TEA for octyl triazone submitted by Morgan, Lewis & Bockius LLP on behalf of BASF AG dated August 21, 2002, is unavailable for public display until the agency determines the releasability of information according to 18 U.S.C. 1905, 5 U.S.C. 552(b), and 21 U.S.C. 331(j).

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August 21, 2002

BY HAND DELIVERY

Contains Trade Secret and Confidential Commercial Information: Not Intended for Release Under the Freedom of Information Act

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Docket No. 96N-0277

Dear Madam or Sir:

On behalf of BASF AG ("BASF") of Ludwigshafen, Germany, and in response to a letter dated June 20, 2002, from Dr. Charles Ganley, Director of the Over-The-Counter Drug (OTC) Division in the Center for Drug Evaluation and Review, we respectfully submit this Time and Extent Application ("TEA") pursuant to 21 C.F.R. Part 330. The TEA is intended to support the inclusion of octyl triazone ("Uvinul T 150") in the Over-The-Counter ("OTC") Sunscreen Drug Products Monograph, consistent with the terms of that Monograph. This

TEA is in addition to our citizen petition submitted November 15, 1996 (CP 7, Docket 78N-0038) requesting the inclusion of Uvinul T 150 in the Tentative Final Monograph for Sunscreen Products for Over-the-Counter Human Use. Based on BASF's prior submission of the citizen petition, BASF requests priority review of this TEA, as described in FDA's Final Rule for Additional Criteria and Procedures for Classifying OTC Drugs as Generally Recognized as Safe and Effective and Not Misbranded. 67 Fed. Reg. 3060 (Jan 23, 2002).

Physical and Chemical Characteristics of Octyl Triazone

Octyl Triazone is a safe and effective active ingredient UV-B sunscreen filter manufactured by BASF. It has significant formulation benefits for sunscreen product manufacture and will be a useful addition to the active ingredients available to the U.S. sunscreen market. Sunscreen formulators have previously suggested to FDA the need for a greater selection of active ingredients.[1] Review Fed. Reg. preamble to TEA rule. The chemical formula and structure of octyl triazone are provided at Attachment 1. The physical and chemical properties of octyl triazone are provided as part of the safety data sheet and Uvinul technical information at Attachments 2 and 3, respectively. As indicated in these materials, BASF proposes to limit use of octyl triazone in sunscreen products to 5% concentration by weight.

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[1] See, e.g., the minutes to the 10/28/1998 FDA Public Feedback Meeting regarding the sunscreen monograph and foreign marketing proposals (Docket 96N-0277, MM1)

Synthesis of Octyl Triazone

The synthesis, purification, and manufacturing specifications for octyl triazone are provided in Attachment 4, which provides a summary of the manufacturing process for Uvinul T 150. Because of the cosmetic status of octyl triazone throughout the world, validation of the manufacturing process has not been required. However, BASF is prepared to validate all manufacturing processes in conformance with applicable good manufacturing practices if FDA concludes octyl triazone is eligible for inclusion in the OTC sunscreen monograph. BASF also has a pending draft USP monograph for octyl triazone.

Octyl Triazone has an Extensive Marketing History

Octyl Triazone is, and has been, widely, safely, and effectively used in topical sunscreen formulations in thirty-five countries outside the United States. BASF has sold approximately 800,000 kg of octyl triazone since 1989. In at least five of these countries, including European countries and Australia, substantial quantities of octyl triazone have been marketed for five continuous years or more. BASF has marketed octyl triazone under the trade name Uvinul T 150, and previously under the trade name Lusantan T3, as a cosmetic sunscreen ingredient since at least 1989. The worldwide marketing data and supporting information for octyl triazone and the sunscreen products in which it has been incorporated are presented in Table 1. A copy of the label for the bulk octyl triazone is provided as Attachment 5.

Octyl Triazone is Regulated as a Cosmetic

Octyl triazone, as with other topical sunscreens, is regulated and marketed worldwide as a cosmetic. To BASF's knowledge, it has not been incorporated into any product sold only as a prescription or over-the-counter (OTC) drug, nor has it been incorporated into any product that has been withdrawn or denied OTC marketing approval. Under the regulatory frameworks of these countries, the labeling of specific sunscreen cosmetics containing octyl triazone are not specifically reviewed by each country's regulatory body, but rather, must generally conform with the regulations governing the labeling of cosmetics. The majority of the countries in which octyl triazone has been marketed utilize the regulatory framework set forth in the European Union (EU) Cosmetic Directive (Council Directive 76/768/EEC, July 27, 1996, O.J. No. L 262).

Furthermore, BDF Beiersdorf and L'Oreal, the manufacturers of the vast majority of products containing octyl triazone marketed worldwide, belong to COLIPA, the European Cosmetic, Toiletry and Perfumery Association which adheres to the labeling requirements of Council Directive 76/768/EEC. This Directive requires that the container and packaging bear the following information: (1) the name or style and the address or registered office of the manufacturer or the person responsible for marketing the cosmetic product who is established within the Community; (2) the nominal content at the time of packaging, given by weight or by volume, (except in certain cases); (3) the date of minimum durability; (4) particular precautions to be observed in use; (5) the batch number of manufacture or the

reference for identifying the goods; (6) the function of the product, unless it is clear from the presentation of the product; and (7) a list of ingredients in descending order of weight at the time they are added. Furthermore, the Directive was amended to permit the use of certain UV filters in cosmetic products. In 1989, Uvinul T 150 was added to this "Positive List" in Annex VII, Part 1 (11th Commission Directive, February 21, 1989, O.J. No. L 64/10) for use in concentrations up to 5% (See Attachment 6). The inclusion of Uvinul T 150 on the EU Positive List has allowed this substance to be marketed throughout the EU, as well as almost all of the Central and South American and Asian countries listed in Table 1, due to many of these countries' acceptance of EU-approved cosmetic ingredients and labeling guidelines. Sunscreens are similarly regulated as cosmetics in Japan and subject to general labeling requirements.

BASF Has no Evidence of Adverse Events for Octyl Triazone

The countries in which octyl triazone is marketed do not have adverse event reporting requirements or systems for recording adverse events for cosmetics and BASF has not independently received any reports of adverse events concerning products containing octyl triazone. Furthermore, BASF conducted a search of available scientific and medical databases, including among others, MEDLINE, TOXLINE, and TOXBIO, and could identify no adverse events concerning octyl triazone or a sunscreen product containing octyl triazone (see Attachment 7).

Product Labeling

As an active ingredient supplier, BASF has provided, to the best of its ability, examples of the labeling of consumer products containing octyl triazone as attachments to Table 1 (See Attachments 8 through 37). Full product labeling is provided for representative products sold in Germany, Japan, Mexico and the United Kingdom (See Attachments 17, 23, 25, and 37, respectively). As the vast majority of octyl triazone products marketed worldwide are manufactured by BDF Beiersdorf and are labeled according to EU regulations, BASF believes that the examples provided adequately represent the labeling of octyl triazone consumer products worldwide.

To the extent applicable for cosmetics, the attached labeling references the ingredients, intended use(s), dosage form(s), route(s) of administration, and directions for use for each product. In all cases, the product is indicated as a topical sunscreen or protectant against the harmful effects of the sun. The directions for use vary slightly among products, depending primarily upon how each product is formulated and marketed (i.e., as a sunscreen or anti-aging skin cosmetic with sunscreen component), and the degree of specificity of the directions (i.e., specifying that the product be applied a certain amount of time before sun exposure). A representative set of directions for use for a sunscreen product include, for example: apply at a minimum of 20 – 30 minutes before sun exposure; apply again after intensive swimming/wiping dry; use a higher SPF to receive longer protection; infants should not have direct sun contact; and avoid intensive midday sun.

Minimum Consumer Exposure

A measure of minimum consumer exposure is included in Table 1 for those countries in which bulk octyl triazone was sold. Minimum consumer exposure was calculated by dividing the cumulative total weight of bulk octyl triazone sold by the total weight of the octyl triazone in the largest package size marketed in each country. For these calculations, it was assumed that the density of the final consumer product was 1.0 (i.e., a 200mL package size contains 200g of sunscreen) and that octyl triazone comprises 5% of the total weight of the consumer product, the highest allowable concentration per package. The density of 1.0, the approximate value calculated for two Nivea Sun products, was chosen to be representative of all octyl triazone-containing sunscreen products marketed worldwide, as Nivea products comprise the majority of this group of products.

Sunscreen products containing octyl triazone have been marketed worldwide in package sizes ranging up to 400 mL. At a 5% concentration for this package size, and given the sale of approximately 700,000 kg of octyl triazone in the European Union and Australia, BASF estimates a minimum consumer exposure of 35,000,000 in these countries. This estimate of minimum consumer exposure is doubled to 70,000,000 if the calculation is performed for the more standard 200 mL product size. Furthermore, assuming a 20 mL application of sunscreen per consumer use, BASF estimates a minimum of 700,000,000 consumer applications of the active ingredient in these regions.

All of the above information demonstrates that octyl triazone has been safely and effectively marketed for a material time and material extent throughout the world through millions of consumer applications. Consequently, as a result of meeting all of the required criteria, BASF requests that octyl triazone be included for review in the OTC sunscreen monograph.

Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted on behalf of BASF AG,

Kathleen M. Sanzo

Kathleen M. Sanzo, Esq.
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Ave., NW
Washington, DC 20004

Attachments and Enclosures

Table 1: Time and Extent of Worldwide Marketing of Octyl Triazone

Country	Marketing Category	Cumulative Total Weight of Bulk Octyl Triazone Sold	Consumer Product Package Sizes	Minimum Consumer Exposure[1]	Population Demographics[2]	Changes or Variations in Use Patterns	Dates of Marketing of Bulk Product	Dates of Current Label Use[3] (Consumer Product)	Copy of Label of Consumer Product	Regulation of Labeling
[redacted]										
Australia	Cosmetic	10,000 kg	50 mL 100 mL	2,000,000	Caucasian 92%; Asian 7%; Aboriginal and other 1%	None	1989 to present H4R	1998 to present	Attachment 9	Labeling must conform with regulations, but individual labels are not reviewed or approved
[redacted]										

Country	Marketing Category	Cumulative Total Weight of Bulk Octyl Triazone Sold	Consumer Product Package Sizes	Minimum Consumer Exposure[1]	Population Demographics[2]	Changes or Variations in Use Patterns	Dates of Marketing of Bulk Product	Dates of Current Label Use[3] (Consumer Product)	Copy of Label of Consumer Product	Regulation of Labeling
[redacted]										

Country	Marketing Category	Cumulative Total Weight of Bulk Octyl Triazone Sold	Consumer Product Package Sizes	Minimum Consumer Exposure[1]	Population Demographics[2]	Changes or Variations in Use Patterns	Dates of Marketing of Bulk Product	Dates of Current Label Use[3] (Consumer Product)	Copy of Label of Consumer Product	Regulation of Labeling
										individual labels are not reviewed or approved
Germany	Cosmetic	250,000 kg	20 mL 50 mL 100 mL 125 mL 150 mL 200 mL 400 mL	12,500,000	German 91.5%; Turkish 2.4%; other (made up largely of Serbo-Croatian, Italian, Russian, Greek, Polish, Spanish) 6.1%	None	1989 to present 14 yr	1999 to present	Attachment 16	Labeling must conform with EU Cosmetic Directive regulations, but individual labels are not reviewed or approved
[redacted]										

Country	Marketing Category	Cumulative Total Weight of Bulk Octyl Triazone Sold	Consumer Product Package Sizes	Minimum Consumer Exposure[1]	Population Demographics[2]	Changes or Variations in Use Patterns	Dates of Marketing of Bulk Product	Dates of Current Label Use[3] (Consumer Product)	Copy of Label of Consumer Product	Regulation of Labeling
					coastal Malays 7.5%; other 26%					complete list of ingredients), but individual labels are not reviewed or approved
[redacted]										
Japan	Cosmetic	10,000 kg	8g 25 g 50 g 60 g 90 mL 140 mL 10 sheets	1,428,571	Japanese 99.4%; Korean 0.6% (1999)	None	1995 to present	1996 to present	Attachment 22	Labeling must conform with regulations (i.e., full list of ingredients), but individual labels are not reviewed or approved
[redacted]										
Mexico	Cosmetic	1,500 kg	50 mL 125 mL 200 mL	150,000	Mestizo (Amerindian-Spanish) 60%; Amerindian or predominantly Amerindian 30%;	None	1997 to present	1998 to present	Attachment 24	Labeling must conform with regulations, but individual labels are not reviewed

Country	Marketing Category	Cumulative Total Weight of Bulk Octyl Triazone Sold	Consumer Product Package Sizes	Minimum Consumer Exposure[1]	Population Demographics[2]	Changes or Variations in Use Patterns	Dates of Marketing of Bulk Product	Dates of Current Label Use[3] (Consumer Product)	Copy of Label of Consumer Product	Regulation of Labeling
					white 9%; other 1%					or approved
[redacted]										

Country	Marketing Category	Cumulative Total Weight of Bulk Octyl Triazone Sold	Consumer Product Package Sizes	Minimum Consumer Exposure[1]	Population Demographics[2]	Changes or Variations in Use Patterns	Dates of Marketing of Bulk Product	Dates of Current Label Use[3] (Consumer Product)	Copy of Label of Consumer Product	Regulation of Labeling
										are not reviewed or approved
[redacted]										

Country	Marketing Category	Cumulative Total Weight of Bulk Octyl Triazone Sold	Consumer Product Package Sizes	Minimum Consumer Exposure[1]	Population Demographics[2]	Changes or Variations in Use Patterns	Dates of Marketing of Bulk Product	Dates of Current Label Use[3] (Consumer Product)	Copy of Label of Consumer Product	Regulation of Labeling
			150 mL							or approved
[redacted]										
U.K.	Cosmetic	17,000 kg	50 mL 200 mL	1,700,000	English 81.5%; Scottish 9.6%; Irish 2.4%; Welsh 1.9%; Ulster 1.8%; West Indian, Indian, Pakistani, and other 2.8%	None	1995 to present	1999 to present	Attachment 36	Labeling must conform with EU Cosmetic Directive regulations, but individual labels are not reviewed or approved
[redacted]										

1 Minimum consumer exposure was calculated by dividing the cumulative total weight of bulk octyl triazone sold by the total weight of the octyl triazone in the largest package size marketed in each country. For these calculations, it was assumed that the density of each consumer sunscreen product is 1.0 (i.e., a 200mL package size contains 200g of sunscreen) and that octyl triazone comprises 5% of the total weight of the consumer product (i.e., 10g of a 200g sunscreen product) (5% is the highest concentration of active ingredient permitted by the relevant EU Directive for octyl triazone).

