

**2003 No. 835**

**CONSUMER PROTECTION**

**The Cosmetic Products (Safety) Regulations 2003**

*Made - - - - -* 20th March 2003

*Laid before Parliament* 24th March 2003

*Coming into force (except as  
provided in regulation 1(2))* 15th April 2003

Whereas the Secretary of State has, in accordance with section 11(5) of the Consumer Protection Act 1987(a), consulted such organisations as appear to her to be representative of interests substantially affected by these Regulations, such other persons as she considers appropriate and the Health and Safety Commission;

And whereas the Secretary of State is a Minister designated(b) for the purposes of section 2 of the European Communities Act 1972(c) in relation to measures for safety and consumer protection as respects cosmetic products and any provisions concerning the composition, labelling, marketing, classification or description of cosmetic products and in relation to indication of origin on imported goods;

Now, therefore, the Secretary of State in exercise of the powers conferred on her by sections 11, 28 and 30 of the 1987 Act and by section 2(2) of the 1972 Act, hereby makes the following Regulations—

**Citation and commencement**

1.—(1) These Regulations may be cited as the Cosmetic Products (Safety) Regulations 2003 and shall come into force on 15th April 2003 other than the provisions referred to in paragraph (2) below.

(2) The following provisions of these Regulations shall come into force on 15th April 2004—

- (a) in Schedule 3, substance number 634 in Part I as amended and Part II in its entirety;
- (b) in Schedule 4, substance numbers 8, 15b, 15c, 16 and 66 in Part I as amended and Part II in its entirety; and
- (c) in Schedule 7, substance numbers 26 and 27 in Part I.

**Revocation**

2. The Regulations set out in Schedule 1 are hereby revoked, save that they continue to apply to the following substances until 15th April 2004—

- (a) substance number 631 in Schedule 1 to the Cosmetic Products (Safety) Regulations 1996(d); and
- (b) substance numbers 8, 15b, 15c and 16 in Part I of Schedule 2 to those Regulations(e).

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(a) 1987 c. 43.

(b) S.I. 1972/1811, S.I. 1975/1707 and S.I. 1993/2661.

(c) 1972 c. 68.

(d) S.I. 1996/2925. Substance number 631 is renumbered substance number 634 in Part I of Schedule 3 to these Regulations.

(e) These substances with the same numbers are situated in Part I of Schedule 4 to these Regulations.

## Interpretation

### 3.—(1) In these Regulations—

“agent” means an agent established within the Community appointed by a manufacturer of a cosmetic product to act on his behalf in relation to these Regulations;

“common ingredients nomenclature” means the labelling nomenclature designated in the inventory of ingredients employed in cosmetic products, drawn up in accordance with the provisions of the Directive and contained in Commission Decision 96/335/EC(a), as amended or substituted from time to time;

“the Community” means the European Community and other States in the European Economic Area;

“the Confidentiality Directive” means Commission Directive 95/17/EC(b);

“cosmetic ingredient” means any chemical substance or preparation of synthetic or natural origin, except for perfume and aromatic compositions, used in the composition of a cosmetic product;

“cosmetic product” means any substance or preparation intended to be placed in contact with any part of the external surfaces of the human body (that is to say, the epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours except where such cleaning, perfuming, protecting, changing, keeping or correcting is wholly for the purpose of treating or preventing disease;

“cosmetic product intended to come into contact with the mucous membranes” means a cosmetic product intended to be applied in the vicinity of the eyes, on the lips, in the oral cavity or to the external genital organs, and does not include any cosmetic product which is intended to come into only brief contact with the skin;

“the Directive” means Council Directive 76/768/EEC(c) as amended by the Community instruments set out in Schedule 2;

“EEA Agreement” means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992 as adjusted by the Protocol signed at Brussels on 17th March 1993(d);

“market research experiment” means any activities conducted for the purpose of ascertaining the opinion of persons of—

