

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(72) 851 final

Brussels, 6 October 1972

PROPOSAL FOR A COUNCIL DIRECTIVE

ON THE APPROXIMATION OF THE LAWS

OF THE MEMBER STATES RELATING TO COSMETIC PRODUCTS

(submitted to the Council by the Commission)

EXPLANATORY MEMORANDUM

I. GENERAL

1. Comparative study of the laws, regulations and administrative provisions in force in the Member States as regards cosmetic products has revealed divergences not only in the technical provisions relative to the composition and acceptance of certain cosmetic products, substances and colorants used in the production of these products, but also in the systems of legislation and delimitation of their scope in relation to the provisions of the laws relating to food and pharmaceuticals.
2. This situation obliges the producers of cosmetic products to adapt their production to the varying provisions in the different countries for which the products are intended.

The national laws in force find their legal justification in the responsibility which the Member States have to protect the consumer, especially in the field of public health. Accordingly, the approximation of these laws appears to be the most appropriate means of eliminating the negative effects following from the disparities found between these provisions.

3. It is for this reason that the cosmetic products sector has been taken up again in the third phase of the "General programme for the removal of the technical barriers to trade resulting from the disparities between national laws", approved by the Council on 28 May 1969.
4. The object of this Directive is the elimination of the divergences, which have come to light, through the approximation of national laws. The legal basis is Article 100 of the Treaty of Rome.

For the purpose of technical consultation, the Commission has formed a working party of experts and a technical study group.

During meetings of these experts, the European representatives of the Comité de Liaisons des syndicats de la Parfumerie have been able to express their points of view on the technical problems.

II. HARMONIZATION SOLUTION

The harmonization solution on which this Directive is based is the total solution. The effect of the solution chosen is the substitution of Community provisions for the national laws in force.

III. NOTES ON THE PROPOSAL FOR A DIRECTIVE

The scope of the proposal for a Directive covers all cosmetic products - with the exception of a few substances - for which a definition is given; it is specified that it refers to substances or preparations intended to be placed in contact with the various superficial parts of the human body or with the teeth and the mucous membranes of the oral cavity for cosmetic purposes (Article 1(1)). This definition is put in a more concrete form by an indicative list of products grouped in categories (Annex 1).

Cosmetic products which, within the limits and restrictions laid down in the Directive, do not constitute a danger to human health, for example creams intended to protect the human skin against detergents, insects or the cold, can accordingly be considered without risk as cosmetic products within the meaning of this Directive.

Products which do not contain a prohibited substance, or which lie within the limits and restrictions fixed with regard to substances, the use of which is limited, are also considered as cosmetic products.

Where the concentration of the substances accepted is higher than that fixed in Annex to the Directive, the products containing these substances are no longer considered as cosmetic products, but may lie in the field of pharmacy or in other fields.

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The general criterion of the acceptance of any cosmetic product for marketing is that it shall not be liable to cause damage to human health where it is applied as intended (Article 2).

From this general principle, there follows, in the sense of total harmonization, the obligation of the Member States to allow on the market only cosmetic products conforming, both with regard to their composition and to their labelling, to the technical criteria laid down for the Community by this proposal for a Directive and by its Annexes (Articles 3 and 6).

The system chosen by the Directive is that of the negative list, constituting an exhaustive and restrictive enumeration of the substances which cosmetic products must not contain. The consequences of this system is that all substances which are not explicitly prohibited by the Directive are accepted. Consequently, all cosmetic products which do not contain any of the prohibited substances, listed in Annex II, and which respect the restrictions laid down in Annexes III and IV are accepted (Article 4).

This rule notwithstanding, the Directive provides provisionally for a period of three years, reckoned from its notification, for the admission of a series of substances and colorants, for which scientific information does not, at present, permit a final classification. Within the period provided, a solution as to their final, or renewed provisional acceptance or as to their prohibition is to be found within the framework of the procedure of the Committee for adaptation to technical progress, taking into account the results of research carried out by scientific agencies during the three-year transition period (Article 5).

In addition to the total harmonization of the laws, the fundamental element of the Directive is the establishment of free movement of cosmetic products conforming to the Community provisions laid down by the Directive and its Annexes. However, in the interests of the consumer, the Member States reserve the right to demand that the labelling data be printed in at least their national language or languages. The possibility of using other languages at the same time is not touched upon by this measure (Article 7).

In addition, the Directive requires that the Member States take the necessary measures to control during marketing or, inasmuch as they consider it necessary, in the warehouses of the manufacturer, the importer or the distributor, the conformity of cosmetic products with the provisions of the Directive (Article 8).

Moreover, this Directive provides, on the one hand, for adaptation of the technical Annexes to technical progress and, on the other hand, for final classification of the substances and colorants provisionally accepted. In the particular case of colorants, a final deletion of any Annex implies the general acceptance of these products, with the exception of cosmetic products which can come into contact with the mucous membranes.

By the same procedure of the Committee, the formulation of the sampling method and methods of analysis are provided for (Articles 9, 10 and 11).

Having regard to the importance of the protection of human health, this Directive includes a clause permitting a Member State, under certain circumstances, to prohibit, in compliance with a decision taken in accordance with the procedure of the Committee, the marketing of a product which, although conforming to the provisions of the Directive and used under the conditions provided, still constitutes a danger to human health. If, after the expiry of a period of 30 days, reckoned from the time at which the Committee received a draft copy of the measures to be taken, no decision has been made, the applicant Member State can apply the measures envisaged until a decision is taken (Article 12).

The Directive also contains as is customary a provision by which the Member States undertake with respect to the party whose product is subjected to a marketing restriction or ban, to indicate the methods of recourse open and the periods to be observed for the introduction of appeals (Article 13).

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The Member States will have the usual period of 18 months for incorporation of the provisions of the Directive in the national law.

To permit the disposal of stocks of cosmetic products which do not conform to the provisions of this Directive, the Directive provides for an option for the Member States to accept the products on their territory, for a period of 36 months from notification of the Directive (Article 14).

Annex I lists the categories of cosmetic products and thus permits more accurate definition of the scope of the Directive.

Annex II comprises an exhaustive list of the substances which cosmetic products must not contain. This list will certainly need very frequent updating as a result of research carried out in the field of toxicology. Supplementary provisions, as concerns those substances prohibited in the form of traces or impurities, will be fixed later within the framework of the procedure of the Committee. In any case, in accordance with the general principle established by the Directive, cosmetic products must never contain traces or impurities of prohibited substances in proportions such that the health of the consumer could be placed at risk.

Annex III contains, on the one hand, the list of substances accepted for the manufacture of cosmetic products up to a fixed concentration and respecting certain restrictions and, on the other hand, the list of colorants permitted in cosmetic products intended to come into contact with the mucous membranes.

Annex IV lists the substances and colorants provisionally accepted under the same restrictions as those figuring in Annex III.

Studies are in hand for these substances and colorants in order to permit their final acceptance or prohibition at the end of the three-year period provided. In the meantime, cosmetic products containing these substances and colorants within the limits and respecting the fixed restrictions benefit from the rules of free movement provided for by this Directive.

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Annex V contains a list of some substances contained in cosmetic products which are at present excluded from the scope of the Directive.

Studies relative to these substances are in progress and in the opinion of the experts consulted, a decision as to the classification of these substances could also be made within the same period of three years provided for the substances and colorants provisionally accepted.

IV. ACCEDING COUNTRIES

In the course of the formulation of the draft of this proposal for a Directive, the departments of the Commission also established technical contacts with the experts of the acceding countries. Only those of the United Kingdom made some observations of a general nature on certain provisions of the Directive and on the Annexes. The Commission has, as far as possible, taken the comments into account, especially as concerns Articles 4 and 6 of the Directive.

Certain other proposals for amendments, especially with regard to the Annexes should be able to be dealt with within the framework of the procedure of the "Committee for adaptation of the Directives to technical progress".

V. CONSULTATION OF THE EUROPEAN PARLIAMENT AND OF THE ECONOMIC AND SOCIAL COMMITTEE

The opinion of these bodies is necessary, in compliance with the provisions of Article 100(2) of the EEC Treaty.