2 Data from The World Factbook 2001, online at http://www.cia.gov/cia/publications/factbook/index.html

3 In most countries, a number of consumer products containing octyl triazone are marketed. The earliest verifiable date at which a consumer product has been issued in each country was chosen as the date listed in this column. The manufacturer(s) of the consumer products have assured BASF that the consumer product labels have not changed since the products' issuance.

N/A = Not Available

ATTACHMENT 1

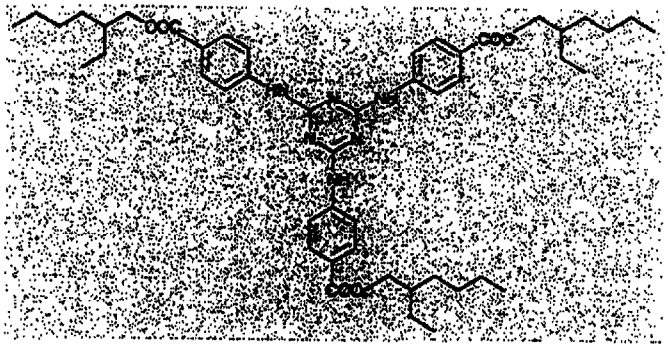
Data Sheet

March 2001
supersedes issue dated April 1999

Register 4

Uvinul® T 150

® = Registered trademark of BASF Aktiengesellschaft

Chemical name	2,4,6-Trianilino-p-(carbo-2'-ethylhexyl-1'-oxy)-1,3,5-triazine
INCI name	Ethylhexyl Triazone
CAS-No.	88122-99-0
Molecular formula and weight	$C_{48}H_{66}N_6O_5$ (823 g/mol)
Structural formula	
Appearance	White to light yellow powder
Solubility	Readily soluble in polar cosmetic oils.
Specification	

Parameter	Specification	Method No.
1. [illegible]	[illegible]	[illegible]
2. [illegible]	[illegible]	[illegible]
3. [illegible]	[illegible]	[illegible]
4. [illegible]	[illegible]	[illegible]
5. [illegible]	[illegible]	[illegible]

Stability	The minimum storage time for Uvinul T 150 is two years in the originally sealed containers.
Toxicology	Uvinul T 150 has been toxicologically assessed for its suitability in cosmetic preparations. On the basis of information at our disposal and provided that the recommended concentrations and fields of application are adhered to, there is no evidence of any toxicological risks associated with its use.
Safety Data Sheet	A Safety Data Sheet is available.

Note

The data submitted in this publication are based on our current knowledge and experience. They do not constitute a guarantee in the legal sense of the term and, in view of the manifold factors that may affect processing and application, do not relieve those to whom we supply our products from the responsibility of carrying out their own tests and experiments. Any relevant patent rights and existing legislation and regulations must be observed.

BASF Aktiengesellschaft
Fine Chemicals Division
67056 Ludwigshafen

BASF

ATTACHMENT 2

2

BASF Aktiengesellschaft

BASF

Safety data sheet

according to 91/155/EEC

BASF Safety data sheet ME 00099 (D/E)
Date / revised: 21.03.2000 version 8.06
Product: UVINUL* T 150

(Print date: 21.03.2000)

1. Substance/preparation and company name

UVINUL* T 150

Company:
BASF Aktiengesellschaft
Unternehmensbereich Feinchemie
D-67056 Ludwigshafen
Tel.: 0621-60-46077 Fax: 0621-60-92930

Emergency information:
BASF works fire brigade Ludwigshafen
Tel.: 0621-60-43333 Fax: 0621-60-92664

2. Composition/information on ingredients

Chemical nature

2,4,6-trianilino-p-(carbo-2-ethylhexyl-1-oxi)-1,3,5-triazine

CAS-No. 88122-99-0 ELINCS-no. 402-070-1

INCI-name: Ethylhexyl Triazone

3. Possible hazards

Advice on critical hazards to man and the environment:
May cause long-term adverse effects in the aquatic environment.

4. First aid measures

General advice: Remove contaminated clothing.

If inhaled: Keep patient calm, remove to fresh air.

On skin contact: Wash thoroughly with soap and water.

On contact with eyes: Wash affected eyes for at least 15 minutes under running water with eyelids held open.

On ingestion: Rinse mouth and then drink plenty of water.

5. Fire fighting measures

Suitable extinguishing media: Powder, water, foam.

Special protective equipment: In case of fire, wear a self contained breathing apparatus.

Further information: Dispose of fire debris and contaminated extinguishing water in accordance with local regulations.

6. Accidental release measures

Personal precautions: Avoid dust formation.

Environmental precautions: Do not let product enter drains.

Methods for cleaning up: Sweep up and then dispose of.

7. Handling and storage

Handling
Protection against fire and explosion: Avoid dust formation. Prevent electrostatic charge - sources of ignition should be kept well clear - fire extinguishers should be kept handy.

Technical protective measures: Breathing must be protected when large quantities are decanted without local exhaust ventilation: dust mask

Storage
Keep tightly closed in a dry and cool place.

8. Exposure controls and personal protection

Additional information on the lay-out of technical plant
(see 7)

Components with workplace control parameters
none

Personal protective equipment

Respiratory protection: If breathable dust is formed: Dust mask.

Hand protection: Rubber gloves.

Eye protection: Safety glasses with side-shields.

General safety and hygiene measures: The usual precautions for the handling of chemicals must be observed.

9. Physical and chemical properties

Form: powder
Colour: off-white - light yellow
Odour: faint specific odour

Change in physical state
Melting point/melting range: ca.129 'C

Flash point:		307 'C	(DIN-ISO 2592)
Explosion limits:			
- lower		1.2 Vol.%	
- upper		8.4 Vol.%	
Ignition temperature:		420 'C	
Vapour pressure:	(50 'C)	<5*10-6 mbar	
	(80 'C)	<6*10-6 mbar	
Density:	(25 'C)	1.10 g/cm3	
Solubility in water:		(25 'C)	0.007 mg/l

Solubility in other solvents: Soluble in many organic solvents.

Octanol/water partition coefficient (log POW): 8.1

Viscosity: (130 'C) < 1620 mm2/s

10. Stability and reactivity

Thermal decomposition: None provided product is correctly processed.

Hazardous reactions: dust explosion hazard

Hazardous decomposition products: None provided product is correctly processed.

11. Toxicological information

Acute toxicity

LD50/oral/rat: > 5 000 mg/kg
LD50/dermal/rat: > 2 000 mg/kg

Primary skin irritation/rabbit/OECD test: non-irritant
Primary mucous membrane irritation/rabbits' eyes/OECD test: non-irritant

Sensitization

Maximization test (40% in olive oil; guinea pig): no sensitizing effect

Other information

Ames-test: no mutagenic effect

12. Ecological information

Elimination information

Test method: OECD 301C/ ISO 9408/ EEC 84/449/V, C.7
Method of analysis: BOD of the ThOD
Degree of elimination: < 20%
Evaluation: not readily biodegradable

Behaviour and environmental fate

The product is virtually insoluble in water and can thus be separated from water mechanically in suitable effluent treatment plants.

Inhibition of degradation activity in activated sludge is not to be anticipated during correct introduction of low concentrations.

Ecotoxic effects

Toxicity to fish (acute):
Test method: OECD 203/ ISO 7346/ EEC 84/449/V, C.1
LC50/Brachydanio rerio/: > 1 000 mg/l/96h
No Observed Effect Concentration (NOEC): 1 000 mg/l

Toxicity to daphnids (acute): Daphnia magna:
Test method: in accordance with EC Directive 79/831
EC/LC0(24 h): 500 mg/l
EC/LC50 (24 h): > 500 mg/l
EC/LC100(24 h): > 500 mg/l
EC/LC0(48 h): 250 mg/l
EC/LC50 (48 h): > 500 mg/l
EC/LC100(48 h): > 500 mg/l

Toxicity to bacteria: Pseudomonas putida:
Test method: DIN 38412 Part 8
EC/LC10(16 h): > 10 000 mg/l
EC/LC50 (16 h): > 10 000 mg/l
EC/LC90(16 h): > 10 000 mg/l

Toxicity to bacteria: Pseudomonas putida:
Test method: DIN 38412 Part 27 (draft)
EC/LC10(0.5 h): > 10 000 mg/l
EC/LC50 (0.5 h): > 10 000 mg/l
EC/LC90(0.5 h): > 10 000 mg/l

Toxicity to algae: Scenedesmus subspicatus:
Test method: In accordance with EC Directive 79/831
EC/LC10(72 h): >=80 mg/l
EC/LC50 (72 h): >80 mg/l
EC/LC90(72 h): >80 mg/l

Further ecological information

COD-Value: 1 600 mg/g
Theoretical OD value: 2 394 mg/g

13. Disposal considerations

Product: Must be disposed of by special means, e.g. suitable incineration, in accordance with local regulations.

14. Transport information

Not classified as hazardous under transport regulations.

15. Regulatory information

Labelling according to EEC Directives

R53 - May cause long-term adverse effects in the aquatic environment.

S61 - Avoid release to the environment. Refer to special instructions/Safety data sheets.

National legislation/regulations

Water hazard class: 1 VwVwS (Germany) of 17.5.1999, Annex 3

16. Other information

A backslash in the left hand margin indicates an amendment from the previous version.

The information contained herein is based on the present state of our knowledge and does not therefore guarantee certain properties. Recipients of our product must take responsibility for observing existing laws and regulations.

ATTACHMENT 3

3

Technical Information

March 2002
Supersedes edition dated February 2002

UV Absorbes

Uvinul® grades and Z-COTE®

Uvinul T 150

S. 3 - 5 S. 27
7 - 9

Formulierungen
S. 19 - 20
22 - 25

® = Registered trademark of BASF Aktiengesellschaft

Fine Chemicals Division

BASF

Contents

Chemical nature

The Uvinul and Z-COTE products are UV filters and pigments based on benzophenones, diphenyl cyanoacrylate, cinnamates, octyltriazone, methylbenzylidene camphor, p-aminobenzoic acid derivates, dibenzoyl methane derivates, titanium dioxide or zinc oxide.

Range

	INCI name	CAS number
Uvinul MC 80	Ethylhexyl Methoxycinnamate	5466-77-3
Uvinul MC 80 N	Ethylhexyl Methoxycinnamate	5466-77-3
Uvinul T 150	Ethylhexyl Triazone	88122-99-0
Uvinul N 539 T	Octocrylene	6197-30-4
Uvinul MBC 95	4-Methylbenzylidene Camphor	36861-47-9
Uvinul M 40	Benzophenone-3	131-57-7
Uvinul MS 40	Benzophenone-4	4065-45-6
Uvinul P 25	PEG-25 PABA	113010-52-9
Uvinul D 50	Benzophenone-2	131-55-5
Uvinul DS 49	Benzophenone-9	3121-60-6
Uvinul BMBM	Butyl Methoxydibenzoyl-methane	70356-09-1
Z-COTE	Zinc Oxide	1314-13-2
Z-COTE HP 1	Zinc Oxide (and) Dimethicone	1314-13-2, 63148-62-9
Uvinul TiO2	Trimethoxycaprylylsilane (and) Titanium Dioxide	100209-12-9, 13463-67-7

Applications

The Uvinul filters are used in a large number of cosmetics to protect the skin or the hair, the product itself, particularly the colorant, the fragrance or the active ingredient against the harmful effects of UV radiation.

Some of the Uvinul grades are typical UV-B absorbers, i. e. their absorption maximum lies in the 280-320 nm band. Other Uvinul grades, particularly the benzophenone derivatives, are broad-band filters, i. e. they absorb both in the UV-A (320-400 nm) and the UV-B (280-320 nm) ranges. One filter absorbs in the UV-A range. The metal oxides are micronized pigments with a broad UV attenuation.

As both oil-soluble and water-soluble types are available, there are products for almost every cosmetic preparations, including emulsions, oils, gels, eau de toilettes, lipsticks, nail varnishes etc. This also applies for the pigments.

Use of the Uvinul and Z-COTE grades in skin protection

UV radiation is responsible for various physiological effects in the skin, as a result of its high energy content. These effects include sunburn, the premature appearance of wrinkles, i. e. accelerated ageing of the skin and, with frequent intensive exposure, an increased risk of skin cancer. UV filters and micro pigments provide vital protection for the skin against these harmful effects of UV radiation. They are now increasingly being used not only in sun preparations but also in other skin cosmetics such as day creams.

The use of UV filters and micro pigments to protect the skin is subject to legislation in many countries. Table 1 shows the approval status and the permitted concentration in the EU, USA and Japan. The concentrations of UV filters in sun preparations depend on the desired degree of protection, measured in terms of the sun protection factor (SPF). To achieve a high SPF in emulsion preparations, it is necessary to use UV filters both in the oil phase and the water phase. Commonly, organic UV filters are combined with micro pigments in products with a high SPF. They can also be used together with radical scavengers, e. g. sodium ascorbyl monophosphate, vitamin E or vitamin E acetate which provide additional passive sun protection.

For day creams, UV filters with low skin penetration are preferable. Uvinul T 150 meets this requirement.

