2-ethylhexyl)ester)	10%		

Colipa Number	Reference Number	Substance	Maximum Authorized concentration	Other limitations And requirements	Conditions of use and Warnings which must be Printed on the Label
S 60	18	3-(4'-Methylbenzylidine)-d-1 camphor 4-Methylbemzylidine)-d-1 camphor (4-Methylbenzylidene Camphor)	4%		
S 61	19	3-Benzylidene camphor (3-Benzylidene camphor)			
S 8	20	2-Ethylhexyl salicylate (Octyl Salicylate)	5%		
	21	4-Dimethyl-aminobenzoate of ethyl (octyl dimethyl PABA)	8%		
	22	2-Hydroxy-4-methoxybenzo-phenone-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, phenol	10%		
	24	Monosodium 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-ethylhexyloxy)-2-hydroxy)-phenyl)-6-(4-methoxyphenyl)	10%		

LIST UV FILTERS WHICH COSMETIC PRODUCTS MAY PROVISIONALLY CONTAIN

ANNEX VII – PART 2

LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MAY PROVISIONALLY CONTAIN

Colipa Number	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

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

ASEAN ADDITIONAL LIST OF UV FILTERS WHICH MAY PROVISIONALLY CONTAIN

ANNEX VII – PART 3

ASEAN ADDITIONAL LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MAY CONTAIN

ASEAN Ref #	Substance	Allowable Concentration (%)	Country of Proposal	Accepted? (Y/N)
5	Glycerol 1,4-aminobenzoate (free from benzocaine)	3	Thailand	
6	Menthyl anthranilate	5	Thailand	
7	Sulisobenzone	10	Thailand	
8	Dioxybenzone	3	Thailand	
9	Digalloyl trioleate	5	Thailand	

The UV filters listed above are currently allowed for use as UV filters in sunscreen products in Thailand. They are considered as safe at the concentrations below the allowable concentrations. They should be allowed for use unless there is the toxicity or unsafety report.

ASEAN HANDBOOK

OF COSMETIC INGREDIENTS

LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF THE COMPOSITION OF COSMETIC PRODUCTS

Part I

LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF THE COMPOSITION OF COSMETIC PRODUCTS

No.	Substance	Country
1	Aminophylline	Malaysia, Singapore, Thailand
2	Androgenic, oestrogenic and progestational substances, the following : Benzoestrol; Derivatives of stilbenes, dibenzyl or naphthalene with oestrogen activity; their esters; their ethers; their salts Steroid compounds with androgenic or oestrogenic or progestational activity; their esters; their ethers; their salts	Singapore
	Sex hormones – androgenic, oestrogenic and progestational –natural or synthetic, the following: Benzoestrol; Derivatives of stilbenes or napthalene with oestrogenic activity; their esters; Steroid compounds with androgenic, oestrogenic or progestational activity; their esters	Brunei, Malaysia
3	Azelaic acid	Thailand, Malaysia
4	Chlorofluorocarbon (CFC)	Indonesia, Thailand
5	Hormones	Thailand
6	Methylene chloride or dichloromethane	Thailand, Phillipines
7	Silver and its derivatives except for use as colorants in nail polish	Indonesia
8	Sodium peroxide	Thailand
9	Theophylline	Malaysia, Singapore
10	Thorium and its compounds	Indonesia
11	Tranexamic acid	Brunei, Malaysia

LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO RESTRICTION AND CONDITION LAID DOWN

PART II

LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO RESTRICTION AND CONDITION LAID DOWN

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
1	1-(4-chlorophenoxy)-1-(1H-imidazolyl)-3,3-dimethyl-2-butanone (Climbazole)		2% in rinsed-off hair and scalp products 0.5% in non rinsed-off hair and scalp products	- Avoid contact with eyes - Stop using if irritation or abnormality occurs and consult physician - Do not use in children under 6 years of age	Thailand
		Hair shampoo		- For external use only. - Avoid contact with eyes. - If contact with eyes, rinse thoroughly with water. If irritation persists, consult a physician.	Phillipines