- (a) any cosmetic product;
- (b) anything in, on or with which the cosmetic product is supplied;
- (c) the appearance or any other characteristic of the cosmetic product or any such thing; or
- (d) the name or description under which the cosmetic product is supplied;

but a cosmetic product is not the subject of a market research experiment unless—

- (i) any person to whom a cosmetic product is supplied in the course of the experiment is informed, at or before the time at which it is supplied to him, that it is supplied for the purpose of a market research experiment; and
- (ii) no consideration in money or money’s worth is given by such a person for the cosmetic product or any other cosmetic product supplied to him for comparison;

“Member State” means a State which is a Contracting Party to the EEA Agreement;

“preservative” means a substance which is added to a cosmetic product for the primary purpose of inhibiting the development of micro-organisms in that product;

“supply” includes offering to supply, agreeing to supply, exposing for supply and possessing for supply, and cognate expressions shall be construed accordingly; and

“UV filter” means a substance which is added to a sunscreen cosmetic product for the primary purpose of filtering ultra violet rays for the purpose of protecting the epidermis of the user from harmful effects of such ultra violet rays.

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(a) O.J. No. L132, 1.6.96, p. 1.

(b) O.J. No. L140, 23.6.95, p. 26.

(c) O.J. No. L262, 27.9.76, p. 169.

(d) The Directive is within the scope of the EEA Agreement by virtue of Chapter XVI of Annex II to that Agreement.

(2) Unless the contrary intention appears, references in these Regulations to a numbered regulation or Schedule are references to the regulation or Schedule so numbered in these Regulations.

### **General requirements**

4.—(1) Subject to paragraph (2) below, no person shall supply any cosmetic product which is liable to cause damage to human health when it is applied under—

- (a) normal conditions of use; or
- (b) conditions of use which are reasonably foreseeable taking into account all the circumstances, including the cosmetic product's presentation, labelling, any instructions for its use and disposal and any other information or indication provided by the manufacturer, his agent or the person who supplies the cosmetic product on the first occasion that it is supplied in the Community.

(2) Paragraph (1) above shall apply only to the supply by the manufacturer in or importer into the United Kingdom or, in the case of cosmetic products manufactured or imported into the United Kingdom on behalf of another person, by that other person.

(3) The provision of any instructions, information or indication referred to in sub-paragraph (b) of paragraph (1) above shall not exempt any person from the obligation to comply with any other provisions of these Regulations which are applicable to him.

### **Particular requirements**

5.—(1) The following provisions of this regulation are without prejudice to regulation 4 and are subject to regulation 6.

(2) No person shall supply a cosmetic product which contains—

- (a) any substance listed in column 2 of Part I of Schedule 3 which is used other than as a fragrance ingredient in relation to a cosmetic product, provided that no account shall be taken of any such substance which is present only as a trace which could not reasonably have been removed during or after manufacture;
- (b) any substance listed in column 2 of Part II of Schedule 3 which is used as a fragrance ingredient in relation to a cosmetic product, provided that no account shall be taken of any such substance which is present only as a trace which could not reasonably have been removed during or after manufacture;
- (c) any substance listed in column 2 of Schedule 4, unless the requirements in columns 3, 4, 5 and (in the case of Part II) 7 of that Schedule in relation to that substance are satisfied;
- (d) any colouring agent listed in columns 1 and 2 of Schedule 5 with the exception of a cosmetic product containing a colouring agent intended solely to colour hair unless—
  - (i) the requirements in columns 3 and 4 of Part I of that Schedule in relation to that colouring agent are satisfied; or
  - (ii) the requirements in columns 3 and 4 of Part II of that Schedule in relation to that colouring agent are satisfied and the cosmetic product in question was supplied on or before the date specified in column 5 of that Part;
- (e) any colouring agent which is not listed in Schedule 5 with the exception of a cosmetic product containing a colouring agent intended solely to colour hair;
- (f) any preservative listed in column 2 of Schedule 6 unless—
  - (i) the requirements in columns 3, 4 and 5 of Part I of that Schedule in relation to that preservative are satisfied; or
  - (ii) the requirements in columns 3, 4 and 5 of Part II of that Schedule in relation to that preservative are satisfied and the preservative in question is supplied on or before the date specified in column 7 of that Part;
- (g) any preservative which is not listed in Schedule 6;
- (h) any preservative listed in column 2 of Part II of Schedule 6 after the date specified in column 7 of that Part;
- (i) any UV filter listed in column 2 of Schedule 7 unless—
  - (i) the requirements in columns 3 and 4 of Part I of that Schedule in relation to that UV filter are satisfied; or