Also the combination of Uvinul MC 80 with Z-COTE HP 1 is recommended.

Approval status

Table 1

	EU	USA	Japan
Uvinul MC 80 (both grades)	+ (10 %)	+ (7.5 %)	+ (10 %)
Uvinul T 150	+ (5 %)	-	+ (5 %)
Uvinul N 539 T	+ (10 %)	+ (10 %)	+ (10 %)
Uvinul MBC 95	+ (4 %)	-	-
Uvinul M 40	+ (10 %)	+ (6 %)	+ (5 %)
Uvinul MS 40	+ (5 %)	+ (10 %)	+ (10 %)
Uvinul P 25	+ (10 %)	-	-
Uvinul D 50	-	-	+ (10 %)
Uvinul DS 49	-	-	+ (10 %)
Uvinul BMBM	+ (5 %)	+ (3 %)	+ (10 %)
Z-COTE	+ (10 %)	+ (25 %)	+ (no limit)
Z-COTE HP1	+ (10 %)	+ (25 %)	+ (no limit)
Uvinul TiO2	+ (25 %)	+ (25 %)	+ (no limit)

+ = Approved as a sunscreen agent (with max. concentration)

- = Not approved

In the EU, cosmetics that contain more than 0.5 % Uvinul M 40 for skin protection must be labelled, „Contains oxybenzone".

Use of the Uvinul grades in Protecting sensitive products (product protection)

UV filters can be used in cosmetics to protect the colorants against fading, to improve the stability of fragrance oils and active constituents against oxidation and to stabilize the viscosity of gels and shampoos. It is always necessary to add a UV filter if the cosmetic product is exposed to UV radiation, as is the case when the packaging is transparent. The protection of products usually requires concentrations of 0.05 - 0.5 %, rather less than for skin protection. In these concentrations, the Uvinul grades are generally not subject to legislation (though such legislation as exists must be observed), i. e. all the Uvinul grades can, in principle, be used to protect products against UV radiation.

Particularly the broad-band UV filters, Uvinul D 50, M 40 and MS 40 have proved effective in protecting colorants against fading, though their efficiency depends on the colorant and on the medium in which it is used.

It is recommended that users conduct their own tests on their finished products.

Apart from the protection they offer against UV rays, the solubility of the individual Uvinul grades also determines their suitability for a particular product. Tables 2 and 3 show their solubility in solvents of different polarity. Further data can be found in the descriptions of the products.

Table 2

Solubility in % at 20 °C

	Ethanol	Propyleneglycol	Luvitol® EHO	Migiyol®1 812	IPM	Liquid paraffin
Uvinul M 40	approx. 6	approx. 1	approx. 7	approx. 15	approx. 12	approx. 1,5
Uvinul D 50	approx. 50	approx. 38	approx. 3	approx. 8	approx. 8	< 0.01

Table 3

Solubility in % at 20 °C

	Water	Ethanol	Propylene glycol
Uvinul MS 40 (neutralized with TEA)	approx. 34	approx. 2	approx. 15
Uvinul DS 49	approx. 5	< 0.01	approx. 1

Use of the Uvinul grades in protecting the hair

Both the ultraviolet and visible components of sunlight have tangible effects on the hair in that they bleach it and make it brittle. As has been demonstrated in studies, it is possible to provide protection against these effects with UV filters.

Broad-band filters such as the benzophenones are particularly suitable and can be used in hair-care products such as gels, setting lotions, normal and gloss hair sprays. But UV-B filters such as Uvinul MC 80 are also effective.

Specifications

The specifications are given on separate data sheets that are updated continuously.

Table 4 **Physicochemical properties of the Uvinul and Z-COTE grades**

	Molecular formula	Molecular weight	Appearance
Uvinul MC 80 (both grades)	$C_{18}H_{26}O_3$	290	Colourless to light yellow liquid
Uvinul T 150	$C_{46}H_{68}N_6O_6$	823	White to light yellow powder
Uvinul N 539 T	$C_{24}H_{27}NO_2$	361	Clear yellow viscous liquid
Uvinul MBC 95	$C_{18}H_{22}O$	254	White powder
Uvinul M 40	$C_{14}H_{12}O_3$	228	Light yellow powder
Uvinul MS 40	$C_{14}H_{12}O_6S$	308	Off white fine to coarse powder
Uvinul P 25	$C_{58}H_{111}NO_{27}$	approx. 1265	Light yellow wax that melts to a clear liquid at 30-40 °C
Uvinul D 50	$C_{13}H_{10}O_5$	248	Yellow powder
Uvinul DS 49	$C_{13}H_{12}O_{11}S_2Na_2$	478	Light yellow powder
Uvinul BMBM	$C_{20}H_{22}O_3$	310	Off white to light yellow powder
Z-COTE	ZnO	81	White powder
Z-COTE HP 1	ZnO	81 (for ZnO)	White powder
Uvinul TiO2	TiO_2	80 (for TiO_2)	White powder

[1] reg. Trademark of Chemische Werke Hüls AG

Table 5

Paraffin oil	Freely miscible
Jojoba oil	
Arachis oil	
Olive oil	
Witconol®[1] APM	
Isopropyl myristate	
Isopropyl palmitate	
Cetiol®[2] V	
Miglyol 812	
Finsolv®[3] TN	
Ethanol	
Isopropanol	
Water	Insoluble
Water/ethanol (to 1 : 7)	Insoluble
Water/isopropanol (to 1 : 7)	Insoluble

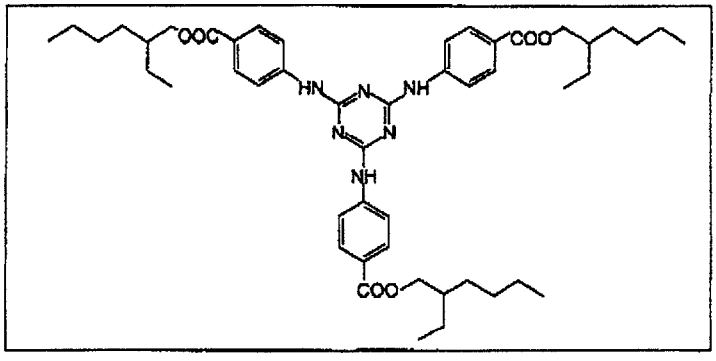
Uvinul MC 80 is also a good solvent for other ingredients of suncare products, e. g. Uvinul T 150 (see Table 6).

Thanks to a new manufacturing process, Uvinul MC 80 always gives a negative result in the Ames test.

The product is available in 2 different grades, giving the user a choice of stabilizer systems.

Uvinul T 150

Structural formula



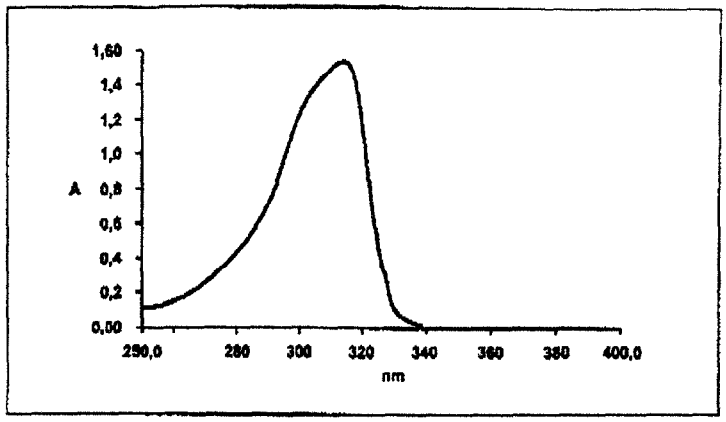
Chemical name 2,4,6-Trianilino-p-(carbo-2'-ethyl-hexyl-1'-oxi)-1,3,5-triazin

CAS number 88122-99-0

[1] reg. Trademark of Witco
[2] reg. Trademark of Cognis GmbH Deutschland
[3] reg. Trademark of Finetex

UV spectrum

Uvinul T 150 (10 mg/l in ethanol)



Properties and application

Uvinul T 150 is a highly effective UV-B filter with an exceptionally high absorptivity of over 1,500 at 314 nm. Because of its high A1/1 value, only small concentrations are required in cosmetic suncare preparations, to achieve a high SPF value. Concentrations up to 5 % are recommended.

The polar nature of Uvinul T 150 gives it good affinity to the keratin in the skin, so that formulations in which it is used are particularly water-resistant. This property is further enhanced by its complete insolubility in water.

As Table 6 shows, Uvinul 150 dissolves readily in polar oils such as Cetiol HE, Velsan[®1] D8P-3, the Cosmacol[®2] - and Myritol[®3] grades, and Witconol APM. Non-polar oils such as liquid paraffin are unsuitable.

Uvinul T 150 can crystallize out after prolonged storage, as a result of supersaturation.

Some of these oils are mentioned in patents, and these must be respected.

We are able to offer a free licence to 31 patents which cover the use of Uvinul T 150 in combination with many different oils and emulsifiers. This formulation know-how allows the use of Uvinul T 150 in concentrations up to 5 %. A table with all 31 patents is available on request.

Uvinul T 150 is also very stable towards light. It remains practically unchanged, even when it is exposed to intense radiation.

Uvinul T 150 is usually dissolved in the oily phase of the emulsion.

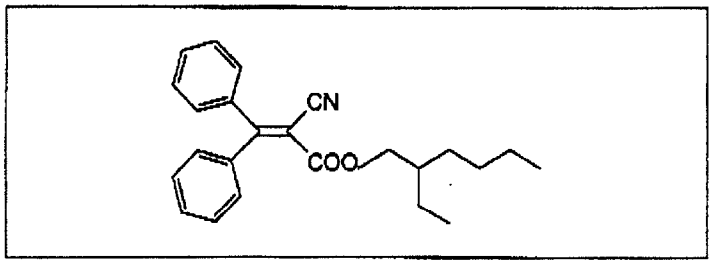
[1] reg. Trademark of Clariant GmbH
[2] reg. Trademark of Condea Augusta S.P.A.
[3] reg. Trademark of Cognis Deutschland GmbH

Table 6 **Solubility of Uvinul T 150 in different oils**

Ceraphyl®[1] 45	Dioctyl Malate	13 %
Cetiol A	Hexyl Laurate	8 %
Cetiol HE	PEG-7 Glyceryl Cocoate	15 %
Cosmacol ECI	Tri-C12-13 Alkyl Citrate	17 %
Cosmacol ELI	C12-13 Alkyl Lactate	22 %
Cosmacol EMI	Di-C12-13 Alkyl Malate	23 %
Cosmacol EOI	C 12-13 Alkyl Octanoate	24 %
Cosmacol ESI	Tridecyl Salicylate	10 %
Cosmacol ETI	Di-C12-13 Alkyl Tartrate	35 %
Cremophor® W07	PEG-7 Hydrogenated Castor Oil	10 %
Crodamol®[2] DOA	Dioctyl Adipate	9 %
Crodamol HE	PEG-7 Glyceryl Cocoate	12 %
Crodamol PMP	PPG-2 Myristyl Ether Propionate	8 %
DUB Synersol®[3]	Isodecyl Neopentanoate (and) Diisopropyl Sebacate (and) Lauryl Lactate	16 %
Estol®[4] 1526	Propylene Glycol Dicaprylate/ Dicaprate	10 %
Miglyol 840	Propylene Glycol Dicaprylate/ Caprate	13 %
Myritol 311	Cocoglycerides	8 %
Myritol 331	Cocoglycerides	10 %
Prisorine®[4] 2034	Propylene Glycol Monoisostearate	9 %
Uvinul MC 80	Ethylhexyl Methoxycinnamate	13 %
Velsan D8P-3	Isopropyl PPG-2 Isodeceth-7-Carboxylate	26 %
Witconol APM	PPG-3 Myristyl Ether	14 %

Uvinul N 539 T

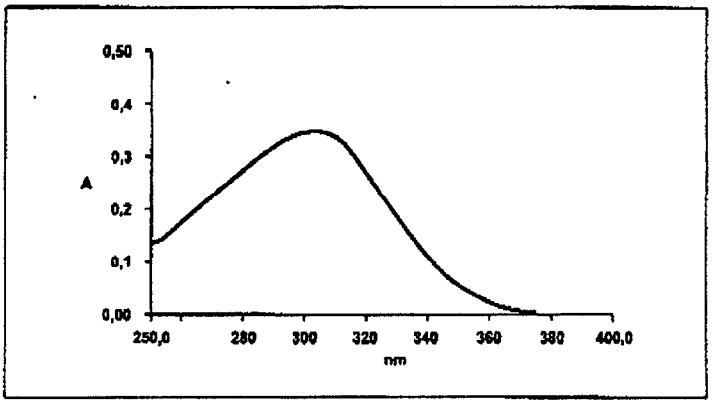
Structural formula



Chemical name 2-Cyano-3,3-diphenylacrylic acid 2'-ethylhexyl ester

CAS number 6197-30-4

UV-Spektrum **Uvinul N 539 T** (10 mg/l in ethanol)



[1] reg. Trademark of ISP
[2] reg. Trademark of Croda
[3] reg. Trademark of Stearinerie Dubois
[4] reg. Trademark of Uniqema

SUN CARE EMULSION

„SUNNY WORLD",
TYPE O/W **53/00210**

	%	Ingredient	Supplier	INCI
A	5.00	Paraffin Oil		Mineral Oil
	6.00	Uvinul MC 80	(1)	Ethylhexyl Methoxycinnamate
	2.50	Uvinul MBC 95	(1)	Methylbenzylidene Camphor
	2.00	Uvinul BMBM	(1)	Butyl methbxydibenzoylmethane
	1.00	Uvinul T 150	(1)	Ethylhexyl Triazone
	5.00	Witconol APM	(47)	PPG-3 Myristyl Ether
	0.10	Oxynex®[1] 2004	(20)	BHT, Ascorbyl Palmitate, Citric Acid, Glyceryl Stearate, Propylene Glycol
	2.00	Lanette®[2] 16	(27)	Cetyl Alcohol
	0.50	Abil 350	(44)	Dimethicone
B	5.00	1,2 Propylene Glycol USP	(1)	Propylene Glycol
	2.00	Amphisol®[3] K	(29)	Potassium Cetyl Phosphate
	0.10	Edeta BD	(1)	Disodium EDTA
	q.s.	Preservative		
	68.80	Water dem.		Aqua dem.
C	q.s.	Luviqel® EM	(1)	Caprylic/Capric Triglyceride, Acrylates Copolymer
D	q.s.	Perfume		

Production

Heat phases A and B separately to about 80 °C.
Stir phase C into phase A.
Stir phase B into phase A whilst homogenizing and continue homogenizing for a while.
Cool to about 40 °C whilst stirring, add phase D and homogenize again.