The application of the provisions of the Directive requires an amendment of the laws of all the Member States.

PROPOSAL FOR A COUNCIL DIRECTIVE

on the approximation of the laws of the Member States relating to cosmetic products

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;

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

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

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

Whereas the provisions of the Directive relate only to cosmetic products with the exception of pharmaceutical specialities and medicaments; whereas for this purpose it is necessary to define the scope of the Directive by delimiting the field of cosmetology from that of pharmaceuticals; whereas this delimitation follows, in particular, from detailed definition of cosmetic products, which refers both to their points of application and to the purposes of their application; whereas, however, it is advisable to specify that certain products come under this definition, whilst products containing the substances figuring in Annexes III and IV beyond the limits authorized by these Annexes, and products containing substances or preparations intended to be ingested, inhaled, injected or implanted in the human body do not come under the field of cosmetology;

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

Whereas, in particular, the determination of the method of sampling and 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, and whereas it is advisable to entrust their adoption to the Commission, under 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 by subsequent Directives, in this field; whereas it is advisable, to facilitate the application of measures necessary to this end, 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 relating to the removal of technical obstacles to trade in the cosmetic products sector;

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

HAS ADOPTED THIS DIRECTIVE:

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Article 1

1. "Cosmetic product" means any substance or preparation intended to be placed in contact with various superficial 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 principally to perfume them, clean them, protect them and keep them in good condition, to change their appearance or to correct body odours.
2. Within the meaning of this definition, the products listed in Annex I to this Directive are to be considered as cosmetic products.
3. Cosmetic products containing one of the substances listed in Annex V are excluded from the scope of the Directive.

Article 2

Cosmetic products put on the market within the Community must not be capable of causing damage to human health, when they are applied as directed.

Article 3

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

Article 4

The Member States shall prohibit the marketing of cosmetic products containing:

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- (a) the substances listed in Annex II;
- (b) the substances listed in the first part of Annex III beyond the limits and outside the conditions which are fixed therein;
- (c) colorants other than those listed in the second part of Annex III and outside the limits indicated therein, if these products are intended to be applied in the vicinity of the eyes, on the lips or in the oral cavity.

Article 5

For a period of three years from notification of this Directive, the Member States shall accept marketing of cosmetic products containing:

- (a) the substances listed in the first part of Annex IV;
- (b) the colorants listed in the second part of Annex IV, if these products are intended to be applied in the vicinity of the eyes or on the lips or in the oral cavity.

Article 6

The Member States shall take all the necessary measures to ensure that cosmetic products can only be put on the market if they conform to the following packaging and labelling provisions:

1. The container or the outside packaging of cosmetic products shall bear the name and address of the manufacturer or of the packer or of the importer or of the distributor having his registered place of business within the Community;
2. The container or the outside packaging of cosmetic products shall state:
 - the net content at the time of packing expressed in legal units of measurement of the metric system;
 - the expiry date - for products which do not have an unlimited shelf life.

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3. The special precautions of use, and, in particular, those indicated in the column "Conditions of use and warnings which must appear on the label" in Annexes III and IV shall appear on the container; where this is impossible for practical reasons, these indications can appear on the outside packaging or on an enclosed leaflet, but in this case an abbreviated external indication must appear on the container, referring to the indications mentioned.
4. The use, both in the labelling and in the presentation for sale of the products covered by Article 1 and in the publicity concerning them, in whatever form this may be, of names, trademarks, images or other signs, figurative or otherwise, suggesting a characteristic which the products considered do not possess, shall be prohibited.

Article 7

1. The Member States shall not be entitled, for reasons relating to the composition, the labelling and packaging, to prohibit or hamper the marketing and use of cosmetic products which conform to the provisions of this Directive and its Annexes.
2. However, they shall be entitled to demand that the particulars required under Article 6 be expressed in their national language or languages.

Article 8

The Member States shall take the necessary measures to supervise, during marketing or, inasmuch as they consider it necessary, in the warehouses of the manufacturer, the importer or the distributor, the conformity of cosmetic products with the provisions of this Directive and its Annexes.

Article 9

1. The procedure for sampling and the analysis methods necessary for the supervision of the composition of cosmetic products are determined in accordance with the procedure provided for in Article 11.

The criteria of bacteriological purity for cosmetic products together with the supervision methods in respect of these criteria are also determined in accordance with the same criteria.

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2. The amendments necessary for the adaptation of Annexes II and III shall be adopted in accordance with the same procedure.
3. In accordance with the same procedure and on the basis of the results of scientific and technical research, the substances and colorants provisionally accepted, listed in the first and second part of Annex IV, shall at the end of the period of three years provided for in Article 5 be:
 - finally included in Annex II or in Annex III;
 - or kept for a further period of three years in Annex IV;
 - or removed from any Annex to this Directive.

Article 10

1. A Committee for adaptation to technical progress of the Directives relating to the removal of technical obstacles to trade in the cosmetic products sector shall be established, hereinafter referred to as "Committee". It shall be composed of representatives of the Member States and chaired by a representative of the Commission.
2. The Committee shall lay down its rules of procedure.

Article 11

1. In cases where reference is made to the procedure defined in this Article, the matter shall be brought before the Committee by its chairman, either on his own initiative, or at the request of the

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representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall give its opinion on this draft within a period which the chairman can fix in the light of the urgency of the question involved. It shall decide by a majority of twelve votes in accordance with the weighting laid down in Article 148(2) of the Treaty. The chairman shall not take part in the vote.
3. (a) The Commission shall lay down the proposed measures when they are in accordance with the opinion of the Committee.
(b) If the proposed measures are not in accordance with the opinion of the Committee, or in the absence of an opinion, the Commission shall forward without delay to the Council a proposal concerning the measures to be taken.

The Council shall act by a qualified majority.

- (c) If, on expiry of a period of three months from the date the matter was brought before the Council, the Council has not acted, the measures proposed shall be adopted by the Commission.

Article 12

1. If a Member State ascertains that a cosmetic product presents a danger to human health, although conforming to the provisions of this Directive and its Annexes and being used as directed, this State can, on its request and in accordance with the procedure provided for in Article 11, be provisionally authorized to restrict or prohibit on its territory the sale, circulation or use of this cosmetic product. To this end, it shall communicate to the Member States and to the Commission the measures envisaged, accompanied by a statement of grounds.

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- 2. If, on expiry of a period of 30 days from the date on which the representative of the Commission submitted a draft of measures to be taken to the Committee, no measure has been laid down, either by the Commission, or by the Council, the applicant Member State may take the measures envisaged and put them into application until such time as a decision be taken in accordance with the procedure provided in Article 11.

Article 13

Precise reasons shall be stated for any individual measure, taken pursuant to this Directive, placing a restriction or ban on the marketing of cosmetic products. It shall be communicated to the interested party together with particulars of the remedies available under the legislation in force in the Member States and of the time-limit for instituting the relevant proceedings.

Article 14

- 1. The Member States shall introduce the provisions necessary to comply with this Directive within a period of eighteen months from the notification thereof and shall so inform the Commission forthwith.
- 2. The 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 this Directive.
- 3. The Member States shall ensure that the text of such provisions of national law as they adopt in the field governed by this Directive is communicated to the Commission.

Article 15

This Directive is addressed to the Member States.

ANNEX IILLUSTRATIVE LIST BY CATEGORY OF COSMETIC PRODUCTS

- Creams, emulsions, lotions, gels and oils for the skin (hands, face, etc.).
- Face masks (with the exception of peeling products).
- Tinted bases (liquids, pastes, powders).
- Make-up powders, after-bath powders and hygienic powders.
- Beauty soaps, deodorants, etc.
- Extracts; 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 and straightening;
 - setting products;
 - cleaning products (lotions, powders, shampoos);
 - conditioning products (lotions, creams, oils);
 - hairdressing products (lotions, lacquers, brilliantines).
- Shaving, pre-shave and after-shave products.
- 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.
- Products for sunburn.
- Products for tanning without sun.
- Skin-whitening products.