- (ii) the requirements in columns 3 and 4 of Part II of that Schedule in relation to that UV filter are satisfied and the UV filter in question is supplied on or before the date specified in column 6 of that Part; or
- (j) any UV filter which is not listed in Schedule 7.

(3) Subject to paragraphs (4) to (6) below, no person shall supply a cosmetic product which contains any of the substances designated as a specified risk material in Annex V to Regulation (EC) No. 999/2001 of the European Parliament and of the Council<sup>(a)</sup>, or any ingredient derived from any of those substances.

(4) For the purposes of paragraph (3) above, no account shall be taken of any substance referred to in that paragraph which is present in the cosmetic product only as a trace which could not reasonably have been removed during or after manufacture.

(5) Paragraph (3) above shall not prohibit the supply of a cosmetic product which contains any tallow derivative so long as the relevant method set out in Schedule 8 was used in the manufacture of that derivative and the manufacturer of the derivative has certified that that method was used in its manufacture.

(6) Paragraph (3) above shall not prohibit the supply of any cosmetic product which contains any substance or ingredient referred to in that paragraph but which was manufactured before 1st April 1998.

(7) No person shall supply a cosmetic product which contains any ingredients or combinations of ingredients which are tested on animals where such testing took place after 30th June 2002 and was undertaken in order that the cosmetic product may satisfy any requirements of these Regulations.

(8) Any reference to testing on animals in the labelling, putting up for sale or advertising of a cosmetic product must state clearly whether the tests carried out involved the cosmetic product itself or its ingredients.

(9) No person shall supply any cosmetic product in respect of which the requirements of paragraph (8) above are not satisfied.

#### **Authorisation by the Secretary of State**

**6.—**(1) The Secretary of State may authorise the use in a cosmetic product for a maximum period of three years of a particular substance, not being a substance or ingredient referred to in regulation 5(3) or a substance listed in Schedule 3 or 4.

(2) In giving an authorisation the Secretary of State may impose conditions relating to the use of a particular substance in a cosmetic product, and such conditions may relate to any matter which the Secretary of State considers appropriate including—

- (a) the purpose of the substance;
- (b) the type of cosmetic product;
- (c) the maximum concentration of the substance in any cosmetic product; and
- (d) information and marking requirements.

(3) The Secretary of State may on reasonable notice vary or revoke any authorisation given under paragraph (1) above.

(4) On giving, varying or revoking an authorisation, the Secretary of State shall arrange for the authorisation, variation or revocation, as the case may be, to be published in such manner as she considers appropriate for bringing it to the attention of persons who, in her opinion, would be likely to have an interest in it.

(5) No person shall be convicted of an offence under section 12 of the 1987 Act by reason of a cosmetic product containing a particular substance provided that at the time when but for this regulation an offence would have been committed—

- (a) the use of that particular substance in that cosmetic product was duly authorised; and
- (b) all of the conditions imposed by the authorisation were complied with.

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(a) O.J. No. L147, 31.5.01, p. 1.

## Marking

7.—(1) Subject to paragraphs (5)(b) and (9) to (12) below, no person shall supply a cosmetic product unless the packaging in which it is supplied bears, in lettering which is visible, indelible and easily legible, a list of its cosmetic ingredients (preceded by the word “ingredients”) in descending order of weight, the weight to be determined at the time the ingredients are added to the product.