Properties

Viscosity	10000 mPa·s	Brookfield RVD VII+
pH value	6.0	

[1] reg. Trademark of Merck KGaA
[2] reg. Trademark of Cognis Deutschland GmbH
[3] reg. Trademark of Hoffmann-La Roche

SUN PROTECTION CREAM GEL **53/00234**

	%	Ingredient	Supplier	INCI
A	8.00	Uvinul MC 80	(1)	Ethylhexyl Methoxycinnamate
	5.00	Uvinul N 539 T	(1)	Octocrylene
	100	Uvinul T 150	(1)	Ethylhexyl Triazone
	3.00	Uvinul MBC 95	(1)	Methylbenzylidene Camphor
	2.00	Vitamin E Acetate	(1)	Tocopheryl Acetate
	1.00	Cremophor® CO 40	(1)	PEG-40 Hydrogenated Castor Oil
	q.s	Perfume		
B	0.20	Carbopol®1 980	(6)	Carbomer
	0.30	Pemulen®1 TR-1	(6)	Acrylates/C10-30 Alkyl Acrylate Crosspolymer
	50.00	Water dem.		Aqua dem.
C	0.67	Triethanolamine Pure C	(1)	Triethanolamine
D	5.00	Glycerin 87 %	(20)	Glycerin
	0.10	Edeta BD	(1)	Disodium EDTA
	0.50	D-Panthenol USP	(1)	Panthenol
	q.s.	Preservative		
	23.23	Water dem.		Aqua dem.

Production

Weigh out and dissolve the components of the phases A and D separately.
Allow phase B to swell and neutralize it with phase C.
Stir the phases A and D one after the other into the neutralized phase B and homogenize.

Properties

Viscosity	10000 mPa·s	Brookfield RVD VII+
pH value	6.6	

[1] reg. Trademark of B. F. Goodrich Company Chemical Division

SUN PROTECTION LOTION **53/00232**

	%	Ingredient	Supplier	INCI
A	6.00	Uvinul M 80	(1)	Ethylhexyl Methoxycinnamate
	2.50	Uvinul MBC 95	(1)	Methylbenzylidene Camphor
	1.00	Uvinul T 150	(1)	Ethylhexyl Triazone
	2.00	Uvinul BMBM	(1)	Butyl Methoxydibenzoylmethane
	2.00	Antaron®[1] V 216	(65)	PVP/Hexadecene Copolymer
	5.00	Witconol APM	(47)	PPG-3 Myristyl Ether
	0.50	Abil 350	(44)	Dimethicone
	0.10	Oxynex 2004	(20)	BHT, Ascorbyl Palmitate, Citric Acid, Glyceryl Steerate, Propylene Glycol
	2.00	Cetyl Alcohol	(27)	Cetyl Alcohol
	2.00	Amphisol K	(29)	Potassium Cetyl Phosphate
B	5.00	1,2 Propylene Glycol USP	(1)	Propylene Glycol
	0.20	Edeta BD	(1)	Disodium EDTA
	65.82	Water dem.		
	q.s.	Preservative		
C	0.20	Carbopol 934	(6)	Carbomer
	5.00	Paraffin Oil		Mineral Oil
D	0.08	Sodium Hydroxide	(20)	Sodium Hydroxide
E	0.20	Sodium Ascorbyl Phosphate	(1)	Sodium Ascorbyl Phosphate
	0.40	Vitamin E Acetate	(1)	Tocopheryl Acetate
	q.s.	Perfume		

Production

Heat phases A and B separately to about 80 °C.
Stir phase B into phase A whilst homogenizing and continue homogenizing for a while.
Mix phase C, stir it into phase A+B, neutralize with phase D and homogenize again.
Cool to about 40 °C, add phase E and homogenize again.

Properties

Viscosity	4200 mPa·s	Brookfield RVD VII+
pH value	5.5	

[1] reg. Trademark of ISP

SUN PROTECTION GEL **53/00246**

	%	Ingredient	Supplier	INCI
A	0.80	Uvinul T 150	(1)	Ethylhexyl Triazone
	5.00	Uvinul N 539 T	(1)	Octocrylene
	8.00	Uvinul MC 80	(1)	Ethylhexyl Methoxycinnamate
	0.80	Uvinul BMBM	(1)	Butyl Methoxydibenzoylmethane
	2.00	Vitamin E Acetate	(1)	Tocopheryl Acetate
	1.00	Cremophor CO 410	(1)	PEG-40 Hydrogenated Castor Oil
	0.20	Phytantriol	(1)	Phytantriol
	0.20	Bisabolol rac.	(1)	Bisabolol
	q.s.	Perfume		
B	0.30	Pemulen TR-1	(6)	Acrylates/C10-30 Alkyl Acrylate Crosspolymer
	0.20	Carbopol 940	(6)	Carbomer
	50.00	Water dem.		Aqua dem.
C	0.60	Triethanolamine Pure C	(1)	Triethanolamine
D	2.00	D-Panthenol USP	(1)	Panthenol
	0.10	Edeta BD	(1)	Disodium EDTA
	5.00	Glycerin 87 %	(20)	Glycerin
	q.s.	Preservative		
	23.80	Water dem.		Aqua dem.

Production

Weigh out and dissolve the components of the phases A and D separately.
Allow phase B to swell and neutralize it with phase C.
Stir the phases A and D one after the other into the neutralized phase B and homogenize.

Properties

Viscosity	14200 mPa·s	Brookfield RVD VII+
pH value	6.7	

SUN PROTECTION GEL **53/00255**

	%	Ingredient	Supplier	INCI
A	10.00	Uvinul MC 80	(1)	Ethylhexyl Methoxycinnamate
	2.00	Uvinul M 40	(1)	Benzophenone-3
	1.00	Vitamin E Acetate	(1)	Tocopheryl Acetate
	0.50	Cremophor CO 40	(1)	PEG-40 Hydrogenated Castor Oil
	q.s.	Perfume		
	2.20	Luviget EM	(1)	Caprylic/Capric Triglyceride, Acrylates Copolymer
B	6.00	1,2 Propylene Glycol USP	(1)	Propylene Glycol
	q.s.	Preservative		
	78.30	Water dem.		Aqua dem.

Production

Dissolve phase A .
Stir phase B slowly into phase A.
Homogenize for a short time.

Properties

Viscosity	45000 mPa·s	Brookfield RVD VII+
pH value	6.0	

SUN PROTECTION LOTION

„BE A SUNCARE FAN" **53/00195**

	%	Ingredient	Supplier	INCI
A	6.00	Uvinul MC 80	(1)	Ethylhexyl Methoxycinnamate
	2.50	Uvinul MBC 95	(1)	Methylbenzylidene Camphor
	1.00	Uvinul T 150	(1)	Ethylhexyl Triazone
	2.00	Uvinul BMBM	(1)	Butyl Methoxydibenzoylmethane
	2.00	Antaron V 216	(65)	PVP/Hexadecene Copolymer
	5.00	Witconol APM	(47)	PPG-3 Myristyl Ether
	0.50	Abil 350	(44)	Dimethicone
	0.10	Oxynex 2004	(20)	BHT, Ascorbyl Palmitate, Citric Acid, Glyceryl Stearate, Propylene Glycol
	2.00	Cetyl Alcohol	(27)	Cetyl Alcohol
	2.00	Amphisol K	(29)	Potassium Cetyl Phosphate
B	5.00	1,2 Propylene Glycol USP	(1)	Propylene Glycol
	0.20	Edeta BD	(1)	Disodium EDTA
	q.s.	Preservative		
	66.42	Water dem.		Aqua dem.
C	5.00	Paraffin Oil		Mineral Oil
	0.20	Carbopol 934	(6)	Carbomer
D	0.08	Sodium Hydroxide	(20)	Sodium Hydroxide
E	q.s.	Perfume		

Production

Heat phases A and B separately to about 80 °C.
Stir phase B into phase A whilst homogenizing and continue homogenizing for a while.
Mix phase C, stir it into phase A+B, neutralize with phase D and homogenize again.
Cool to about 40 °C, add phase E and homogenize again.

Properties

Viscosity	3400 mPa·s	Haake Viscotester VT-02
pH value	6.5	
Sun Protection Factor	30	Colipa Task Force „Sun Protection Measurement"

SUN PROTECTION LOTION **53/00248**

	%	Ingredient	Supplier	INCI
A	2.00	Uvinul T 150	(1)	Ethylhexyl Triazone
	3.00	Uvinul M 40	(1)	Benzophenone-3
	7.00	Uvinul MC 80	(1)	Ethylhexyl Methoxycinnamate
	13.00	Witconol APM	(47)	PPG-3 Myristyl Ether
	2.00	Vitamin E Acetate	(1)	Tocopheryl Acetate
	0.50	Cremophor CO 60	(1)	PEG-60 Hydrogenated Castor Oil
	0.20	Bisabolol rac.	(1)	Bisabolol
	0.10	Phytantriol	(1)	Phytantriol
	q.s.	Perfume		
B	0.50	Carbopol 940	(6)	Carbomer
	0.30	Pemulen TR-1	(6)	Acrylates/C10-30 Alkyl Acrylate Crosspolymer
	50.00	Water dem.		Aqua dem.
C	0.70	Triethanolamine Pure C	(1)	Triethanolamine
D	1.00	Triethanolamine Pure C	(1)	Triethanolamine
	5300	Glycerin 87 %	(20)	Glycerin
	2.00	D-Panthenol USP	(1)	Panthenol
	0.03	Edeta BD	(1)	Disodium EDTA
	2.00	Uvinul MS 40	(1)	Benzophenone-4
	q.s.	Preservative		
	12.67	Water dem.		Aqua dem.

Production

Weigh out and dissolve the components of the phases A and D separately.
Allow phase B to swell and neutralize it with phase C.
Stir the phases A and D one after the other into the neutralized phase B and homogenize.

Properties

Viscosity	13300 mPa·s	Brookfield RVD VII+
pH value	5.9	

SUN PROTECTION SPRAY **53/00237**

	%	Ingredient	Supplier	INCI
A	8.00	Uvinul MC 80	(1)	Ethylhexyl Methoxycinnamate
	4.00	Uvinul MBC 95	(1)	Methylbenzylidene Camphor
	2.00	Uvinul BMBM	(1)	Butyl Methoxydibenzoylmethane
	5.00	Uvinul N 539 T	(1)	Octocrylene
	0.50	Abil 350	(44)	Dimethicone
	5.00	Finsolv TN	(52)	C12-15 Alkyl Benzoate
	2.00	Vitamin E Acetate	(1)	Tocopheryl Acetate
	1.00	Arlacel®1 1689 V	(30)	Sorbitan Oleate, Polyglyceryl-3 Ricinoleate
	q.s.	Perfume		
B	0.20	Pemulen TR-1	(6)	Acrylates/C10-30 Alkyl Acrylate Crosspolymer
	50.00	Water dem.		Aqua dem.
C	0.08	Sodium Hydroxide	(20)	Sodium Hydroxide
D	4.00	D-Panthenol 50 P	(1)	Panthenol, Propylene Glycol
	0.20	Edeta BD	(1)	Disodium EDTA
	3.00	Glycerin 87 %	(20)	Glycerin
	0.20	Allantoin	(28)	Allantoin
	q.s.	Preservative		
	14.82	Water dem.		Aqua dem.

Production

Weigh out and dissolve the components of the phases A and D separately.
Allow phase B to swell and neutralize it with phase C.
Stir the phases A and D one after the other into the neutralized phase B and homogenize.

Properties

Viscosity	2500 mPa·s	Brookfield RVD VII+
pH value	6.7	

[1] reg. Trademark of ICI Specialty Chemicals Atlas Chemie

44. Goldschmidt AG
Goldschmidtstr. 100, 45127 Essen, Germany
or Postfach 10 14 61, 45116 Essen, Germany
Tel.: +49 (201) 173-01
Fax: +49 (201) 173-3000

47. Witco Corporation
1 American Lane, CT 06831-2559, Greenwich, USA
Tel.: +1 (203) 552-3373
Fax: +1 (203) 552-2893

German subsidiary:
Witco Surfactants GmbH
Industriegebiet West, Postfach 11 60,
36392 Steinau an der Straße
Tel.: +49 (6663) 540
Fax: +49 (6663) 54129

62. Distribution for Finsolv-grades:
C.H. Erbslon KG
Düsseldorfer Straße 103; 47809 Krefeld
Tel.: +49 (2151) 525-00
Fax: +49 (2151) 525-200

65. ISP Internat. Specialty Products
1361 Alps Road, 07470 Wayne, NJ, USA
Tel.: +1 (973) 628-3000
Fax: +1 (973) 628-4117

German subsidiary:
ISP Global Technologies Deutschland GmbH
Emil-Hoffmann-Str. 1 a, 50006 Köln
Tel.: +49 (2236) 9649-0
Fax: +49 (2236) 9649-211

73. Tromm GmbH, Wachs- und Ceresin-Fabriken
Feuerstraße 7 - 17; 50735 Köln
Tel.: +49 (221) 974552-0
Fax: +49 (221) 974552-30

Stability

The minimum storage times for the different Uvinul grades in the original sealed containers are as follows:

1 year	2 years	3 years
MC 80 N	MC 80	M 40
	T 150	D 50
	TiO2	
	Z-COTE	
	Z-COTE HP 1	
	N 539 T	
	MBC 95	
	MS 40	
	P 25	
	DS 49	
	BMBM	

Toxicology

The Uvinul range of UV absorbers and micro pigments have been toxicologically assessed for their suitability in cosmetic preparations. On the basis of information at our disposal and provided that the recommended concentrations and fields of application are adhered to, there is no evidence of any toxicological risk associated with their use.