ANNEX IIList of substances which cosmetic products must not contain

1. 3-acetoxy-N-allylhexahydro-1,3,4,9,10 -iminoethano-(10,4)-phenanthrene
or
3-acetoxy-N-allylmorphinane (racemic, levorotatory, dextrorotatory)
and their salts.
2. 17 Acetoxy-6'-methyl progesterone.
3. 17 Acetoxy progesterone.
4. N-acetyl-p-aminobenzene sulphonyl-n-butyl cyanamide.
5. 2-acetylamino-5-chlorobenzoxazole.
6. Acetylcholine and its salts.
7. 2-Acetylethyl-crotonyl urea.
8. N-acetylglutamate of N-dimethylamino ethanol.
9. 7' acetylthio-3,3-dioxo-2(17')-spiro(1:17 cyclopentyl-4' androstene).
10. [6-(4'-Hydroxy-3'-iodophenoxy)-3,5-diodophenyl]-acetic acid and its salts
11. 4-Amino-10-methylfolic acid and its salts.
12. 6-Aminohexanoic acid and its salts.
13. Hydrofluoric acid, its salts, its complexes and hydrofluorides,
with the exception of those given in Annex IV, Part 1.
14. 2-Phenylquinoline-4-carbonic acid, its derivatives and salts of these
derivatives (Trade names: Cinchophene, Atophane).
15. 3-(4'-Hydroxy-3'-iodophenoxy)3,5-diodophenyl]-propionic acid
and its salts.
16. Trichloroacetic acid.
17. Aconitum napellus L (Ranunculaceae) (leaves, roots and galenic
preparations).
18. Aconitine (principal alkaloid of Aconitum) and its salts.
19. Adonis vernalis (Ranunculaceae) and its galenic preparations.

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20. Adrenaline.
21. Rauwolfia (Apocynaceae) alkaloids and their salts.
22. Acetylene alcohols, their esters, ether oxides and salts.
23. 3,4-Dihydroxy- α -((isopropylamino)methyl)-benzylalcohol (Isoproterenol or Isoprenaline, Aludrine).
24. Allylisothiocyanate.
25. 2-Allyloxy-4-chloro-N-(2'-diethylaminoethyl)-benzamide and its salts.
26. N-Allylnormorphine, its salts and ether oxides (Nalorphine).
27. Stimulant amines, amphetamines and the like and their salts.
28. Aminobenzene, its salts, its halogenated and sulphonated derivatives (aniline).
29. 3-Amino-4-butoxybenzoic acid-2-(diethylamino)ethyl ester and its salts (Trade names Bethoxycaïne, Millicaine).
30. 2-Amino-5-chlorobenzoxazole (Deflexol, Flexilone, Zoxazolamine).
31. p-Amino-N-(3'-diethylaminopropyl)-benzamide and its salts.
32. p-Amino-o-chloro-N-(3'-diethylamino-ethyl)-benzamide and its salts.
33. p-Amino-N-(2-diethylaminoethyl)benzamide) and its salts (Procainamide, Novocamide).
34. p,p'-Diaminodiphenyl, Benzidine.
35. Aminoheptane, its isomers and salts.
36. 2-Amino-6-methylheptane and its salts (=2-Isooctylamine).
37. 2-Amino-1,2-bis(4-methoxyphenyl)-ethanol and its salts.
38. 2-Amino-4-methylhexane and its salts (=4-methyl-2-hexylamine) (Forthane).
39. p-Aminosalicylic acids and their salts.
40. Aminotoluenes (toluidines), their salts and halogenated and sulphonated derivatives.
41. Aminoxylenes (xylidines), their salts and halogenated and sulphonated derivatives.
42. Ammidine (imperatorine).
43. Ammi mejus and its galenic preparations.
44. Amylene chloride.
45. Substances with androgenic effect.

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- 46. Anthracene oil.
- 47. Antibiotics, with the exception of those given in Annex III.
- 48. Antimony and its organic and inorganic compounds.
- 49. Apocynum cannabinum (plants and galenic preparations).
- 50. Apomorphine and its salts.
- 51. Arsenic and its organic and inorganic compounds.
- 52. Atropa belladonna (leaves, roots, powder and galenic preparations)
- 53. Atropine, its salts and derivatives.
- 54. Bacitracine.
- 55. Barium salts, with the exception of barium sulphate, lacquers and pigments prepared from the colorants listed in Annex III, Part 2 and Annex IV, Part 2, and other adequate colorants.
- 56. Benzene.
- 57. Benzimidazolone (=N,N'-methenyl-o-phenylenediamine).
- 58. Benzazepine and dibenzazepine, their salts and derivatives.
- 59. 1-(Dimethylamino)-2-methyl-2-butanol benzoate and its salts (Amylocaine).
- 60. N-(-1-Benzoyl ethyl) diethylamine and its salts (Anorex, Dobessine).
- 61. Benzoyl-trimethyl-oxypiperidine and its salts (Eucaine).
- 62. 1-Benzyl-ethyl-methylamine and its salts.
- 63. 3-(N-Benzylhydrazinocarbonyl)-5-methyl-isoxazole (Isocarboxazide).
- 64. 1,1-Dioxo-3-benzyl-6-trifluoromethyl-3,4-dihydro-7-sulphonyl-2 H-1, 2,4-benzothiodiazine.
- 65. Beryllium, oxide and salts, powder and solution.
- 66. Bromine, elementary.
- 67. Paratoluenesulphonate of p-bromobenzylethyldimethylammonium.
- 68. Bromodiethylacetyl urea (Adaline) (Carbromal).
- 69. Bromoisovaleryl urea (Bromural) (Bromisoval).
- 70. p-bromophenylpropanol and its salts.
- 71. 1-p-bromophenyl-1-pyridyl-(2)-3-dimethylaminopropane and its salts.
- 72. Bromopivaloyl urea.
- 73. 3-Benzyloxy-1,1-diethylpyrrolidine hydrobromide (Benzilonium).

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74. N-[(4-Hydroxy-4-phenyl)-4-(2-thienyl)-butin(2)-yl] diethyl-methyl-ammonium bromide.
75. [2(3-phenylcumarone)-ethyl]-diethylmethylammonium bromide.
76. Tetraethylammonium bromide.
77. Brucine.
78. p-Butylaminobenzoyl-dimethylaminoethanol and its salts (Tetracaine), also p-butylaminobenzoic acid-2-dimethylaminoethyl ester.
79. 4-Butyl-3,5-dioxo-1-phenylpyrazolidine.
80. N-sulphonyl-p-methylbenzene N'n-butylcarbamide.
81. N¹-Sulphanilyl-N²-butyl urea (Glybutamide, Carbutamide).
82. N-n-Butyl-N-o-methoxyphenyl urea and its salts.
83. 4-Butyl-1,2-diphenyl-3,5-pyrazolidinedione (Phenylbutazone) also: 3,5-dioxo-1,2-diphenyl-4-n-butylpyrazolidine.
84. Cadmium and its compounds.
85. Cantharides (Spanish Fly), whole, powder and galenic preparations.
86. Cantharidine.
87. 1-Phenyl-1-propanolcarbamate.
88. Nitroderivatives of carbazol.
89. 1'-Carbethoxy-4-ethyleneiminocarbonyl piperazine.
90. Carbon disulphide.
91. Catalase.
92. Cephaline and its salts.
93. Chemopodium ambrosioides (ethereal oil).
94. Chloral hydrate.
95. Chlorine.
96. N-Propyl-N'-4-chlorobenzenesulphonyl urea.
97. 1,1-Dioxo-6-chloro-3-cyclopentylmethyl-7-sulphamyl-3,4-dihydro-1,2,4-benzo-thiadiazine (Cyclopenthiazide).
98. 1,1-Dioxo-6-chloro-7-sulphamyl-1,2,4-benzothiadiazine (Chlorthiazide).
99. 1,1-Dioxo-6-chloro-7-sulphamyl-3,4-dihydro-1,2,4-benzothiadiazine.
100. N-(1-Dimethylamino-propyl)-imino-diphenyl ether.
101. 1-(3-cyano-3,3-diphenylpropyl)-4-phenyl-4-piperidine-carbonic acid ethyl ester (hydrochloride).
102. 2,4-Diaminophenylazobenzenehydrochloride-citrate.
103. 5-Chlorobenzoxazolinone.
104. 2-Chloro-4-dimethylamino-6-methylpyrimidine (Crimidine).
105. 2-Chloro-9-(-dimethylaminopropylidene)-thioxanthene and its salts (trans form).