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
2	Aluminium chlorhydrate (chlorhydrol)	Anti-perspirant	25%	- Do not apply to broken skin. - If rash develops, discontinue use. - Apply to skin of underarm. - Not to be used generally over the body	Phillipines
3	Aluminium chlorhydrate alantoinate		25%	- Do not apply to broken skin. If rash develops, discontinue use. - Apply to skin of underarm. - Not to be used generally over the body	Cambodia
4	Aluminium chloride (Aluminium chloride hexahydrate)		15% calculated as hexahydrate form in aqueous solution	- Some users of the products will experience skin irriation - Apply to skin or underarm. - Not to be used generally over the body.	Cambodia, Phillipines

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
5	Aluminium potassium hydroxide sulphate			-	Cambodia
6	Aluminium sulphate		30%	-	Cambodia
7	Aluminium pyrithione	Anti-dandruff	2%	- Avoid contact with eyes - Stop using if irritation or abnormality occurs and consult physician - Do not use in children under 6 years of age	Thailand
7 (Cont.)	Aluminium pyrithione		2%	- Avoid contact with eyes - Stop using if irritation or abnormality occurs and consult physician - Do not use in children under 6 years of age	Cambodia
8	a) Biosulfur fluid b) Sulfur		a) 2-10% b) 2-10% c) 2%	-	Cambodia

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
	a) Biosulfur fluid b) Sulfur	Liquid Shampoos	a) 0.5-2.0% b) <2.0%	-	Phillipines
	a) Biosulfur fluid b) Sulfur	a) Anti Dandruff b) Anti Acne	a) 2-10% b) 2-10%	-	Indonesia
9	Bromochlorophene	Antiseptic	0.1%	-	Indonesia, Cambodia
10	Camphor	Cooling products	Limited at 1.5% only in body powder	Not to be used in children less than 3 years of age	Thailand
11	Capsicum tincture		1%	-	Cambodia, Indonesia
12	Cetylpyridinium chloride		Limited at 0.06% in mouthwash and mouthspray products	Do not use in children under 6 years of age	Thailand
		Antiseptic	0.5% in non rinse-off products	-	Indonesia
13	Chlorhexidine digluconate	Antiseptic/Deodorant	0.2% rinse-off preparations 0.05% non rinse-off preparations	-	Indonesia
14	Chloroxylenol	Deodorant	6%	-	Indonesia, Cambodia
15	Citric acid trethylester		3%	-	Cambodia
16	Copper		150 ppm	-	Cambodia, Singapore

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
17	Dihydroxyacetone	Tanning products	5%	- Keep away from light - Stop using if irritation or rash occurs at contact area and consult physician.	Thailand, Cambodia
18	Farnesol (Geranyl farnesyl acetate)	Deodorant	1.2%	-	Indonesia, Cambodia
19	Fluoride salts and derivatives*	Oral hygiene products	1100 ppm*	Not to be ingested by children under 7 years of age.	Thailand
20	Ginger tincture		1%	-	Cambodia, Indonesia
21	Glyceryl monolaurate	Deodorant	0.09%	-	Indonesia, Cambodia
22	Halocarbane	Antiseptic	0.3% in rinse-off products 0.2% in non rinse-off products	-	Indonesia, Cambodia
23	Lawsone with dihydroxyacetone	Tanning products	0.25 and 3%	- Keep away from light - Stop using if irritation or rash occurs at contact area and consult physician.	Thailand, Cambodia

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
24	Low molecular weight hydrocarbon, *i.e.* propane		10%	-	Cambodia, Phillipines
25	Menthol	Cooling products	Limited at 1% only in body powder	Not to be used in children less than 3 years of age	Thailand
26	PEG-80 sorbitan oleate sulphur	Anti-dandruff	2% in rinse-off products 1% in non rinse-off products	-	Indonesia, Cambodia
27	Persulfates of ammonium or potassium or sodium	Hair bleaching products	45% of persulfate before mixing with hydrogen peroxide and not exceed 20% after mixing with hydrogen peroxide	- Avoid contact with eyes - Test for allergic reaction before use (see label or packaging insert for allergic test method) - Stop using and rinse with water if irritation, burning or rash occur at contact area - Do not use if there is scratch on scalp or dermatiis; Do not scratch heavily during hair wash. - Keep out from reach of children and in cool place	Thailand
	Persulfates of ammonium or		45% of derivative of persulfate	- Avoid contact with	Cambodia,