Safety Data Sheets

Safety Data Sheets are available on request.

Note

The data submitted in this publication are based on our current knowledge and experience. They do not constitute a guarantee in the legal sense of the term and, in view of the manifold factors that may affect processing and application of our products, do not relieve processors from the responsibility of carrying out their own tests and experiments. Any relevant patent rights and existing legislation and regulations must be observed.

ATTACHMENT 4

26 pages redacted for confidential, commercial reasons

ATTACHMENT 5

BASF

Uvinul® T 150

INCI: Ethylhexyl Triazone

Caution: For manufacturing, processing or repacking

402-070-1

Art.: 57811988

Lot: 1234567890

R: 53 S: 61

BASF Aktiengesellschaft
67056 Ludwigshafen Germany
Tel. +49-(0)621-60-43333

60 kg net

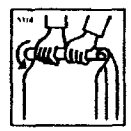
® = Reg. Trademark BASF

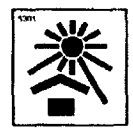
(D) **Kann in Gewässern längerfristig schädliche Wirkungen haben.**
Freisetzung in die Umwelt vermeiden. Besondere Anweisungen einholen/Sicherheitsdatenblatt zu Rate ziehen.
(CH) BAG T-Nr.: 620000 Gift-Kl. frei
(GB) **May cause long-term adverse effects in the aquatic environment.**
Avoid release to the environment. Refer to special instructions/Safety data sheets.
(F) **Peut entraîner des effets néfastes à long terme pour l'environnement aquatique.**
Éviter le rejet dans l'environnement. Consulter les instructions spéciales/la fiche de données de sécurité.
(NL) **Kan in het aquatisch milieu op lange termijn schadelijke effecten veroorzaken.**
Voorkom lozing in het milieu. Vraag om speciale instructies/veiligheidskaart.
(E) **Puede provocar a largo plazo efectos negativos en el medio ambiente acuático.**
Evítese su liberación al medio ambiente. Recábense instrucciones específicas de la ficha de datos de seguridad.
(P) **Pode causar efeitos nefastos a longo prazo no ambiente aquático.**
Evitar a libertação para o ambiente. Obter instruções específicas/fichas de segurança.
(I) **Può provocare a lungo termine effetti negativi per l'ambiente acquatico.**
Non disperdere nell'ambiente. Riferirsi alle istruzioni speciali/schede informative in materia di sicurezza.
(GR) **Μπορεί να προκαλέσει μακροχρόνιες δυσμενείς επιπτώσεις στο υδάτινο περιβάλλον.**
Αποφύγετε την ελευθέρωσή του στο περιβάλλον. Αναφερθείτε σε ειδικές οδηγίες/δελτίο δεδομένου ασφαλείας.

7051

(DK) **Kan forårsage uønskede langtidsvirkninger i vandmiljøet.**
Undgå udledning til miljøet. Se særlig vejledning/sikkerhedsdatablad.
(N) **Kan forårsake uønskede langtidsvirkninger i vannmiljøet.**
Unngå utslipp i miljøet. Se produktdatablad for ytterligere informasjon.
(S) **Kan orsaka skadliga långtidseffekter i vattenmiljön.**
Undvik utsläpp i miljön. Läs särskilda instruktioner/skyddsinformationsblad.
(FIN) **Voi aiheuttaa pitkäaikaisia haittavaikutuksia vesiympäristössä.**
Vältettävä päästämistä ympäristöön. Lue erityisohjeet/käyttöturvallisuustiedote.

(D) Für kosmetische und technische Zwecke.
(GB) For cosmetic and technical purposes
(F) Pour usages cosmétiques et techniques.
(NL) Voor cosmetische en technische doeleinden.
(E) Para uso cosmético y técnico.
(P) Para fins cosméticos e técnicos.
(I) Per scopi cosmetici e tecnici.
(GR) Για σκοπούς της κοσμητικής και τεχνικής
(DK) Til kosmetiske og tekniske formål.
(N) Til kosmetiske og tekniske formål.
(S) För kosmetiska och tekniska ändamål.
(FIN) Kosmeettisiin ja teknisiin tarkoituksiin.





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ATTACHMENT 6

The rules governing cosmetic products
in the European Union

Volume 1

Cosmetics legislation

Cosmetic products

1999 Edition

EUROPEAN COMMISSION
Enterprise Directorate-General
Pharmaceuticals and cosmetics

THE RULES GOVERNING COSMETIC PRODUCTS IN THE EUROPEAN UNION

Volume 1 Cosmetics legislation
Cosmetic products

Volume 2 Methods of analysis
Cosmetic products

Volume 3 Guidelines
Cosmetic products

FOREWORD

In the early 1970's, the Member States of the EU decided to harmonise their national cosmetic regulations in order to enable the free circulation of cosmetic products within the Community. As a result of numerous discussions between experts from all Member States, Council Directive 76/768/EEC was adopted on 27 July 1976. The principles laid down in the Cosmetics Directive take into account the needs of the consumer while encouraging commercial exchange and eliminating barriers to trade. For example, if a product is to move freely within the EU, the same labelling, packaging and safety regulations must apply. This is one of the main objectives of the Cosmetics Directive: to give clear guidance on what requirements a safe cosmetic product should fulfil in order to freely circulate within the EU, without pre-market authorisation. The Cosmetics Directive aims to guarantee the safety of cosmetic products for human use. This safety relates to composition, packaging and information and it falls totally under the responsibility of the producer or the importer into the EU who is responsible for the marketing liability. There is no pre-market control for cosmetic products at Member State or EU level. Control of cosmetic products within the EU is assured through the responsibility of the person who places the product on the market, a simple notification of manufacturing/importing site, and an in-market surveillance system.

Volume 1 is the first part of a series of volumes entitled "The Rules governing cosmetic products in the European Union", published by the Office for Official Publications of the European Communities and listed on the preceding page. Volume 1 includes the legislation applicable to cosmetic products. This legislation consists of the basic Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, and Commission Directive 95/17/EC laying down detailed rules for the application of Council Directve 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products. This legislative framework has been completed by an Inventory and Common Nomenclature of Ingredients employed in cosmetic products established in Commission Decision 96/335/EC of 8 May 1996 which is not incorporated in this Volume.

Council Directive 76/768/EEC has already undergone six amendments and 23 adaptations to technical progress. With a view to facilitating consultation, it is set out here in codified form for internal use by the competent Commission departments. This codified text is available to the public but has no force in law. Where doubts exist, the original texts as published in the Official Journal of the European Communities, should be consulted.

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LIST OF OFFICIAL TEXTS OF DIRECTIVE 76/768/EEC INCLUDING ALL TECHNICAL ADAPTATIONS AND AMENDMENTS

Existing EEC directive	Reference number	Date of signature	EC Publication O.J.		CONTENT (main items)
			Number	Date	
Basic Council Directive	76/768/EEC	27.07.1976	L 262	27.09.1976	Articles 1 to 15 Ann. I: Illustrative list by category of cosmetic products Ann. II: List of forbidden substances Ann. III: List of restricted substances Positive List (PL) for cosmetic colouring agents permitted for all uses Ann. IV: List of restricted substances provisionally allowed List of cosmetic colouring agents provisionally allowed Ann. V: List of substances regulated at national level by EC Member States
1st amendment Council Directive	79/661/EEC	24.07.1979	L 192	31.07.1979	Ann. IV: Provisional authorisations prolonged
1st adapting Commission Directive	82/147/EEC	11.02.1982	L 63	06.03.1982	Ann. II: Ban AETT (362)
2nd amendment Council Directive	82/368/EEC	17.05.1982	L 167	15.06.1982	Articles: — provisional authorisations Ann. IV prolonged — new procedure to adapt Annexes (Art. 8.2) — introduction procedure of Prior National Approval limited to 3 years (Art. 8.a) — Unavoidable traces of banned materials permitted (Art. 4.2) Ann. III: new version Part 1 Ann. III + IV: new version of PL for cosmetic colouring agents Ann. VI: introduction of PL for preservatives
2nd adapting Commission Directive	83/191/EEC	30.03.1983	L 109	26.04.1983	Ann. II, III, IV, V: — Ba/Sr/Zr lakes — Al/Zr complexes, silver nitrate
3rd adapting Commission Directive	83/341/EEC	29.06.83	L 188	13.07.1983	Ann. II, III, V: Hair Dyes - ban OPD + salts 2,4 DAT + salts; permanent listing PPD + salts
4th adapting Commission Directive	83/496/EEC	22.09.1983	L 275	08.10.1983	Ann. VI: addition 36, 45
3rd amendment Council Directive	83/574/EEC	26.10.1983	L 332	28.11.1983	Articles: new definition of the date of minimum durability, period reduced to 30 months Introduction Ann. VII : PL for UV-Filters
5th adapting Commission Directive	84/415/EEC	18.07.1984	L 228	25.08.1984	Ann. II: ban aristolochic acid Ann. III: hydrogen peroxide, hydroquinone, nicomethanol hydrofluoride, silver nitrate

■ List of official texts of Directive 76/768/EEC and its official amendments

Existing EEC directive	Reference number	Date of signature	EC Publication O.J. Number	EC Publication O.J. Date	CONTENT (main items)
6th adapting Commission Directive	85/391/EEC	16.07.1985	L 224	22.08.1985	Ann. II: ban specific hydroquinone ethers Ann. III: selenium disulfide; Al/Zr complexes Ann. VI: labelling formaldehyde
7th adapting Commission Directive	86/179/EEC	28.02.1986	L 138	24.05.1986	Ann. II: ban chloroform, TCDD, dimethoxane, sodium pyrithione Ann. III : DMET, 8-hydroxyquinoline Ann. III+IV: new version of PL for cosmetic colouring agents
8th adapting Commission Directive	86/199/EEC	26.03.1986	L 149	03.06.1986	Ann. IV : introduction of other uses 43 Ann. VI : new version of PL for preservatives
9th adapting Commission Directive	87/137/EEC	02.02.1987	L 56	26.02.1987	Ann. II: ban Captan (370), Hexachlorophene (371), Minoxidil (372) Ann. III : Methanol, 77288 - 77289 Ann. VI: — permanent: 40 — deleted: 9, 12, 13
10th adapting Commission Directive	88/233/EEC	02.03.1988	L 105	26.04.1988	Ann. II: ban tribromsalan, retinoic acid, phytolacca, 2,4-DAA, 2,5-DAA, 12140, 26105, 42555 Ann. III/1: etidronic acid, phenoxypropanol Ann. III/2: delete 13065, add Acid Red 195 Ann. IV/2: delete 12700, 44025, 73312 Ann. VI: — permanent: 41, 42, 43 — deleted: 7, 8, 10, 11, 14, 18, 22, 23, 24
4th amendment Council Directive	88/667/EEC	21.12.1988	L 382	31.12.1988	Articles: — Hair dyes excluded from cosmetic colouring agents list — labelling container + packaging — elimination 6 week deadline in Safeguard Clause (Art. 12) Ann. III becomes only restrictive list Ann. IV becomes only cosmetic colouring agents PL
11th adapting Commission Directive	89/174/EEC	21.02.1989	L 64	08.03.1989	Ann. II: ban Padimate A, benzoyl peroxide, 2A-4NP, 2A-5NP Ann. III/2: add 8-OH-quinoline Ann. IV/2: delete 15800, 19120, 20470, 21115, 42170, 45190, 47000, 73905, 75660 Ann. V: delete oestrogens Ann. VI: — 39 reduce concentration — add 48 (prov.) Ann. VII: new version Part 2
5th amendment Council Directive	89/679/EEC	21.12.1989	L 398	30.12.1989	Articles: — CATP procedure prolonged indefinitely
12th adapting Commission Directive	90/121/EEC	20.02.1990	L 71	17.03.1990	Ann. II: ban steroid antiandrogens, zirconium compounds, thyrothricine, acetonitrile, tetrahydrozoline, 13065, 42535, 42640, 61554, Ann. III: lead acetate Ann. IV: — delete 21110, 42045, 44045 — add Solvent Yellow 98 (prov.) Ann. V: transfers to other Annexes

Existing EEC directive	Reference number	Date of signature	EC Publication O.J. Number	EC Publication O.J. Date	CONTENT (main items)
13th adapting Commission Directive	91/184/EEC	12.03.1991	L 91	12.04.1991	Ann. II: ban 8-OH-quinoline, pyrithione diS, lidocaine, 12075, 45170 Ann. III: add Mg fluoride Ann. IV: 15585 move to Part 2 Ann. V: transfers to other Annexes Ann. VI: add 27 (prov.) Ann. VII: add 7
14th adapting Commission Directive	92/8/EEC	18.02.1992	L 70	17.03.1992	Prolongation of all provisionally listed substances until 30.06.1992
15th adapting Commission Directive	92/86/EEC	21.10.1992	L 325	11.11.1992	Ann. II: — ban 15585, Sr lactate, Sr nitrate, Sr polycarboxylate, Pramocaine, 4-Ethoxy-MPD, 2,4-Diaminophenyl-ethanol, catechol, pyrogallol, nitrosamines, secondary dialkanolamines Ann. III: — add Sr chloride, Sr acetate, talc, nitrosamines precursors — H_2O_2 add oral hygiene Ann. III Part 2 + Ann. IV Part 2: nothing listed anymore Ann. VI — 36 sunscreen use with limit — add 51 , 29 (prov.) Ann. VII: — delete 1, 4, 16
6th amendment Council Directive	93/35/EEC	14.06.1993	L 151	23.06.1993	Articles: — definition modified — overall safety clause modified — ban animal testing foreseen — inventory cosmetic ingredients — off-pack labelling in some cases — labelling of product function — ingredient labelling — claims concerning animal testing — requirements to Poison Centres modified — Product Information required — Notification manufacturing premises — All Annexes via CATP procedure — new Annex VIII
16th adapting Commission Directive	93/47/EEC	22.06.1993	L 203	13.08.1993	Ann. II: — ban 4 A-2NP Ann. III: — warning: gloves for hair dyes + H_2O_2 — add (Part 2) Sr peroxide, phenolphthalein Ann. VII: — move 33 to prov.
17th adapting Commission Directive	94/32/EC	29.06.1994	L 181	15.07.1994	Ann. II: — ban 2-Methyl-MPD Ann. III: — talc lab. baby prod. modified — add SrO_2, $Sr(OH)_2$ Ann. VI: — add formic acid and its sodium salt — 21 reduction conc. + RO only — delete 26, 27, 28 Ann.VII: — add 11 (prov.) — delete 24