- 106. 4-Chloro-1,3-disulphamyl benzene.
- 107. Bis-(chloroethyl)-methylamine-N-oxide and its salts.
- 108. Bis-(chloroethyl)-methylamine and its salts (Chloromethine, Chloroethazine).
- 109. N,N-bis(-chloroethyl) N-O-propylenephosphoramidic anhydride and its salts (=Cyclophosphamide).
- 110. 1,6-Bis (2-chloroethylamino) 1,6-desoxymannitol and its salts.
- 111. 6-chloro-2-methyl-3-chloromethyl-7-sulphamyl-3,4-dihydro-1-benzothia-2,4-diazine-1,1-dioxide.
- 112. 2-Methyl-6-chloroanilide of n-butylamino acetic acid and its salts.
- 113. 2-(4-chlorophenyl)-3-methyl-metathiazonone-1,1-dioxide (Chloromezanone, Fenarol).
- 114. 1-(p-(2-Diethylaminoethoxy)phenyl)-1-(p-tolyl)-2-(p-chlorophenyl)-ethanol (Triparanol).
- 115. 1-[1-(4-chlorophenyl)-phenyl]-2 acetyl-1,3-dioxo indane.
- 116. 1-(p-chlorophenyl)-1-phenyl (-dimethylaminoethoxy)-ethane hydrochloride (Chlorophenoxamine, Systral).
- 117. 1-p-chlorophenyl-2-methyl-2-aminopropane and its salts.
- 118. 2-p-chlorophenyl-3-methyl-2,3-butane diol.
- 119. 1-p-chlorophenyl-1-propanol and its salts.
- 120. 3-(3'-Phenyl-2'-thiopropyl)-6-chloro-7-sulphamyl-2,3-dihydro-1,2,4-benzothiadiazine-1,1-dioxide and its salts.
- 121. 6-Chloro-3-(2-thiapentene-4-yl)-7-sulphamyl-3,4 2H-dihydro-1,2,4-benzo-(S) thiadiazine-1,1-dioxide and its salts.
- 122. Ethyl chloride.
- 123. Chromic acid and its alkali salts.
- 124. Ergot, its alkaloids and galenic preparations (*Claviceps purpurea*).
- 125. *Conium maculatum* (Umbelliferae) (Fruit, powder, galenic preparations).
- 126. N-sulphonyl-p-methylbenzene N' cyclohexylcarbamide.
- 127. Cobalt benzene sulphonate.
- 128. Colchicine, its salts and derivatives.
- 129. Colchicosides and their derivatives.
- 130. *Colchicum autumnale* (Liliaceae).
- 131. Convallariatoxine and galenic preparations.
- 132. *Cocculus indicus*.
- 133. Croton oil.

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- 134. N-p-crotonylaminobenzene sulphonyl-N'-butyl urea.
- 135. Curare and curarine.
- 136. Synthetic curarisants.
- 137. Hydrocyanic acid and its salts.
- 138. 1-Cyclohexyl-3-diethylamino-1-(2-diethylaminomethylphenyl) propane and its salts.
- 139. 2-Cyclohexyl-3,5-dimethylphenol and its salts. Common name: Cyclomenol.
- 140. 1-Hydroxymethyl-1-cyclohexyl acetic acid, Na salts.
- 141. 1-Cyclohexyl-1-propanol and its esters.
- 142. 1-Propinyl-1-cyclohexylcarbamate.

- 143. Dextropropoxyphene and its salts (= -d-4-dimethylamino-3-methyl-1,2-diphenyl-2-butanol propionate).
- 144. Diacetyl-N-allyl-normorphine.
- 145. 2-(2-Piperidinethoxy)-ethyl-10-thia-1,9-diaza-9-antracene-carboxylate and its salts (pipazetates).
- 146. 5-(1,3-dibromo-phenylethyl)-5-methyl-hydantoin.
- 147. 1,4-bis-trimethylamminumpentane-dibromide (Pentamethonium dibromide).
- 148. 1,1 cyclopentanedimethanol dicarbanilate.
- 149. 3-Methyl-3-aza-1,5-bis-(ethyl-dimethyl-ammonium)-pentane dibromide (pentamethazene dibromide)
- 150. Hexamethylene-bis(trimethylammonium bromide) (Hexamethonium bromide)
- 151. Dichlordiphenyltrichloroethane (DDT).
- 152. 2,4-Dichloro-6-phenyl phenoxyethyl-diethylamine and its salts.
- 153. Hexamethylene-bis(trimethylammonium chloride) = hexamethonium chloride.
- 154. Dichloroethane (ethylene chloride).
- 155. Dichloroethylene (acetylene chloride).
- 156. Lysergic acid diethylamide and its salts (LSD).
- 157. 2(Diethylamino)ethyl-4-phenyl-3-hydroxybenzoate and its salts.
- 158. 2-Butoxy-N-(2-diethylaminoethyl)-cinchoninamide hydrochloride and other salts (Dibucaine hydrochloride, butylcaine).
- 159. 3-diethylaminopropyl cinnamate.
- 160. Diethyl-p-nitrophenyl-thiophosphate in powder and paste form.

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161. (2'-diethylaminoethyl)-benzimidazole and its salts.
162. N,N'-bis (2-diethylaminoethyl)-oxamido-bis(2-chlorobenzyl) and its salts (Amibenonium chloride).
163. 2,5 Dioxo-3,3 diethyl-5-methyl piperidine and its salts (methylprylon).
164. 2'-diethylaminopropiophenone and its salts.
165. N-(3'-Diethylaminopropyl)-benzamide and its salts.
166. Diethyl-chloroethinyl carbinol, its salts and esters.
167. Digitalis purpurea (leaves, powder, galenic preparations).
168. Digitaline and all glycosides and heterosides of digitalis.
169. 7-(2,6-dihydroxy-4-methyl-4-aza-hexyl)-theophylline.
170. 1-(3,4-Dihydroxyphenyl)-2-ethylamino-1-propanol and its salts.
171. 1,6-Carbamoylcholine hexane dihydrate.
172. Diethylamino-ethoxyethyl--phenyl--piperidine acetate-diiodomethylate.
173. 3-Cyclopentylpropionate of dimethylaminoethyl and its salts.
174. 1-Phenyl-2,3-dimethyl-4-isopropyl-5-pyrazolone (propylphenazone).
175. 2-Oxo-3-isobutyl-9,10-dimethoxy-1,2,3,4,6,7-hexahydro-11 H-benzoquinolizine and its salts.
176. p-Butylmercaptobenzohydril--dimethylaminoethyl sulphide and its salts.
177. 4-(3,4-Dimethoxyphenyl)ethyl-1-(2-chlorophenyl)-piperazine and its salts.
178. Dimethylamine.
179. 1-Dimethylamino-2-dimethylaminomethyl-2-butanolbenzoate (Amydracaine, Alypine).
180. Methapyrilene = 2-(2-Dimethylaminoethyl)-2-thenylamino-pyridine.
181. 5-(3-Dimethylamino-2-methylpropyl)iminodibenzyl (Trimipramine).
182. 2-(Dimethylamino)-propiophenone (Metamfepyrone).
183. N-(3-Dimethylamino-1-propyl)iminostilbene and its salts.
184. 5-(--dimethylaminopropylidene)-5H-dibenzo, d -10,11-dihydrocycloheptene and its salts (Amitriptyline, Laroxyl).
185. Dimethylchloroxanthinate of phenylmethylmorpholine.
186. N,N-Dimethylguanylguanidine and its salts.