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
	potassium or sodium		before mixed with hydrogen peroxide	eyes - Test for allergic reaction before use (see label or packaging insert for allergic test method) - Stop using and rinse with water if irritation, burning or rash occur at contact area - Do not use if there is scratch on scalp or dermatiis; Do not scratch heavily during hair wash. - Keep out from reach of children and in cool place	Indonesia
28	Piroctone olamine		1% in rinsed-off anti-dandruff products 0.1% in non rinsed-off hair products	- Stop using if irritation or abnormality occurs and consult physician	Thailand

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
		Anti-dandruff	1%	- For external use only - Avoid contact with eyes - If irritation persists, contact physician	Phillipines, Cambodia
29	Quarternary ammonium compounds a) Cetylpyridinium chloride b) Benzethonium chloride c) Benzalkonium chloride (Listed in EU) d) Alkyl (C12-C22) Trimethyl ammonium chloride	a) Feminine wash b) Feminine wash c) d) Feminine wash	a) 0.1% b) 0.1% c) As listed in EU Directive d) 0.1%	-	Cambodia, Phillipines
30	Quinolin-8-ol and bis (8-hydroxyquinolinium) sulphate	a) Stabilizer for hydrogen peroxide in rinse-off haircare preparations b) Non rinse-off hair care preparations	a) 0.3% calculated as base b) 0.03% calculated as base		Phillipines

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
31	Ricinol polyethioxylate sulphide	Anti Dandruff	2% in rinse-off products 1% in non rinse-off products	-	Cambodia, Indonesia
32	Salicylic acid		2%	-	Thailand
	Salicylic acid		a) 1.5-2.0% b) 0.5-2.0%	- Not to be used by children under 2 years of age - Not to be used in large portion of the body - Not to be used for prolonged period of time	Cambodia
	Salicylic acid	Skin care	2.0%	- Not to be used by children under 3 yrs of age. - Not to be used in large portion of the body. - Not to be used for prolonged period of time.	Phillipines

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
	Salicylic acid	a) Exfoliating b) Anti acne	a) 1.5 – 2 % b) 0.5 – 2 %	-	Indonesia
33	Sodium lauryl sulfate		15%	-	Thailand
34	Sulfur		3%	-	Thailand
35	Thiolactic acid	Hair waving products	8.5%, pH not more than 9.5	- Avoid contact with eyes - Test for allergic reaction before use (see label or packaging insert for allergic test method) - Stop using and rinse with water if irritation, burning or rash occur at contact area - Do not use if there is scratch on scalp or dermatitis; Do not scratch heavily during	Thailand, Cambodia, Indonesia

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
				hair wash. - Keep out from reach of children	
36	Tranexamic acid		0.05%	-	Singapore
37	Trichlorocarbanilide (TCC, Triclocarban)		a) 1.5% in rinse-off products 0.3% in non rinse-off products b) 2%	-	Cambodia
	Trichlorocarbanilide (TCC, Triclocarban)	Deodorant	2%	-	Phillipines
	Trichlorocarbanilide (TCC, Triclocarban)	Antiseptic	1.5% in rinse-off products 0.3% in non rinse-off products	-	Indonesia
38	Triclosan (Irgasan DP-300)		a) 2% b) 0.5% c) 2% in rinse-off products d) 0.3% in non rinse-off products	-	Cambodia
38 (cont.)	Triclosan (Irgasan DP-300)	a) Deodorant b) Toothpaste	a) 2% b) 0.5%	Irgasan DP 300 is not to be formulated in feminine hygiene products.	Phillipines
	Triclosan (Irgasan DP-300)	Antiseptic	2% for rinse-off products 0.3% in non rinse-off products	Not to be used in babies under six months old.	Indonesia
39	Undecylenic acid monoethanol amide sodium sulphosuccinate	Antiseptic	2% in rinse-off products 1% in non rinse-off products	-	Indonesia, Cambodia