■ List of official texts of Directive 76/768/EEC and its official amendments

Existing EEC directive	Reference number	Date of signature	EC Publication O.J.		CONTENT (main items)
			Number	Date	
18th adapting Commission Directive	95/34/EC	10.07.1995	L 167	18.07.1995	Ann.II: — ban furocoumarines — ban musk ambrette — ban benzethonium chloride — ban cells, tissues, products of human origin — ban phenolphthalein Ann.VII/1: — add octocrylene (10)
19th adapting Commission Directive	96/41/EC	25.06.1996	L 198	08.08.1996	Ann. II: — ban urocanic acid (418) Ann. III: — add $Ca(OH)_2$ and LiOH Ann. VI: — Part 1: add 52 Ann. VII: — Part 1: add 11
20th adapting Commission Directive	97/1/EC	10.01.1997	L 16	18.01.1997	Ann. II: — ban bovine, ovine and caprine tissues and fluids from encephalon, spinal cord and eyes, and derivatives
Commission Directive postponing the ban on animal testing	97/18/EC	17.04.1997	L 114	01.05.1997	The ban on animal testing of cosmetic ingredients and their combinations is postponed until 30 June 2000
21st adapting Commission Directive	97/45/EC	14.07.1997	L 196	24.07.1997	Ann. II: — ban crude and refined coal tars Ann. VI/1: — add benzethonium chloride (53) Ann. VII/1: — add octyl methoxycinnamate (12)
22nd adapting Commission Directive	98/16/EC	05.03.1998	L 77	14.03.1998	Ann. II: — amendment of reference number 419 to derogate tallow derivatives
23rd adapting Commission Directive	98/62/EC	03.09.1998	L 253	15.09.1998	Ann. II: — ban of moskene (421) and musk tibetene (422) Ann. VI/1: — add benzalkonium chloride (54) Ann. VII/1: — add 13, 14, 15, 16, 17, 18, 19, 20

Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products

Note: The text of the recitals below only covers the recitals included with the original Directive of 1976 and with the 6th Amendment of 1993.

Recitals of original Directive 76/768/EEC

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas the provisions laid down by law, regulation or administrative action in force in the Member States define the composition characteristics to which cosmetic products must conform and prescribe rules for their labelling and for their packaging; whereas these provisions differ from one Member State to another;

Whereas the differences between these laws oblige Community cosmetic producers to vary their production according to the Member State for which the products are intended; whereas, consequently, they hinder trade in these products and, as a result, have a direct effect on the establishment and functioning of the common market;

Whereas the main objective of these laws is the safeguarding of public health and whereas, as a result, the pursuit of the same objective must inspire Community legislation in this sector; whereas, however, this objective must be attained by means which also take account of economic and technological requirements;

Whereas it is necessary to determine at Community level the regulations which must be observed as regards the composition, labelling and packaging of cosmetic products;

Whereas this Directive relates only to cosmetic products and not to pharmaceutical specialities and medicinal products; whereas for this purpose it is necessary to define the scope of the Directive by delimiting the field of cosmetics from that of pharmaceuticals; whereas this delimitation follows in particular from the detailed definition of cosmetic products, which refers both to their areas of application and to the purposes of their use; whereas this Directive is not applicable to the products that fall under the definition of cosmetic products but are exclusively intended to protect from disease; whereas, moreover, it is advisable to specify that certain products come under this definition, whilst products containing substances or preparations intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetics;

Whereas in the present state of research, it is advisable to exclude cosmetic products containing one of the substances listed in Annex V from the scope of this Directive;

Whereas cosmetic products must not be harmful under normal or foreseeable conditions of use; whereas in particular it is necessary to take into account the possibility of danger to zones of the body that are contiguous to the area of application;

Whereas, in particular, the determination of the methods of analysis together with possible modifications or additions which may have to be made to them on the basis of the results of scientific and technical research, are implementing measures of a technical nature; whereas it is advisable to entrust their adoption to the Commission, subject to certain conditions specified in this Directive, for the purpose of simplifying and accelerating the procedure;

Whereas technical progress necessitates rapid adaptation of the technical provisions defined in this Directive and in subsequent Directives in this field; whereas it is advisable, in order to facilitate implementation of the measures necessary for this purpose, to provide for a procedure establishing close cooperation between the Member States and the Commission within the Committee for adaptation to technical progress of Directives aimed at the removal of technical obstacles to trade in the cosmetic products sector;

Whereas it is necessary, on the basis of scientific and technical research, to draw up proposals for lists of authorized substances which could include antioxidants, hair dyes, preservatives and ultraviolet filters, taking into account in particular the problem of sensitization;

Whereas it could happen that although conforming to the provisions of this Directive and its Annexes, cosmetic products placed on the market might endanger public health; whereas it is therefore advisable to provide for a procedure intended to remove this danger,

Recitals of 6th Amendment - Directive 93/35/EEC

Whereas the legal ambiguities in Directive 76/768/EEC particularly in Articles 1 and 2, should be removed;

Whereas it has become apparent that it is desirable that data on the ingredients employed in cosmetic products be gathered so that all issues relating to their use and the resulting action at Community level may be assessed with a view, in particular, to the establishment of a common nomenclature of ingredients used in cosmetic products; whereas the gathering of that data can be facilitated if the Commission compiles an inventory of the ingredients concerned; whereas that inventory will be indicative and is not intended to constitute a limitative list of substances used in cosmetic products;

Whereas greater transparency is needed regarding the ingredients employed in cosmetics if the latter are to be placed on the market without any prior procedure, if the necessary information on the finished product is to be available solely at the place of manufacture or of initial importation into the Community and if better information is to be provided to the consumer; whereas such transparency should be achieved by indication of a product's function and of the ingredients used in a cosmetic product on its packaging; whereas where for practical reasons it is impossible to indicate the ingredients and any warnings regarding use on the container or the packaging, such particulars should be enclosed so that the consumer may have access to all necessary information;

Whereas, with regard to the finished cosmetic product, it should be made clear which information is to be made available to the monitoring authorities of the place of manufacture or of initial importation into the Community market; whereas that information should include all the necessary particulars relating to identity, quality, safety for human health and the effects claimed for the cosmetic product;

Whereas, however, for reasons of monitoring, the competent authority should be apprised of the place of manufacture and of the information needed for rapid and appropriate medical treatment in the event of difficulties;

Whereas the Commission should be authorized to amend Annexes I and VIII to Directive 76/768/EEC in view of their illustrative and technical nature;

Whereas assessment of the safety of use of the ingredients employed in cosmetics and of the final product should take account of the requirements of Directive 86/609/EEC which concerns the protection of animals used for experimental and other scientific purposes, and in particular Article 7 (2) thereof;

Whereas testing on animals of ingredients or combinations of ingredients should be banned as from 1 January 1998; whereas, however, that date should be postponed where alternative methods of testing have not been scientifically validated; whereas the Commission should submit a report on progress made with regard to such methods,

HAS ADOPTED THIS DIRECTIVE:

COSMETICS DIRECTIVE 76/768/EEC

Article 1

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

2. The products to be considered as cosmetic products within the meaning of this definition are listed in Annex I.

3. Cosmetic products containing one of the substances listed in Annex V shall be excluded from the scope of this Directive. Member States may take such measures as they deem necessary with regard to those products.

Article 2

A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market.

The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in this Directive.

Article 3

Member States shall take all necessary measures to ensure that only cosmetic products which conform to the provisions of this Directive and its Annexes may be put on the market.

Article 4

1. Without prejudice to their general obligations deriving from Article 2, Member States shall prohibit the marketing of cosmetic products containing:

(a) substances listed in Annex II;

(b) substances listed in the first part of Annex III, beyond the limits and outside the conditions laid down;

(c) colouring agents other than those listed in Annex IV, Part 1, with the exception of cosmetic products containing colouring agents intended solely to colour hair;

(d) colouring agents listed in Annex IV, Part 1, used outside the conditions laid down, with the exception of cosmetic products containing colouring agents intended solely to colour hair;

(e) preservatives other than those listed in Annex VI, Part 1;

(f) preservatives listed in Annex VI, Part 1, beyond the limits and outside the conditions laid down, unless other concentrations are used for specific purposes apparent from the presentation of the product;

(g) UV filters other than those listed in Part 1 of Annex VII;

(h) UV filters listed in Part 1 of Annex VII, beyond the limits and outside the conditions laid down therein;

(i) ingredients or combinations of ingredients tested on animals after 30 June 2000 in order to meet the requirements of this Directive.

If there has been insufficient progress in developing satisfactory methods to replace animal testing, and in particular in those cases where alternative methods of testing, despite all reasonable endeavours, have not been scientifically validated as offering an equivalent level of protection for the consumer, taking into account OECD toxicity test guidelines, the Commission shall, by 1 January 1997, submit draft measures to postpone the date of implementation of this provision, for a sufficient period, and in any case for no less than two years, in accordance with the procedure laid down in Article 10. Before submitting such measures, the Commission will consult the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers.

The Commission shall present an annual report to the European Parliament and the Council on progress in the development, validation and legal acceptance of alternative methods to those involving experiments on animals. That report shall contain precise data on the number and type of experiments relating to cosmetic products carried out on animals. The Member States shall be obliged to collect that information in addition to collecting statistics as laid down by Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes. The Commission shall in particular ensure the development, validation and legal acceptance of experimental methods which do not use live animals.

2. The presence of traces of the substances listed in Annex II shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 2.

Article 5

Member States shall allow the marketing of cosmetic products containing:

(a) the substances listed in Annex III, Part 2, within the limits and under the conditions laid down, up to the dates in column (g) of that Annex;

(b) the colouring agents listed in Annex IV, Part 2, within the limits and under the conditions laid down, until the admission dates given in that Annex;

(c) the preservatives listed in Annex VI, Part 2, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex. However, some of these substances

may be used in other concentrations for specific purposes apparent from the presentation of the product;

(d) the UV filters listed in Part 2 of Annex VII, within the limits and under the conditions laid down, until the dates given in column (f) of that Annex.

At these dates, these substances, colouring agents, preservatives and UV filters shall be:

— definitively allowed, or

— definitively prohibited (Annex II), or

— maintained for a given period specified in Part 2 of Annexes III, IV, VI and VII, or

— deleted from all the Annexes, on the basis of available scientific information or because they are no longer used.

Article 5a

1. No later than 14 December 1994 the Commission shall, under the procedure laid down in Article 10, compile an inventory of ingredients employed in cosmetic products, on the basis in particular of information supplied by the industry concerned.

For the purposes of this Article "cosmetic ingredient" shall mean any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of cosmetic products.

The inventory shall be divided into two sections: one concerning perfume and aromatic raw materials and the second concerning other substances.

2. The inventory shall contain information on:

— the identity of each ingredient, in particular its chemical name, the CTFA name, the European Pharmacopoeia name, the international non-proprietary names recommended by the World Health Organisation, the EINECS, IUPAC, CAS and colour index numbers, and the common name referred to in Article 7 (2),

— the usual function(s) of the ingredient in the final product,

— where appropriate, restrictions and conditions of use and warnings which must be printed on the label by reference to the Annexes.

3. The Commission shall publish the inventory and shall update it periodically under the procedure provided for in Article 10. The inventory shall be indicative and shall not constitute a list of the substances authorized for use in cosmetic products.

Article 6

1. Member States shall take all measures necessary to ensure that cosmetic products may be marketed only if the container and packaging bear the following information in indelible, easily legible and visible lettering; the information mentioned in point (g) may, however, be indicated on the packaging alone:

(a) the name or style and the address or registered office of the manufacturer or the person responsible for marketing the cosmetic product who is established within the Community. Such information may be abbreviated in so far as the abbreviation makes it generally possible to identify the undertaking. Member States may require that the country of origin be specified for goods manufactured outside the Community;

(b) the nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five millilitres, free samples and single-application packs; for pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging. This information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually;

(c) the date of minimum durability. The date of minimum durability of a cosmetic product shall be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with Article 2.

The date of minimum durability shall be indicated by the words: "Best used before the end of ... " followed by either:

— the date itself, or

— details of where the date appears on the packaging.

If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

The date shall be clearly expressed and shall consist of the month and the year in that order. Indication of the date of durability shall not be mandatory for cosmetic products the minimum durability of which exceeds 30 months;

(d) particular precautions to be observed in use, especially those listed in the column "Conditions of use and warnings which must be printed on the label" in Annexes III, IV, VI and VII, which must appear on the container and packaging, as well as any special precautionary information on cosmetic products for professional use, in particular in hairdressing. Where this is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain that information to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on the container and the packaging;

(e) the batch number of manufacture or the reference for identifying the goods. Where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the packaging;

(f) the function of the product, unless it is clear from the presentation of the product;

(g) a list of ingredients in descending order of weight at the time they are added. That list shall be preceded by the word "ingredients". Where that is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain the ingredients to which the consumer is referred either by abbreviated information or the symbol given in Annex VIII, which must appear on the packaging.