187. 1,1-Dimethyl-2-phenylethyl-amine and its salts (Phentermine).
188. 1,4,3,6-Dianhydrosorbitol-2,5-dinitrate (Isosorbitdinitrate).
189. Amlonodinitrile.
190. Succinodinitrile.
191. Dinitrophenols (all isomers).
192. 2,5-(di-n-propoxy)-di-3,6(ethylenimino)-1,4-benzoquinone.
193. 2,2-Diphenyl-4-dimethylaminovaleramide and its salts.
194. Diphenyl methyl-4-oxy-1-methylpiperidine and its salts.
195. 3,5-Dioxo-1,2-diphenyl-4-(2'-phenylsulphinyloethyl)pyrazolidine.
196. 2,2-Diphenyl-4-diisopropylaminobutyramide and its salts.
197. N-Diethylaminoethylbenzilate and its salts (Benactyzine).
198. 1-Diphenylmethyl-4-methylpiperazine (Cyclizine).
199. 3-Diphenylmethoxytropane and its salts (Benzatropine).
200. 5,5-Diphenyl-tetrahydroimidazolone-(4).
201. p-(Dipropylsulphamyl)benzoic acid.
202. Tetraethylthiuramdisulphide.
203. Emetine, its salts and derivatives.
204. Ephedrine and its salts.
205. 2-Ethyl-2,3-epoxyhexamide and its derivatives.
206. Eserine and its salts.
207. p-Aminobenzoic acid esters with free amino group, with the exception of those given in Annex III.
208. Esters of choline and lethylcholine and their salts.
209. 1-Phenylcyclopentane-1-carbonic acid diethylaminoethyl ester and its salts.
210. Phosphoric acid-(p-nitrophenyl)-diethylester.
211. 1,3-Dimethyl-4-phenyl-4-carboxyethyl-hexamethylene imine and its salts. Common name: Metethoheptazine.
212. 1-(p-Hydroxy-2-phenylethyl)-4-phenyl-4-carbomethoxy-piperidine and its salts. Common name: Oxypheneridine.
213. 1-Methyl-4-phenyl-4-carbomethoxy-hexamethylene imine and its salts. Common name: Ethoheptazine.

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214. 1,2-Dimethyl-4-phenyl-4-carbomethoxyhexamethylene imine and its salts.
Common name: Metheptazine.
215. d-Phenyl-2'-piperidyl-acetic acid methyl ester and its salts.
216. Ether oxide of 2-dimethylaminoethyl and 1-phenyl-2-pyridyl-1-ethyl and its salts.
217. Phenyl acetic ester of phenylmethylnorphyl-(N)-ethanol and its salts.
218. p-Tolyl boric acid ester of 2-methyl-2-n-propyl-1,3-propane diol.
219. Hydroquinone monobenzyl ether.
220. Diethylaminoethanol-4-ethoxybenzoate and its salts (Parathoxycaine).
221. p-Ethoxy-N-3-diethylaminopropyl)benzamide and its salts.
222. 4-Ethoxy-o-chloro-N-(-2-diethylaminoethyl)-benzamide and its salts.
223. Para(4-ethoxyethyl-amino)benzoyl-piperidine-ethanol and its salts.
224. 2-Ethylamino-3-trifluoromethyl-7-sulphamyl-3,4-dihydro-1,2,4-benzothiadiazine. Common name: Eluphenazine.
225. 5-Phenyl-2-ethylamino-4-oxazolidone.
226. 2,6-Dioxo-3-phenyl-3-ethylpiperidine and its salts.
227. Ethylene oxide.
228. 2-Ethyl-5-methylglutarimide and its salts.
229. 2-Ethyl-5-methylvaleramide.
230. 17-Ethinyl-17 α -hydroxy-3-methoxy-1,3,5(10)-oestratriene.
231. 4'-Fluoro-4-(4'-hydroxy-4-(p-chlorophenyl)-piperidino butyrophenone (Haloperidol).
232. 9 α -Fluoro-16 α -methyl-11 β , 17 α , 21-trihydroxy-3,20-dioxo-1,4-pregnane diol (Paramethasone).
233. 1-(4-Fluorophenyl)-4-[4-(2-methoxyphenyl)piperazinyl]-1-butanone.
Proposed proper name: Halosinone.
234. 1-(4-Fluorophenyl)-4-[4-(3-trifluoromethylphenyl)-4-hydroxy-piperidinyl] butanone and its salts.
235. p-Fluorophenylethylsulphone.
236. 2,4-Dioxo-5'-fluoropyrimidine (5-Fluoruracil).
237. Hydrofluoric acid (see No 13).
238. Paratoluene sulphonate of furfuryltrimethylammonium.

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239. Galanthamine and its salts (of *Galanthus woronowii*).
240. Gestagenes, apart from those listed in Annex V.
241. Hexachlorocyclohexane.
242. Hexachloro-epoxy-octahydro-endo-endo-dimethylene-naphthaline (Endrine).
243. Hexachloroethane.
244. Hexachloro-hexahydro-endo-endo-dimethylene naphthaline (Isodrine).
245. 2-Hexoxy-4-aminothiobenzoate of α -diethylaminoethyl and its salts.
246. Homatropine and its salts and derivatives.
247. Fish liver oil phosphate.
248. Hydrastine, hydrastinine and its salts (alkaloids of *Hydrastis canadensis*).
249. Hydrazides and their salts.
250. Hydrazine and its salts.
251. 2-Hydrazino-octane and its salts.
252. Hydrocortisone.
253. 1-(4'-Hydroxy-3'-cumarinyl)-1-phenyl-3-butanone and its salts.
254. 1-(4'-Hydroxycyclopentyl)-(2)-butine-(3).
255. d-Hydroxydiphenylacetate of 1-methyl-3-hydroxymethylpyrrolidine and its salts.
256. Bis-(4-Hydroxycumarinyl) acetic acid ethyl ester and salts of the acid.
257. 8-Hydroxy-7-iodo-5-nitroquinoline and its salts.
258. 3-(o-methoxyphenoxy)-2-hydroxy-1-propyl carbamate.
259. Trinitro ester of bis-2,2-hydroxymethyl-1,1-butanol. Proposed proper name: Trinetriol.
260. 1,1-Bis-(4-hydroxy-2-oxo-2H-1-benzopyran-3-yl)-3-methylthiopropane.
261. 2-(p-Hydroxyphenyl)-1,3,4-oxadiazol.
262. 8-Hydroxy-5-nitro-quinoline and its salts (including the 6-nitro salt).
263. Hyoscyamine, its salts and derivatives.
264. Hyoscyamus (leaves, seeds, powder and galenic preparations).
265. 2-Imino-5-phenyl-4-oxazolidinone and its salts.
266. Iodine.

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267. m-Hydroxyphenyldiethylamine-diethyl-carbamate - Iodomethylate.
268. Decamethylene-bis-(trimethylammonium iodide) (Decamethonium iodide).
269. Trimethylactylammonium iodide.
270. Ipecacuanha (roots, powder, galenic preparations).
271. Isopropylallylacetyl urea (Apronalide).
272. Santonine (1-santonine).
273. Lobelia (powder and galenic preparations).
274. Lobeline and its salts.
275. Derivatives of malonyl urea and its salts.
276. Mercury, its organic and inorganic compounds, with the exception of those listed in other Annexes.
277. Mescaline and its salts.
278. Metaldehyde.
279. 2-(2-Methoxy-4-allyl-phenoxy)-N,N-diethylacetamide and its salts.
280. 1-Methoxy-2,2-bis(4-hydroxy-3-cumarinyl)-ethane.
281. d-3-Methoxy-N-methylmorphinane and its salts. Proper name: Dextromethorphan.
282. 1-(3-Methoxypropyl)-3-(4-toluyyl-sulphonyl)-urea.
283. 2-Methylaminoheptane and its salts.
284. 6-Methylamino-2-methyl-2-heptene and its salts.
285. 2,2,3-trimethyl-3-methylaminonorborene and its salts.
286. 3,4-Methoxyphenoxy-1,2-propane diol.
287. 3,3-Methylene-bis(4-Hydroxycumarine) (Proper name: Bishydroxycumarine).
288. d-(3,4-Methylenedioxyphenyl)-4-aminopropane and its salts.
289. (2-Methylaminopropyl)-benzene and its salts.
290. 2-Phenyl-3-methyl-2-butanol.
291. 3-Methyl-2-phenyl-morpholine and its salts.
292. 1-Methyl-2-mercapto-imidazole.
293. (2'-Methyl-2'-methoxy-4'-phenyl)-3,4-dihydropyrancumarine (= Cyclocumarol).