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
40	Zinc phenolcarbonate	Deodorant product	2%	-	Cambodia, Phillipines
41	Zinc p-phenol sulphonate	Deodorant product	6%	- Avoid contact with eyes	Thailand
	Zinc p-phenol sulphonate	Antiseptic	6% Rinse-off preparation 2% Non-rinse-off preparation	-	Indonesia
42	Zinc pyrithione (pyrithione zinc, zinc omadine)		2% in rinsed-off anti-dandruff products 0.5% in non rinsed-off hair products	- Stop using if irritation or abnormality occurs and consult physician	Thailand
	Zinc pyrithione (pyrithione zinc, zinc omadine)		2%	- For external use only - Avoid contact with eyes - If irritation persists, contact physician	Cambodia

No.	Substance	Field of application and/or use	Maximum authorised concentration in the finished cosmetic products (%)	Labeling requirements	Country
	Zinc pyrithione (pyrithione zinc, zinc omadine)	a) Hairgroom preparation b) Hair shampoo	a) 0.25% (leave-on products only)	a) Apply a small amount to scalp daily a) & b) - For external use only. - Avoid contact with eyes. - If contact with eyes, rinse with water. - If irritation persists consult a physician.	Philippines
	Zinc pyrithione (pyrithione zinc, zinc omadine)	Antidandruff	2% in rinse-off products 1% in non rinse-off products	- Avoid contact with eyes	Indonesia
43	Zinc ricinoleate	Antiseptic	5% in powder preparations 3% in other preparations	-	Indonesia

* Special case, dued to high fluoride content in drinking water in some areas of Thailand. Extensive investigation on safety/risk of use of the fluoride toothpaste in Thailand is ongoing.

LIST OF COLOURING AGENTS ALLOWED

FOR USE IN COSMETIC PRODUCTS

PART III
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 intendednto 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 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.

Column 5 Colouring agents allowed exclusively in cosmetic products intended to be applied externally.

CI Number	**Colour**	**Field of Application**					**Country**
		1	2	3	4	5	
14600	Orange			X			Singapore
16150	Red			X			Singapore
16155	Red			X			Singapore
46035	Red	X					Phillipines
75480	Henna*	To color hair only					Phillipines
77013	Complex of sodium aluminium sulfosilicate (ultramarine green)					X	Thailand
		X					Indonesia
77019	Mica*	X					Thailand, Indonesia, Phillipines
77520	Ferric ammonium ferrocyanide					X	Thailand
		X					Indonesia, Phillipines
N/A	Bismuth citrate				X		Indonesia
N/A	Dihydroxyacetone**					X	Phillipines
N/A	Aceton Dihydroxide		X				Indonesia
N/A	Disodium EDTA-copper				X		Indonesia
N/A	Guiazulene (1,4-Dimethyl-7-(1-Methyl-ethyl) Azulene)					X	Thailand
			X				Indonesia

*Not considered as colouring agent and allowed for use without restriction elsewhere.
*Not considered as colouring agent elsewhere. Limited use in tanning products in Thailand and Cambodia (see Part II).

LIST OF PRESERVATIVES ALLOWED

PART IV
LIST OF PRESERVATIVES ALLOWED

No.	Substance	Allowable Concentration (%)	Country
1	Aluminium pyrithione	0.1% in non-rinsed-off cosmetic products	Thailand
2	Butylated hydroxyanisole	0.2% (for products rinsed off after use)	Phillipines
3	Cetylpyridinium chloride	0.01-0.05% (For products that come in contact with the mucous membrane) 0.01-1.0% (Other products)	Phillipines
4	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride (+)	0.3% expressed as chlorhexidine; *Not allowed for use in oral hygiene products.*	Thailand
5	Chloro-N-(hydroxymethyl) acetamide	0.3%	Phillipines
6	Phenol and its alkali salts	1.0% in soap or shampoo	Thailand
7	Phenonip	1%	Phillipines
8	Piroctone olamine	0.5% in rinsed-off cosmetic products (Prohibited for oral hygienic products) 0.1% in non-rinsed-off cosmetic products	Thailand
9	Thymol	0.1%	Thailand