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.

Perfume and aromatic compositions and their raw materials shall be referred to by the word "perfume" or "flavour". Ingredients in concentrations of less than 1% may be listed in any order after those in concentrations of more than 1%. Colouring agents may be listed in

any order after the other ingredients, in accordance with the colour index number or denomination adopted in Annex IV.

For decorative cosmetic products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the terms "may contain" are added.

An ingredient must be identified by the common name referred to in Article 7 (2) or, failing that, by one of the names referred to in Article 5a (2), first indent.

In accordance with the procedure laid down in Article 10, the Commission shall, no later than 14 December 1994, adopt the criteria and conditions under which a manufacturer may, for reasons of trade secrecy, apply not to include one or more ingredients on the abovementioned list.

Where it is impracticable, for reasons of size or shape, for the particulars referred to in points (d) and (g) to appear in an enclosed leaflet, those particulars shall appear on a label, tape or card which is enclosed or attached to the cosmetic product.

In the case of soap, bath balls and other small products where it is impracticable, for reasons of size or shape, for the particulars referred to in point (g) to appear on a label, tag, tape or card or in an enclosed leaflet, those particulars shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.

2. For cosmetic products that are not pre-packaged, are packaged at the point of sale at the purchaser's request, or are pre-packaged for immediate sale, Member States shall adopt detailed rules for indication of the particulars referred to in paragraph 1.

3. Member States shall take all measures necessary to ensure that, in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have. Furthermore, any reference to testing on animals must state clearly whether the tests carried out involved the finished product and/or its ingredients.

Article 7

1. Member States may not, for reasons related to the requirements laid down in this Directive and the Annexes thereto, refuse, prohibit or restrict the marketing of any cosmetic products which comply with the requirements of this Directive and the Annexes thereto.

2. They may, however, require that the particulars provided for in Article 6 (1) (b), (c), (d) and (f) be expressed at least in their own national or official language or languages; they may also require that the particulars provided for in Article 6 (1) (g) be expressed in a language easily understood by the consumer. To that end, the Commission shall adopt a common ingredients nomenclature in accordance with the Article 10 procedure.

3. Furthermore, a Member State may, for purposes of prompt and appropriate medical treatment in the event of difficulties, require that appropriate and adequate information on substances used in cosmetic products be made available to the competent authority, which shall ensure that that information is used only for the purposes of such treatment.

Each Member State shall designate a competent authority and send details thereof to the Commission, which shall publish that information in the *Official Journal of the European Communities*.

Article 7a

1. The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6 (1) (a):

(a) the qualitative and quantitative composition of the product; in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier;

(b) the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product;

(c) the method of manufacture complying with the good manufacturing practice laid down by Community law or, failing that, laid down by the law of the Member State concerned; the person responsible for manufacture or first importation into the Community must possess an appropriate level of professional qualification or experience in accordance with the legislation and practice of the Member State which is the place of manufacture or first importation;

(d) assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredient, its chemical structure and its level of exposure.

Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be kept available. In this connection, and when so requested for monitoring purposes, he shall be obliged to indicate the place so chosen to the monitoring authority/authorities concerned;

(e) the name and address of the qualified person or persons responsible for the assessment referred to in (d). That person must hold a diploma as defined in Article 1 of Directive 89/48/EEC in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline;

(f) existing data on undesirable effects on human health resulting from use of the cosmetic product;

(g) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product.

2. The assessment of the safety for human health referred to in paragraph 1 (d) shall be carried out in accordance with the principle of good laboratory practice laid down in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances [1].

3. The information referred to in paragraph 1 must be available in the national language or languages of the Member State concerned, or in a language readily understood by the competent authorities.

4. The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent authority of the Member State of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial

[1] OJ No L 15, 17.1.1987, p. 29.

importation into the Community of the cosmetic products before the latter are placed on the Community market.

5. Member States shall designate the competent authorities referred to in paragraphs 1 and 4 and shall send details thereof to the Commission, which shall publish that information in the *Official Journal of the European Communities*.

6. The Member States shall ensure that the abovementioned authorities continue to co-operate in areas where such cooperation is necessary to the smooth application of this Directive.

Article 8

1. In accordance with the procedure laid down in Article 10 the following shall be determined:

— the methods of analysis necessary for checking the composition of cosmetic products, .

— the criteria of microbiological and chemical purity for cosmetic products and methods for checking compliance with those criteria.

2. The common nomenclature of ingredients used in cosmetic products and, after consultation of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, the amendments necessary for the adaptation to technical progress of the Annexes shall be adopted in accordance with the same procedure, as appropriate.

Article 8a

1. Notwithstanding Article 4 and without prejudice to Article 8 (2), a Member State may authorize the use within its territory of other substances not contained in the lists of substances allowed, for certain cosmetic products specified in its national authorization, subject to the following conditions:

(a) the authorization must be limited to a maximum period of three years;

(b) the Member State must carry out an official check on cosmetic products manufactured from the substance or preparation use of which it has authorized;

(c) cosmetic products thus manufactured must bear a distinctive indication which will be defined in the authorization.

2. The Member State shall forward to the Commission and to the other Member States the text of any authorization decision taken pursuant to paragraph 1 within two months of the date on which it came into effect.

3. Before expiry of the three-year period provided for in paragraph 1, the Member State may submit to the Commission a request for the inclusion in a list of permitted substances of the substance given national authorization in accordance with paragraph 1. At the same time, it shall supply supporting documents setting out the grounds on which it deems such inclusion justified and shall indicate the uses for which the substance or preparation is intended. Within 18 months of submission of the request, a decision shall be taken on the basis of the latest scientific and technical knowledge, after consultation, at the initiative of the Commission or of a Member State, of the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers and in accordance with the procedure laid down in Article 10 as to whether the substance in question may be included in a list of permitted substances or whether the national authorization should be revoked. Notwithstanding paragraph 1 (a), the national authorization shall remain in force until a decision is taken on the request for inclusion in the list.

Article 9

1. The Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector, hereinafter called "the Committee", is hereby set up. It shall consist of representatives of the Member States with a representative of the Commission as chairman.

2. The Committee shall adopt its own rules of procedure.

Article 10

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit set by the chairman according to the urgency of the matter. Opinions shall be adopted by a majority of 62 votes, the votes of Member States being weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the proposed measures when they are in accordance with the opinion of the Committee.

   (b) Where the proposed measures are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

   (c) If, within 3 months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 11

Without prejudice to Article 5, and not later than 1 year after expiry of the period laid down in Article 14 (1) for implementation of this Directive by the Member States, the Commission shall, on the basis of the results of the latest scientific and technical research, submit to the Council appropriate proposals establishing lists of permitted substances.

Article 12

1. If a Member State notes, on the basis of a substantiated justification, that a cosmetic product, although complying with the requirements of the Directive, represents a hazard to health, it may provisionally prohibit the marketing of that product in its territory or subject it to special conditions. It shall immediately inform the other Member States and the Commission thereof, stating the grounds for its decision.

2. The Commission shall as soon as possible consult the Member States concerned, following which it shall deliver its opinion without delay and take the appropriate steps.

3. If the Commission is of the opinion that technical adaptations to the Directive are necessary, such adaptations shall be adopted by either the Commission or the Council in accordance with the procedure laid down in Article 10. In that event, the Member State which has adopted safeguard measures may maintain them until entry into force of the adaptations.

Article 13

Precise reasons shall be stated for any individual measures placing a restriction or ban on the marketing of cosmetic products taken pursuant to this Directive. It shall be notified to the party concerned together with particulars of the remedies available to him under the laws in force in the Member States and the time limits allowed for the exercise of such remedies.

Article 14

1. Member States shall bring into force the provisions needed in order to comply with this Directive within 18 months of its notification and shall forthwith inform the Commission thereof.

2. Member States may, however, for a period of 36 months from notification of this Directive, authorize the marketing in their territory of cosmetic products which do not conform to the requirements of the Directive.

3. Member States shall ensure that the texts of such provisions of national law which they adopt in the field governed by this Directive are communicated to the Commission.

Article 15

This Directive is addressed to the Member States.

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.

ANNEX II

List of substances which must not form part of the composition of cosmetic products

1. N-5-Chlorobenzoxazol-2-ylacetamide
2. ß-Acetoxyethyl trimethyl ammonium hydroxide (acetylcholine) and its salts
3. Deanol aceglumate*
4. Spironolactone*
5. [4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl] 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. Sympathicomimetic amines acting on the central nervous system: any substance contained in the first list of medicaments which 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

(*) In this Directive, names followed by an asterisk are those published in "Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1-33 of proposed INN", WHO, Geneva, August 1975.

28. Octodrine* and its salts
29. 2-Amino-1,2-bis (4-methoxyphenyl) ethanol and its salts
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)-7H-furo [3,2-g] chromen-7-one)
35. *Ammi majus* and its galenical preparations
36. 2,3-Dichloro-2-methylbutane
37. Substances with androgenic effect
38. Anthracene 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-dihydric alcohol) and its salts
43. Arsenic and its compounds
44. *Atropa belladona L.* and its preparations
45. Atropine, its salts and derivatives
46. Barium salts, with the exception of barium sulphate, barium sulphide under the conditions laid down in Annex III, Part 1, and lakes, salts and pigments prepared from the colouring agents listed with the reference (3) in Annex IV, Part 1, and Annex IV, Part 2.
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

(*) In this Directive, names followed by an asterisk are those published in "Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1-33 of proposed INN", WHO, Geneva, August 1975.

60. Benzilonium bromide*
61. Tetrylammonium bromide*
62. Brucine
63. Tetracaine* and its salts
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 carbazole
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-Phenylazophenylene-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)

(*) In this Directive, names followed by an asterisk are those published in "Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1-33 of proposed INN", WHO, Geneva, August 1975.

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*
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-Cyclohexylbenzyl (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)

(*) In this Directive, names followed by an asterisk are those published in "Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1-33 of proposed INN", WHO, Geneva, August 1975.

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. [Oxalylbis(iminoethylene)] 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)
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

(*) In this Directive, names followed by an asterisk are those published in "Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1-33 of proposed INN", WHO, Geneva, August 1975.

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
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. Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in Annex III, Part 1
192. Furfuryltrimethylammonium salts, e.g. furtrethonium iodide*

(*) In this Directive, names followed by an asterisk are those published in "Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1-33 of proposed INN", WHO, Geneva, August 1975.

193. Galantamine*

194. Progestogens

195. 1,2,3,4,5,6-Hexachlorocyclohexane (BHC - ISO)

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-dimethanonaphthalene (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, hydrastinine 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 salts of the acid

205. Methocarbamol*

206. Propatylnitrate*

207. 4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin

208. Fenadiazole*

209. Nitroxoline and its salts

210. Hyoscyamine, its salts and derivatives

211. *Hyoscyamus 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 and 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-trimethylnaphto [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

(*) In this Directive, names followed by an asterisk are those published in "Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1-33 of proposed INN", WHO, Geneva, August 1975.

224. 2-(4-Allyl-2-methoxyphenoxy)-N-N-diethylacetamide and its salts
225. Coumetarol*
226. Dextromethorphan* 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
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 metal 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

(*) In this Directive, names followed by an asterisk are those published in "Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1-33 of proposed INN", WHO, Geneva, August 1975.

257. Noradrenaline and its salts
258. Noscapine* and its salts
259. Guanethidine* and its salts
260. Oestrogens
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-Phenylindane-1,3-dione (phenindione)
272. Ethylphenacemide*
273. Phenprocoumon*
274. Fenyramidol*
275. Triamterene* and its salts
276. Tetraethyl pyrophosphate (TEPP - ISO)
277. Tritolyl phosphate
278. Psilocybine*
279. Phosphorus and metal phosphides
280. Thalidomide* and its salts
281. *Physostigma venenosum Balf.*
282. Picrotoxin
283. Pilocarpine and its salts
284. α-Piperidin-2-yl-benzyl acetate laevorotatory threoform (levophacetoperane) and its salts
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, No 55 under the conditions stated

(*) In this Directive, names followed by an asterisk are those published in "Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1-33 of proposed INN", WHO, Geneva, August 1975.

290. Coniine

291. *Prunus laurocerasus L.* ("cherry laurel water")

292. Metyrapone*

293. Radioactive substances (1)

294. *Juniperus sabina L.* (leaves, essential oil and 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 No 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 preparations

302. Strophantines, their aglucones and 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 Tables I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961

307. Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the $-NH_2$ 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

313. Xylometazoline* and its salts

314. Tetrachloroethylene

315. Carbon tetrachloride

316. Hexaethyl tetraphosphate

317. Thallium and its compounds

318. *Thevetia neriifolia Juss.*, glycoside extract

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(1) The presence of natural radioactive substances and of radioactive substances caused by artificial contamination from the environment is permitted, provided that the radioactive substances are not enriched for the manufacture of cosmetic products and that their concentration falls within the limits set in the Directive laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiations (OJ No 11, 20.2.1959, p. 221/59).