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294. 2-Methyl-4-p-bromophenyl-2,4-pentane diol.
295. 3-Methyl-3-pentanol and its salts.
296. 2-(1'-Methyl-2'-piperidyl)-3-ethylindol and its salts.
297. 6-Methyl-3,5,20-pregnatriene-3,17 α ,20-trioltriacetate.
298. 2-Methyl-2-propyl-1-isopropylcarbamoyloxy-3-carbamoyloxypropane.
299. 2-Methyl-2-n-propyl-1,3-propane diol dicarbamate.
300. 1'-Methyl-2-(5,6,7,8-tetrahydronaphthyl)-4,5-dihydroimidazole and its salts.
301. N-Methyl-1,2,5,6-tetrahydro-3-nicotinic acid methyl ester (Arecoline).
302. Methyl sulphate of 2-benzyloxyloxymethyl-1,1-dimethylpyrrolidine.
303. 8-Methoxypsoralene (Ammoidine, Methoxalene).
304. N-Acetylglutaminic acid monoamide and its salts.
305. N-(4'-monochloro-diphenylmethyl)-N'-(-hydroxyethoxyethyl) piperazine.
306. α -Naphthol.
307. α and β -Naphthylamines.
308. α -Naphthyl-3-hydroxy-4-cumarine.
309. 2-Naphthyl-1-methylimidazoline (naphthazoline and its salts).
310. α -Naphthylthio urea.
311. Neostigmine and its salts.
312. Nicotine and its salts.
313. Amyl nitrite.
314. Inorganic nitrites, with the exception of sodium nitrite under the conditions of use given in Annex III.
315. Nitrobenzene
316. Nitrocresols and their alkali salts.
317. n-(5-Nitro-2-furfurylidene)-1-aminohydantoin.
318. 3-(5-Nitrofurfurylidene-amino)-2-oxazolidinone (Furozolidone).
319. Nitroglycerine.
320. 3-(4-nitrophenyl)-5-acetyloxy-4-hydroxycumarine (Acenocumarol).
321. Nitroprussiates (alkali nitroferricyanides).
322. Nitrostilbenes, their homologues and their derivatives.
323. Noradrenaline and its salts.

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324. Noscapine (old name Narcotine) and its salts.
325. 2-(1-N,N-heptamethyleneimino) ethylguanidine and its salts (Guanethidines).
326. Oestrogens, with the exception of those given in Annex V.
327. Oleandrine.
328. Ouabain (G-strophantine).
329. 1-Oxo-3-(3-sulphamoyl-4-chlorophenyl)-3-hydroxyisoindoline.
330. Poppy, papaver somniferum (capsules).
331. Pelletierine and its salts.
332. Pentachloroethane.
333. Pentaerythritol tetracarbamate.
334. Pentaerythritol tetranitrate.
335. Pentaerythritol chloral.
336. Penta-methyl-benzoyl-oxypiperidine-methyl carbonate and its salts.
337. Pentylaminomethyl heptane, its isomers and salts.
338. Phenol and its alkali salts.
339. 3-(4-Phenyl-2-acetyethyl-4-hydroxycumarine (Warfarine)).
340. Phenylacetyl urea (Phenacemide).
341. 1-Phenyl-2-aminopropane and its salts.
342. (2-Phenyl-p-chlorobenzyl-2-oxyethyl)-N-morpholine and its salts.
343. 2-Phenylethylamino-3-phenyl-1-propanol.
344. 4-(2-hydroxy-3-phenyl-p-chlorobenzyl)-pyridine.
345. 2-Phenyl-1,3-dioxoindane. Proper name: Phenindione.
346. N-(2-phenylbutyryl)-urea (Phenylethylacetyl urea).
347. Phenylhydrazine.
348. Phenylethylhydrazine and its salts. Proper name: Phenelzine.
349. 3-(2-Phenylpropyl)-4-hydroxycumarine.

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350. *o*-Phenyl-(2-pyridylamino)-ethanol. Proper name: Ferynamide.
351. 1-Phenyl-2-pyrrolidinylpentane and its salts.
352. 6-Phenyl-2,4,7-triamino-pteridine and its salts.
353. Tetraethylpyrophosphate.
354. Tricresylphosphate.
355. *o*-Phosphoryl-4-hydroxy-N,N dimethyltryptamine.
356. Inorganic phosphides.
357. 3-Phthalimido-piperidine-2,6-dione and its salts.
358. Physostigma venenosum (Calabar bean).
359. Picrotoxine.
360. Pilocarpine and its salts.
361. 2-*p*-piperidyl benzyl acetate, levorotatory threoform and its salts.
362. (2-Piperidyl)-diphenylmethanol and its salts.
363. (4-Piperidyl)-diphenylmethanol and its salts.
364. *o*-Piperidyl-diphenylmethane and its salts.
365. *o*-Piperidyl-(*o*-phenyl)-N-acetate of 2-diethylaminoethyl.
366. *o*-Piperidyl-(*o*-phenyl)-N-acetate of 2-Butoxyethyl and its salts (Butopiprin).
367. *o*-9-(2-Piperidyl)-xanthene and its salts.
368. *o*-9-(2-Piperidyl)-9-xanthydroxol and its salts.
369. Lead, its inorganic and organic compounds, with the exception of those listed in Annex IV, Part I.
370. Prednisolone and derivatives } Steroids with glucocorticoid effect.
371. Prednisone (delta cortisone) }
372. 2-Propyl-piperidine (Coniine).
373. 4-Propionylaminophenol and its salts.
374. Prunus laurocerasus (Cherry laurel).
375. *d*-Pseudococaine (Dextrocaine).
376. bis-1,2-(3-Pyridyl)-2-methylpropanone.
377. Radioactive elements, their salts and derivatives. All forms of preparation of natural and synthetic radioactive elements and their salts and derivatives, with the exception of those listed in Annex III, Part I.
378. Sabine (*Juniperus sabina*), leaves, essence (eth. oil).
379. Scopolamine, its salts and derivatives.
380. Gold salts.
381. Selenium and its inorganic and organic compounds, with the exception of those listed in Annex IV.
382. Black nightshade (*Solanum nigrum*).

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383. Extracts of the posterior lobe of the hypophysis.
384. Sparteine and its salts.
385. Steroids with glucocorticoid effect (Corticosteroids).
386. Stramonium (leaves, powder and galenic preparations).
387. Strophantines, their genines (Strophantidine) and all derivatives.
388. Strophantus (seeds and galenic preparations).
389. Strychnine and its salts.
390. Nux vomica (powder and galenic preparations). *Strychnos nux-vomica*.
391. Narcotics, natural and synthetic.
392. Sulphamides (Sulphonamides) (p-aminobenzene sulphamide and its derivatives obtained by substitution of one or more H-atoms of the NH_2 groups).
393. 2-(4'-Sulphamoyl-1'-phenyl-)-3,4,5,6-tetrahydro-1,2,S-thiazine-1,1-dioxide.
394. 1,1-Dioxo-6-trifluoro-methyl-7-sulphamyl-3,4-dihydro-1,2,4-benzothiadiazine.
395. Neodymium salt of sulphoisonicotinic acid.
396. N,N,N-Triethylene thiophosphoramidate (Tris-ethyleneimino-1-1-phosphine sulphide).
397. Jaborandi tincture.
398. Tellurium, elementary, and its organic and inorganic compounds.
399. 2-(4'-tert-butyl-2',6'-dimethylbenzyl)-imidazoline (Xylometazoline). (Otrivan) and its salts.
400. Tetrachloroethylene.
401. Carbon tetrachloride.
402. Tetrahydronorharmane ethylcarboxylate and its derivatives.
403. Hexaethyltetraphosphate.
404. Thallium salts.
405. Glucoside extract of *Thevetia neriifolia*.
406. Ethylisonicotinic acid thiaamide.
407. Alkali sulphocarbonates (thiocarbonates).
408. Acetylcholine thiocyanate (Acetylcholine rhodanate).
409. Thiodiphenylamine (Phenothiazine), its salts, compounds and derivatives.
410. 1-(Orthotoluoxy)-2,3 bis (2,2,2-trichloro-1-hydroethoxy) propane.