(2) Subject to paragraphs (3), (4), (5)(a), (6) to (8), (13) and (14) below, no person shall supply a cosmetic product unless the container and packaging in which it is supplied bear the following particulars in lettering which is visible, indelible and easily legible—

- (a) the name or trade name and the address or registered office of the manufacturer of the product or of the supplier thereof, being a manufacturer or supplier established within a Member State of the Community;
- (b) in the case of a cosmetic product likely within 30 months from the manufacture thereof to cease either to comply with the requirements of regulation 4 or to fulfil the purpose for which it was intended, the words “Best before...” immediately followed by—
  - (i) the earliest date on which it is likely to so cease; or
  - (ii) an indication of where that date appears on the labelling,and any particular precautions to be observed to ensure that the product does not so cease before that date;
- (c) in the case of a cosmetic product containing a substance listed in column 2 of Schedule 4, the information specified in column 6 of that Schedule in relation to that substance;
- (d) in the case of a cosmetic product containing a preservative listed in column 2 of Schedule 6, the information specified in column 6 of that Schedule in relation to that preservative;
- (e) in the case of a cosmetic product containing a UV filter listed in column 2 of Schedule 7, the information specified in column 5 of that Schedule in relation to that UV filter;
- (f) any particular precautions to be observed in use and any special precautionary information on a cosmetic product for professional use, in particular in hairdressing (not being precautions included in the information referred to in sub-paragraphs (b), (c), (d) and (e) above);
- (g) a means of identifying the batch in which the product was manufactured (or, if the product was not manufactured in a batch, a reference from which the date and place of manufacture can be identified); and
- (h) the function of the product unless this is clear from its presentation;

Provided that the requirements specified in sub-paragraphs (b) and (g) above need not be complied with in relation to a cosmetic product which is the subject of a market research experiment.

(3) The particulars referred to in paragraph (2)(a) above may be abbreviated if such abbreviation does not prevent the person concerned from being identified.

(4) The date referred to in paragraph (2)(b) above shall include the month and the year, and the month shall precede the year.

(5) The particulars referred to—

- (a) in paragraph (2)(b) to (f) and (h) above shall be in English, but this shall not prohibit the additional use of other languages;
- (b) in paragraph (1) above shall be in language easily understood by the consumer.

(6) Where it is impossible for practical reasons for the particulars referred to in paragraph (2)(c) to (f) above to appear on the container and packaging, they shall appear on a leaflet, label, tag, tape or card enclosed with the cosmetic product, to which the consumer is referred either by abbreviated information or by the symbol given in Schedule 9, which must appear on the container and packaging; and where it is impracticable for reasons of size or shape for the particulars so to appear, they shall appear on a label, tag, tape or card attached to the product.

(7) Where it is impossible, for reasons of size, for the particulars referred to in paragraph (2)(g) above to appear on the container and packaging, the said particulars shall appear on the packaging.

(8) In the case of a supply of soap which is not in a container, either the soap itself or the packaging in which it is exposed for supply or the container in which it was last contained before the supply shall bear the particulars referred to in paragraph (2)(a) and (g) above, and in so far as any of the particulars referred to in paragraph (2)(b) to (f) and (h) above are required they shall appear on a leaflet which shall be delivered to the buyer with the soap; and where either of the particulars referred to in paragraph (2)(a) and (g) above appears on the soap itself the requirement of indelibility shall apply only until it has been put into use.