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319. Ethionamide*
320. Phenothiazine* and its compounds
321. Thiourea and its derivatives, with the exception of the one listed in Annex III, Part 1
322. Mephenesin* and its esters
323. Vaccines, toxins or serums listed in the Annex to the second Council Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ No 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. *Schoenocaulon 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*
348. Tetrachlorosalicylanilides
349. Dichlorosalicylanilides
350. Tetrabromosalicylanilides
351. Dibromosalicylanilides

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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, furocoumarines 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',6',8',8'-tetramethyl-2'-acetonaphthone;

Syn.: 1,1,4,4-tetramethyl-6-ethyl-7-acetyl-1,2,3,4-tetrahydro-naphthalene (acetyl ethyl tetramethyl tetralin, AETT)

363. o-Phenylenediamine and its salts

364. 4-Methyl-m-phenylenediamine and its salts

365. Aristolochic acid and its salts

366. Chloroform

367. 2,3,7,8,-Tetrachlorodibenzo-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 and derivatives

373. 3,4',5-Tribromosalicylanilide (Tribromsalan)

374. *Phytolacca Spp.* and their preparations

375. Tretinoin* (retinoic acid and its salts)

376. 1-Methoxy-2,4-diaminobenzene (2,4-diaminoanisole - CI 76050) and their salts

377. 1-Methoxy-2,5-diaminobenzene (2,5-diaminoanisole) and their salts

378. Colouring agent CI 12140

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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. 11-α-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. Antiandrogens with steroid structure

391. Zirconium and its compounds, with the exception of the complexes under reference No 50 in Annex III, Part 1 and of zirconium lakes, salts and pigments of colouring agents listed with reference No 3 in Annex IV, Part 1

392. Thyrothricine

393. Acetonitrile

394. Tetrahydrozoline and its salts

395. Hydroxy-8-quinoline and its sulphate, except for the uses provided for in No 51 in Annex III, Part 1

396. Dithio-2,2'-bispyridine-dioxide 1,1' (additive with 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. Catechol

409. Pyrogallol

410. Nitrosamines

411. Secondary dialkanolamines

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, tonsils and spinal cord of:

— bovine animals aged 12 months

— ovine and caprine animals which are aged over 12 months or have a permanent incissor 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: 200 °C, 40 bars (40,000 hPa) for 20 minutes (glycerol and fatty acids and esters),

— saponification with NaOH 12M (glycerol and soap):

— batch process: at 95 °C for 3 hours

or

— continuous process: at 140 °C, 2 bars (2 000 hPa) for 8 minutes or equivalent conditions.

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)

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ANNEX III – PART 1

List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
1	Boric acid	(a) Talcs (b) Products for oral hygiene (c) Other products	(a) 5 % (b) 0.5 % (c) 3 %	(a) Not to be used in products for children under three years old	(a) Not to be used for children under three years of age
2a	Thioglycolic acid and its salts	(a) Hair waving or straightening products: — general use — professional use (b) Depilatories (c) Other hair care products which are removed after application	— 8 % ready for use pH 7 to 9.5 — 11 % ready for use pH 7 to 9.5 — 5 % ready for use pH 7 to 12.7 — 2 % ready for use pH 7 to 9.5 The abovementioned percentages are calculated as thioglycolic acid.	(a) (b) (c) The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: — Avoid contact with eyes — In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice — Wear suitable gloves (a) and (c) only)	(a) — Contains thioglycolate — Follow the instructions — Keep out of reach of children — For professional use only (b) and (c) — Contains thioglycolate — Follow the instructions — Keep out of reach of children

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
2b	Thioglycolic acid esters	Hair waving or straightening products: — general use — professional use	 — 8 % ready for use pH 6 to 9.5 — 11 % ready for use pH 6 to 9.5 The abovementioned percentages are calculated as thioglycolic acid	The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: — May cause sensitisation in the event of skin contact — Avoid contact with eyes — In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice — Wear suitable gloves	— Contains thioglycolate — Follow the instructions — Keep out of reach of children — For professional use only
3	Oxalic acid, its esters and alkaline salts	Hair care products	5 %		— For professional use only
4	Ammonia		6 % calculated as NH_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	

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
8	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 to dye eyelashes or eyebrows (b) — For professional use only — Contains phenylenediamines — Can cause an allergic reaction — Wear suitable gloves
9	Methylphenylene-diamines, their N-substituted derivatives and their salts (1) with the exception of substance No 364 in Annex II	Oxidizing colouring agents for hair dyeing (a) general use (b) professional use	10 % calculated as free base		(a) — Can cause an allergic reaction — Contains phenylenediamines — Do not use to dye eyelashes or eyebrows (b) — For professional use only — Contains phenylene-diamines — 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 the value given in column d.

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
10	Diaminophenols (1)	Oxidizing colouring agents for hair dyeing (a) general use	10 % calculated as free base		(a) — Can cause an allergic reaction — Contains diaminophenols — Do not use to dye eyelashes or eyebrows
		(b) professional use			(b) — For professional use only — Contains diaminophenols — Can cause an allergic reaction — Wear suitable gloves
11	Dichlorophen (*)		0.5 %		— Contains dichlorophen
12	Hydrogen peroxide, and other compounds or mixtures 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_2O_2 present or released		
		(d) Oral hygiene products	0.1 % of H_2O_2 present or released		(a) — 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 the value given in column d.

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
13	Formaldehyde	Nail hardeners	5 % calculated as formaldehyde		Protect cuticles with grease or oil Contains formaldehyde (2)
14	Hydroquinone (1)	(a) Oxidizing colouring agent for hair-dyeing: 1. general use	2 %		(a) 1. — Do not use to dye eyelashes or eyebrows — Rinse the eyes immediately if the product comes into contact with them — Contains hydroquinone
		2. professional use			2. — For professional use only — Contains hydroquinone — Rinse the eyes immediately if the product comes into contact with them
		(b) Agents for localized skin lightener	2 %		(b) — Contains hydroquinone — Avoid contact with the eyes — Apply to small areas — If irritation develops discontinue use — Do not use on children under the age of 12

(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 the value given in column d.

(2) Only if the concentration exceeds 0.05%.

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
15a	Potassium or sodium hydroxide	(a) Nail cuticle solvent	(a) 5 % by weight (1)		(a) — Contains alkali — Avoid contact with eyes — Can cause blindness — Keep out of reach of children
		(b) Hair straightener 1. general use	(b) 1. 2 % by weight (1)		(b) 1. — Contains alkali — Avoid contact with eyes — Can cause blindness — Keep out of reach of children
		2. professional use	2. 4.5 % by weight (1)		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 of children
		2. professional use	2. 4.5 % by weight (1)		2. — For professional use only — Avoid contact with eyes — Can cause blindness
		(b) Other uses			

(1) The quantity of sodium, potassium or lithium hydroxide is expressed as weight of sodium hydroxide. In case of mixtures, the sum should not exceed the limits given in column d.

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
15c	Calcium hydroxide	(a) Hair straighteners containing two components: calcium hydroxide and a guanidine salt (b) Other uses	(a) 7 % by weight calcium hydroxide		— Contains alkali — Avoid contact with eyes — Can cause blindness — Keep out of reach of children
16	Alpha-naphthol	Colouring agent for hair dyeing	0.5 %		— Contains alpha-naphthol
17	Sodium nitrite	Rust inhibitor	0.2 %	Do not use with secondary and/or tertiary amines or other substances forming nitrosamines	
18	Nitromethane	Rust inhibitor	0.3 %		
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		

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
22	Resorcinol (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 eyes immediately if product comes into contact with them
		2. professional use			2. — For professional use only — Contains resorcinol — Rinse eyes immediately if product comes into contact with them
		(b) Hair lotions and shampoos	(b) 0.5 %		(b) — Contains Resorcinol
23	(a) Alkali sulphides	a) Depilatories	a) 2 % calculated as sulphur pH ≤ 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 ≤ 12.7		(b) — Keep out of reach of children — Avoid contact with the eyes

(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 the value given in column d.

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
24	Water-soluble zinc salts with the exception of zinc-4-hydroxybenzene-sulphonate and zinc pyrithione		1 % calculated as zinc		
25	Zinc 4-hydroxybenzene sulphonate	Deodorants, antiperspirants and astringent lotions	6 % calculated as % of anhydrous substance		— Avoid contact with eyes
26	Ammonium monofluoro-phosphate	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 monofluorophosphate
27	Sodium monofluoro-phosphate	Ditto	0.15 % Ditto		— Contains sodium monofluorophosphate
28	Potassium monofluoro-phosphate	Ditto	0.15 % Ditto		— Contains potassium monofluorophospate
29	Calcium monofluoro-phosphate	Ditto	0.15 % Ditto		— Contains calcium monofluorophosphate
30	Calcium fluoride	Ditto	0.15 % Ditto		— Contains calcium fluoride
31	Sodium fluoride	Ditto	0.15 % Ditto		— Contains sodium fluoride
32	Potassium fluoride	Ditto	0.15 % Ditto		— Contains potassium fluoride

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
33	Ammonium fluoride	Ditto	0.15 % Ditto		— Contains ammonium fluoride
34	Aluminium fluoride	Ditto	0.15 % Ditto		— Contains aluminium 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-hydroxyethyl-ammonio) propylbis (2-hydroxyethyl) ammonium dihydrofluoride	Ditto	0.15 % Ditto		— Contains 3-(N-Hexadecyl-N-2-hydroxyethyl-ammonio) propylbis (2-hydroxyethyl) ammonium dihydrofluoride
38	N,N',N'-Tris(polyoxyethylene)-N-hexadecyl-propylenediamine dihydrofluoride	Ditto	0.15 % Ditto		— Contains N,N',N'-tris(polyoxyethylene)-N-hexadecylpropylenediamine dihydrofluoride
39	Octadecenyl-ammonium fluoride	Ditto	0.15 % Ditto		— Contains octadecenyl-ammonium fluoride
40	Sodium fluorosilicate	Ditto	0.15 % Ditto		— Contains sodium fluorosilicate
41	Potassium fluorosilicate	Ditto	0.15 % Ditto		— Contains potassium fluorosilicate

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
42	Ammonium fluorosilicate	Ditto	0.15 % Ditto		— Contains ammonium fluorosilicate
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 aerosols dispensers (sprays) (b) The pH of the product as applied must be less than 4	— Contains 1,3-bis(hydroxymethyl) imidazolidine-2-thione
45	Benzyl alcohol	Solvents, perfumes and flavourings			
46	6-methylcoumarin	Oral hygiene products	0.003 %		
47	Nicomethanol hydrofluoride	Oral hygiene products	0.15 % calculated as F When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.15 %		— Contains nicomethanol hydrofluoride
48	Silver nitrate	Solely for products intended for colouring eyelashes and eyebrows	4 %		— Contains silver nitrate — Rinse the eyes immediately if product comes into contact with them
49	Selenium disulphide	Anti-dandruff shampoos	1 %		— Contains selenium disulphide — Avoid contact with eyes or damaged skin

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
50	Aluminium zirconium chloridehydroxide complexes $Al_xZr(OH)_yCl_z$ and the aluminium zirconium chloridehydroxide glycine complexes	Anti-perspirants	20 % as anhydrous aluminium zirconium chloridehydroxide 5.4 % as zirconium	1. The ratio of the number of aluminium atoms to that of zirconium atoms must be between 2 and 10 2. The ratio of the number of (Al + Zr) atoms to that of chlorine atoms must be between 0.9 and 2.1 3. Prohibited in aerosol dispensers (sprays)	— Do not apply to irritated or damaged skin
51	Quinolin-8-ol and bis (8-hydroxy-quinolinium) sulphate	Stabilizer for hydrogen peroxide in rinse-off hair-care preparations Stabilizer for hydrogen peroxide in non-rinse-off hair-care preparations	0.3 % calculated as base 0.03 % calculated as base		
52	Methanol	Denaturant for ethanol and iso-propyl alcohol	5 % calculated as a % of ethanol and isopropyl alcohol		
53	Etidronic acid and its salts (1-hydroxy-ethylidene-diphosphonic acid and its salts)	(a) Hair-care (b) Soap	1.5 % expressed as etidronic acid 0.2 % expressed as etidronic acid		
54	1-Phenoxypropan-2-ol	— Rinse-off products only — Prohibited in oral hygiene products	2 %	As a preservative, see Annex VI, Part 1, No 43	

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
55	Lead acetate	Only for hair dyeing	0.6 % calculated in lead		— Keep away from children — Avoid all contact with the eyes — Wash hands after use — Contains lead acetate — Do not use to dye eyelashes, eyebrows or moustaches — If irritation develops, discontinue use
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	3.5 % calculated as strontium. When mixed with other permitted strontium compounds 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	2.1 % calculated as strontium When mixed with other permitted strontium compounds the total strontium content must not exceed 2.1 %		

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
58	Strontium acetate hemihydrate	Toothpaste	3.5 % calculated as strontium When mixed with other permitted strontium products the total strontium content must not exceed 3.5 %		— Contains strontium acetate — Frequent use by children is not advisable
59	Talc: Hydrated magnesium silicate	(a) Powdery products intended to be used by children under three years of age (b) Other products			(a) — Keep powder away from children's nose and mouth
60	Fatty acid dialkanolamides		Maximum dialkanolamine content: 0.5 %	— Do not use with nitrosating systems — Maximum dialkanolamine content: 5 % (concerns raw materials) — Maximum N-nitroso-dialkanolamine content: 50 µg/kg — Keep in nitrite-free containers	

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
61	Monoalkanolamines		Maximum dialkanolamine content: 0.5 %	— Do not use with nitrosating systems — Minimum purity: 99 % — Maximum secondary alkanolamine content: 0.5 % (concerns raw materials) — Maximum N-nitroso-dialkanolamine content: 50 µg/kg — Keep in nitrite-free containers	
62	Trialkanolamines	(a) non-rinse-off products (b) other products	(a) 2.5 %	(a) (b): — Do not use with nitrosating systems — Minimum purity: 99 % — Maximum secondary alkanolamine content: 0.5 % (concerns raw materials) — Maximum N-nitroso-dialkanolamine content: 50 µg/kg — Keep in nitrite-free containers	

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
63	Strontium hydroxide	pH-regulator in depilatory products	3.5 % calculated as strontium, max. pH of 12.7		— 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 product comes into contact with them — For professional use only — Wear suitable gloves

ANNEX III – PART 2

List of substances provisionally allowed

Reference number	Substance	RESTRICTIONS			Conditions of use and warnings which must be printed on the label	Allowed until
		Field of application and/or use	Maximum authorized concentration in the finished cosmetic product	Other limitations and requirements		
a	b	c	d	e	f	g

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