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411. 3-Tolyloxy-1,2-propane diol (=Cresoxypropane diol), its esters and salts. Proper name: Mephenesine.
 412. Toxines, modified or otherwise.
 413. 2-trans-phenyl-cyclopropylamine and its salts (Tranlycypromine).
 414. Triamcinolone acetamide.
 415. Trichloronitromethane (Chloropicrine).
 416. Tribromoethanol (Tribromoethyl alcohol).
 417. Tri-(β -chloroethyl)amine and its salts.
 418. 2,4,6-Triethyleneimino-1,3,5-triazine.
 419. 1,2,3-Tri-(β -diethylaminoethoxy)benzene-triiodoethylate (Gallamine triiodoethylate).
 420. *Urginea maritima* (*Scilla maritima*). Squill, powder and galenic preparations.
 421. Veratrine, its salts and galenic preparations.
 422. Hellebore (*Veratrum album*), roots and preparations.
 423. Vitamin D.
 424. Xanthates and alkali salts of the alkyl xanthates.
 425. Yohimbine and its salts.
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ANNEX IIIPart 1: List of substances which cosmetic products must not contain except subject to the restrictions laid down

Reference number	Product	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application	Maximum concentration authorized	Other limitations and requirements	
a	b	c	d	e	f
1	Oxalic acid and its alkali salts	Hair treatment products	5%		For hairdressers only
2	Trichloro-tertiary butyl alcohol (chlorobutanol)	As an antiseptic	0.5%	Prohibited in aerosols	Contains chlorobutanol
3	Ammonia		6% calculated as free ammonia gas		Above 2%: contains ammonia
4	Chloramine T		0.2%		
5	Alkaline chlorates	Toothpastes Other uses	5% 3%		
6	Methylene chloride		35% (when mixed with 1,1,1 trichloroethane, total concentration must not exceed 35%)	0.2% as maximum impurity content	For preparations in aerosol packs: Must not be used near a flame or electrical equipment with glowing elements

Annex III, Part 1

Reference number	Product	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application	Maximum concentration authorized	Other limitations and requirements	
a	b	c	d	e	f
7	Diaminobenzenes (ortho meta, para, their nitro-derivatives and their salts)	Hair treatment products	6% calculated as free base		Can cause an allergic reaction (in persons sensitive to it). Requires a patch test (behind the ear or on the inside of the elbow) at least 24 hours before application. Particulars of the method of making the patch test
8	Diamino-toluenes (ortho, meta, para), their nitro-derivatives and their salts	Hair treatment products	10% calculated as free base		Can cause an allergic reaction (in persons sensitive to it). Requires a patch test (behind the ear or on the inside of the elbow) at least 24 hours before application. Particulars of the method of making the patch test
9	Diamino-phenols	Hair treatment products	10% calculated as free base		Can cause an allergic reaction (in persons sensitive to it). Requires a patch test (behind the ear or on the inside of the elbow) at least 24 hours before application. Particulars of the method of making the patch test

ANNEX III, Part 1

Reference number	Product	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application	Maximum concentration authorized	Other limitations and requirements	
a	b	c	d	e	f
10	Hydrogen peroxide		40 Vol.%, i.e. 12% H ₂ O ₂	The actual H ₂ O ₂ content must be stated on the label	
11	Formaldehyde	a) Nail hardeners b) Used as a preservative c) Other uses prohibited	5%) calculated 0.2%) as formaldehyde		a) Protect the cuticles with grease or oil
12	Hydroquinone		2%		Do not use to dye eyelashes or eyebrows Rinse the eyes immediately if the product comes into contact with them
13	*-Naphthol	Hair dye	0.5%		Requires a patch test (behind the ear or inside the elbow) at least 24 hours before application. Particulars of the method of making the patch test
14	Sodium nitrite		0.2%		
15	Picric acid		1%		

Annex III, Part 1

Reference number	Product	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application	Maximum concentration authorized	Other limitations and requirements	
a	b	c	d	e	f
16	Caustic potash (potassium hydroxide)	a) Nail cuticle solvent b) Hair straightener c) Other uses as a neutralizer	5% calculated as free base 2% calculated as free base up to pH 11		a) Avoid contact with the eyes
17	Pyrogallol		5%		
18 (1)	Radionuclides contained in water				

(1) The presence of radionuclides by transfer from the natural background radiation or from artificial contamination of the atmosphere is permitted provided that their concentration complies with the requirements of Annex 3 of the Euratom Radioprotection Standards for drinking-water outside controlled zones.

Furthermore, the presence of natural radionuclides is permitted in certain waters and natural muds used in cosmetology provided that there is no addition to their concentration and that the total radioactive concentration is less than 100 mCg/l for natural uranium, 25 mCg/l for natural thorium and 10^{-4} mCg/l for radium-226 in respect of water; for muds, the limits can be multiplied by a factor of 10.

Annex III, Part I

Reference Number	Product	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application	Maximum concentration authorized	Other limitations & requirements	
a	b	c	d	e	f
19	Resorcine	a) Hair dyes	5%		<p>a) Can cause an allergic reaction</p> <p>Requires a patch test (behind the ear or inside the elbow) at least 24 hours before application.</p> <p>Rinse the hair well after application.</p> <p>Do not use to dye eyelashes or eyebrows.</p> <p>Rinse the eyes immediately if the product comes into contact with them.</p> <p>-----</p> <p>Particulars of the method of making the patch test</p>
		b) Hair lotions and shampoos	0.5%		<p>b) Can cause an allergic reaction</p> <p>Requires a patch test (behind the ear or inside the elbow) at least 24 hours before application.</p> <p>Rinse the hair well after application.</p> <p>-----</p> <p>Particulars of the method of making the patch test.</p>

Reference number	Product	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application	Maximum concentration authorized	Other limitations and requirements	
a	b	c	d	e	f
20	Caustic soda (sodium hydroxide)	a) Nail cuticle solvents b) Hair straightening c) In all other products as neutraliser	5% calculated as free base 2% calculated as free base Up to pH 11		a) Avoid contact with the eyes
21	Ammonium sulphide and alkali sulphide		2% in pastes up to 20% for the mono-sulphides in aqueous solution without additive		
22	Thioglycolic acid and its salts	a) Hair waving or straightening - home use - professional use b) Depilatories c) Other hair care products which are removed after application	8% pH 9.5 11% pH 9.5 5% pH 12.5 2% calculated as thio-glycolic acid		
23	Tyrothricin		0.05%	Use in products for intimate hygiene prohibited	

Annex III, Part 1

Reference number	Product	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application	Maximum concentration authorized	Other limitations and requirements	
a	b	c	d	e	f
24	Zinc (chloride and sulphate)		1% calculated as zinc		
25	Zinc phenol-sulphonate	a) Astringent in lotions b) As a deodorant in aerosols	6%		a) Keep away from the eyes during use b) Do not spray into the eyes
26	Monoglyceryl ester of para-amino-benzoic acid		5%		
27	Hexachlorophene	a) soaps b) Preparations in aerosol pack c) Other uses	1% 0.1% 0.5%		

ANNEX III

Part 2: List of colorants which can be contained in cosmetic products intended to come into contact with the mucous membranes (1) (2)
(a) Reds

Reference number	Colour index number	Schultz number	Colorant No according to EEC 1962 Directives concerning food colorants	Restrictions		
				Field of application	Maximum concentration authorized	Purity conditions
1	12,085					
2	12,490					
3	14,720					
4	14,815					
5	15,525					
6	15,580			r		
7	15,585					
8	15,630 (Ca) 15,630 (Ba) 15,630 (Sr) 15,630 (Na)				3%	
9	15,850 (Na) 15,850 (Ca)					
10	15,865					
11	15,880					
12	16,185					
13	16,255					
14	16,290					
15	45,170 45,170 Ba			r		

(1) Of course, these colorants can also have other cosmetic uses.