LIST OF UV FILTERS WHICH

COSMETIC PRODUCTS MAY CONTAIN

PART V
LIST OF UV FILERS WHICH
COSMETIC PRODUCTS MAY CONTAIN

ASEAN Ref #	Substance	Allowable Concentration (%)	Country
1	2-Ethoxyethyl-p-methoxycinnamate (cinoxate)	3 (mixture : 1-3%)	Indonesia
		3	Phillipines
2	4-Isopropyl-dibenzoyl-methane	5	Phillipines
3	Benzyl salicylate	10	Thailand
4	Camphor benzalkonium methosulfate	6	Phillipines
5	Diethanolamine methoxycinnamate	10	Phillipines
		10 (mixture : 8-10%)	Indonesia
6	Digalloyl trioleate	5	Thailand, Phillipines
7	Dioxybenzone	3	Thailand
8	Ethyl 4-[bis(Hydroxypropyl)] Aminobenzoate	5	Phillipines
		5 (mixture : 1-5%)	Indonesia
9	Ethyl diethyaminoenzoate	1	Thailand
10	Ethyl N-dihydroxypropyl PABA	5	Thailand, Phillipines
11	Ethyl-p-dimethylaminobenzoate	1	Thailand
12	Glycerol 1,4-aminobenzoate (free from benzocaine) (Glyceryl aminobenzoate, Glyceryl PABA)	3	Thailand, Phillipines
13	Lawsone / dihydroacetate	0.25 / 3	Phillipines
14	Menthyl anthranilate	5	Thailand, Phillipines
15	Red petrolatum	100	Phillipines
16	Sulisobenzone	10	Thailand
17	TEA Salicylate (triethanolamine Salicylate, trolamine salicylate)	12 (mixture : 5-12%)	Indonesia
		12	Phillipines
18	Terephthalylidene dicamphor sulfonic acid	10	Cambodia

ASEAN Ref #	Substance	Allowable Concentration (%)	Country
		(expressed as acid)	
19	Titanium dioxide*	25	Phillipines
20	Zinc oxide*	20	Phillipines

*** Allowed for use as physical sunscreen without restriction elsewhere.**

LIST OF CONTACT POINT FOR COSMETIC

IN ASEAN MEMBER COUNTRIES

LIST OF CONTACT POINT FOR COSMETIC IN ASEAN EMMBER COUNTRIES

1. Department of Pharmaceutical Services
   Ministry of Health
   Brunei Darussalam
   Jalan Menteri Besar
   Bandar Seri Begawan, BB 3910
   Brunei Darussalam
   Tel: (673)-2-242424
   Fax: (673)-2-242690

2. Bureau of Drug and Cosmetic
   Department of Drug and Food
   Ministry of Health
   #8 Ung Pokoun Street
   Sangkat Mittapheap
   Khan 7 Makara, Phom Penh
   Kingdom of Cambodia
   Tel/Fax: (855)-023-880247

3. Directorate of Cosmetic, Food Supplement and Traditional Drug Assessment
   Drug and Food Control Agnecy (Badan POM)
   Jl. Percetakan Negara 23
   Jakarta 10560
   Indonesia
   Tel: (62)-21-424-4819
   Fax: (62)-21-424-4819

4. Food and Drug Department
   Ministry of Health
   Vientiane
   Lao PDR
   Tel: (85621) 214013-4, 213495
   Fax: (85621) 214015

5. National Pharmaceutical Control Bureau
   Ministry of Health Malaysia
   Jalan University P.O. Box 319
   46730 Petaling Jaya
   Malaysia
   Tel: (603) 79573611
   Fax: (603) 79581312

6. Food and Drug Administration
Department of Health
Ministry of Health
35, Minkyaung Road
Dagon PO 11191, Yangon
Myanmar
Tel: +95-1-250283
Fax: +95-1-202060

7. Bureau of Food and Drugs (BFAD)
Department of Health
Civic Drive, Filinvest Corporate City
Alabang Muntinlupa City
Philippines
Tel: (632) 807-07-21
Fax: (632) 807-07-51

8. Centre for Pharmaceutical Administration
Health Sciences Authority, Singapore
2 Jalan Bukit Merah, Singapore 169547
Singapore
Tel: 662 590 7272
Fax: 662 591 8468

9. Cosmetics Control Division
Food and Drug Adminsitration
Ministry of Public Health
Thailand
Tel: 662 590 7272
Fax: 662 591 8468

10. Drug and Cosmetic Management Division
Drug Administration of Vietnam
Ministry of Health
138A Giang Vo-Hanoi
Vietnam
Tel: 84 4 8462010
Fax: 84 4 8234758