(2) For certain colorants, restrictions are provided which may relate to the field of application of the colorant (the letter r in the column of restrictions relative to the field of application signifies that the colorant is prohibited in the manufacture of cosmetic products which can come into contact with the mucous membranes of the eye, especially eye make-up and eye make-up removers) or to the maximum authorized concentration.

(a) Reds (continued)

Reference number	Colour index number	Schultz number	Colorant No according to EEC 1962 Directives concerning food colorants	Restrictions		
				Field of application	Maximum concentration authorized	Purity conditions
16	45,370					Adequate purity conditions including not more than 1% fluorescein and 2% monobromofluorescein
17	45,380 45,380 acid					Ditto
18	45,405			r		Ditto
19	45,410 45,410 acid					Ditto
20	45,430					
21	73,360					
22	75,470					
23	77,491					
24 (anthocyanin)		1,394	E 163			
25 (betanin)			E 162			
26 other forms of dissociation of (range 12)	45,425 acid 45,425 Na 45,425 K 45,425 NH ₄					

Annex III, Part 2

(b) Oranges and Yellows

Reference number	Colour index number	Schultz number	Colorant No according to EEC 1962 Directive concerning food colorants	Restrictions		
				Field of application	Maximum concentration authorized	Purity conditions
1	10,316			r		
2	11,920					
3	12,075					
4	13,015					
5	14,270					
6	15,510			r		
7	15,980					
8	15,985					
9	19,140					
10	45,350			r	6%	
11	47,005					
12	75,100					
13	75,120					
14	75,125					
15	75,130					
16	75,135					
17	75,300					
18	77,492					
19 orange 16			E 160 e			
20 orange 17			E 160 f			
21 orange 14			E 101			

(b) Oranges and yellows (contd.)

Reference Number	Colour index number	Schultz number	Colorant No according to EEC 1962 Directives concerning food colorants	Restrictions		
				Field of application	Maximum concentration authorized	Purity conditions
22 Orange 7	43,395				When used in lipstick, only the acid product is accepted and in a maximum authorized concentration of 1%	
23 Orange 13			E 160 c			

(c) Greens and blues

1	42,051					
2	42,090					
3	44,090					
4	69,825					
5	73,000					

Annex III, Part 2

(c) Greens and blues (contd.)

Reference number	Colour index number	Schultz number	Colorant No according to EEC 1962 Directives concerning food colorants	Restrictions		
				Field of application	Maximum concentration authorized	Purity conditions
6	73,015					
7	74,260			r		
8			E 140			
9	77,007					
10	77,346					
11	77,510					Free from cyanide ions
12 Anthraquinone blue solan- thene Blue R.S.	69,800	1228				

(d) Violets, browns, blacks and whites

1	28,440					
2	42,640					As aluminium lacquer
3	73,385					
4	77,000					
5	77,002					
6	77,005					
7	77,120					
8	77,220					
9	77,231					
10	77,266					
11	77,267					

Annex III, Part 2

(d) Violets, browns, blacks and whites (contd.)

Reference number	Colour index number	Schultz number	Colorant No according to EEC 1962 Directives concerning food colorants	Restrictions		
				Field of application	Maximum concentration authorized	Purity conditions
12	77,400					
13	77,480					
14	77,499					
15	77,713					
16	77,742					
17	77,745					
18	77,820					
19	77,891					Titanium dioxide and its mixtures with mica
20	77,947					
21 (Black 7)	77,294					
22 Guanine or pearl essence						Natural guanine
23 (White 9) Aluminium, zinc, magnesium & calcium stearates						

ANNEX IVPart 1: List of substances provisionally allowed

Reference number	Products	Restrictions		Conditions of use and warnings which must be printed on the label
		Field of application	Maximum concentration authorized	
1	Lead acetate		1.75% calculated as lead	Contains lead acetate
2	Methyl alcohol	As a denaturant for ethyl and isopropyl alcohols	5%	
3	Chloroform	Toothpastes	4%	
4	Calcium fluoride	Mouth hygiene products	0.3% calculated as fluorine. Accumulation of several fluoride additives beyond the maximum concentrations - these concentrations being calculated proportionally - is not permitted	Mention of the presence of this type of fluoride
5	Ammonium mono-fluorophosphates	Mouth hygiene products	0.2% ditto	ditto
6	Sodium mono-fluorophosphate	ditto	0.2% ditto	ditto
7	Potassium mono-fluorophosphate	ditto	0.2% ditto	ditto
8	Calcium mono-fluorophosphate	ditto	0.2% ditto	ditto
9	Sodium fluoride	ditto	0.125% ditto	ditto
10	Potassium fluoride	ditto	0.125% ditto	ditto

Annex IV, Part 1

Reference number	Product	Restrictions		Conditions of use and warnings to be printed on the label
		Field of application	Maximum concentration authorized	
11	Ammonium fluoride	Mouth hygiene products	0.125% calculated as fluorine. Accumulation of several fluoride additions beyond the maximum concentrations - these concentrations being calculated proportionally - is not permitted	Mention of the presence of this type of fluoride
12	Aluminium fluoride	ditto	0.125% ditto	ditto
13	Stannic fluoride	ditto	0.125% ditto	ditto
14	Organic fluorides	ditto	0.125% ditto	ditto
15	Sodium silicofluoride	ditto	0.125% ditto	ditto
16	Potassium silicofluoride	ditto	0.125% ditto	ditto
17	Ammonium silicofluoride	ditto	0.125% ditto	ditto
18	Magnesium silicofluoride	ditto	0.125% ditto	ditto
19	Ethylmercurithio-salicylate		0.007% calculated as the finished product. This % relates to the total content of permitted mercury derivatives	
20	Phenylmercuric and its salts		ditto	

Annex IV, Part 1

Reference number	Product	Restrictions		Conditions of use and warnings to be printed on the label
		Field of application	Maximum concentration authorized	
21	1.1.1. Trichloroethane (methyl chloroform)		35% (When mixed with methylene chloride, the total concentration must not exceed 35%)	For preparations in aerosol packs: Do not use in the vicinity of a flame or an electric appliance with exposed elements
22	Xylocaine		0.1%	

ANNEX IVPart 2: List of colorants provisionally allowed, for cosmetic products intended to come into contact with the mucous membranes(a) Reds

Reference number	Colour index number	Schultz number	Colorant No according to EEC 1962 Directives concerning food colorants	Purity conditions
1	12,120			
2	12,150			Check the skin tolerance with respect to this colorant
3	12,350			
4	12,385			
5	14,700			
6	15,500			
7	15,620			
8	15,800			
9	58,000			
10 Orcein		1,386	E 121	

(b) Oranges and yellows

1	47,000			
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(c) Greens and blues

1	42,040			
2	42,053			
3	42,140			

Annex IV, Part 2

(c) Greens and blues (contd.)

Reference number	Colour index number	Schultz number	Colorant No according to EEC 1962 Directives concerning food colorants	Purity conditions
4	42,170			
5	42,735			
6	44,040			
7	44,045			
8	61,565			
9	61,570			
10	77,288			Free from chromate ions
11	77,289			ditto

(d) Violets, browns, blacks and whites

Reference number	Colour index number	Schultz number	Colorant number according to EEC 1962 Directives concerning food colorants
1	20,170		
2	45,190		
3	60,725		
4	77,163		
5 product obtained exclusi- vely by heating sacchar- ose or other sugar			E 150