(9) In relation to the compilation of the list of ingredients referred to in paragraph (1) above—

- (a) the following shall not be regarded as cosmetic ingredients—
  - (i) impurities in the raw materials used;
  - (ii) subsidiary technical materials used in the preparation of the cosmetic product but not present in the final product;
  - (iii) materials used in strictly necessary quantities as solvents or as carriers for perfumes and aromatic compositions;
- (b) perfume and aromatic compositions and their raw materials shall be referred to by the words “perfume” or “flavour”;
- (c) ingredients in concentrations of less than 1 per cent may be listed in any order after those in concentrations of 1 per cent or more;
- (d) colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination found in Schedule 5;
- (e) for decorative cosmetic products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the words “may contain” are added; and
- (f) an ingredient shall be identified by the name provided for in the International Nomenclature of Cosmetic Ingredients (INCI) or, in the absence of such identification, by its chemical name, its CTFA name, its European Pharmacopoeia name, its International Non-proprietary Name (INN) as recommended by the World Health Organization, its EINECS, IUPAC or CAS identification reference or its colour index number<sup>(a)</sup>.

(10) Subject to paragraph (11) below, where a cosmetic product has no packaging or it is impossible for practical reasons for the list of ingredients referred to in paragraph (1) above to appear on the packaging, the list shall appear on the container; and where a cosmetic product is supplied or delivered pursuant to any supply in neither a container nor packaging, the list shall appear on the container in which the product is exposed for supply or a notice in immediate proximity to that container.

(11) Subject to paragraph (12) below, where it is impossible for practical reasons for the list of ingredients referred to in paragraph (1) above to appear on the packaging or container of a cosmetic product, it shall appear on a leaflet, label, tag, tape or card enclosed with the product, to which the consumer is referred either by abbreviated information or by the symbol given in Schedule 9, which must appear on the packaging; and where it is impracticable for reasons of size or shape for the list so to appear, it shall appear on a label, tag, tape or card attached to the cosmetic product.

(12) In the case of soap, bathballs and other small products, where it is impracticable for reasons of size or shape for the list of ingredients referred to in paragraph (1) above to appear on an enclosed leaflet or on a label, tag, tape or card enclosed with or attached to the product, it shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.

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(a) An ingredient’s CTFA name is the name given to it by the Cosmetics, Toiletries and Fragrances Association (CTFA) and listed in the ninth edition of the International Cosmetic Ingredient Dictionary Handbook published in 2002. Its EINECS identification reference is the reference given in the European Inventory of Existing Commercial Chemical Substances. Its IUPAC identification reference is the reference given by the International Union of Pure and Applied Chemistry. Its CAS identification reference is the reference assigned by the Chemical Abstracts Service. An ingredient’s colour index number is the number specified in the third edition of The Colour Index published in 1971 by the Society of Dyers and Colourists. European Pharmacopoeia names, International Non-proprietary Names and EINECS, IUPAC and CAS identification references are listed in Commission Decision 96/335/EC (O.J. No. L132, 1.6.96, p. 1.).

(13) Where two or more cosmetic products are supplied together as a single item, each product being in a separate container and the containers being enclosed together in packaging which bears clear and conspicuous instructions to the effect that the products must be mixed together in specified proportions before use, the particulars referred to in paragraph (2)(c) to (f) above shall appear on an enclosed leaflet and an indication shall appear on both the containers and on the packaging referring the consumer to the information in the leaflet.

(14) Where a cosmetic product other than soap is supplied or delivered pursuant to a supply in neither a container nor packaging, the particulars referred to in paragraph (2) above shall appear on the container in which the product is exposed for supply or a notice in immediate proximity to that container.

### **Responsible Persons and Competent Authorities**

8.—(1) For the purposes of regulations 9 (except regulation 9(3) and (4)), 10, 11 and 12—

- (a) “responsible person” means, in relation to a relevant cosmetic product,
  - (i) the manufacturer of that product;
  - (ii) the manufacturer’s agent;
  - (iii) the person to whose order that cosmetic product is manufactured; or
  - (iv) where the manufacturer or the person to whose order the cosmetic product is manufactured is not established in the Community and either—
    - (aa) the manufacturer has not appointed an agent; or
    - (bb) the manufacturer’s agent is not the supplier of that cosmetic product, the person who first supplies the cosmetic product in the Community;
- (b) “competent authority” means a body responsible for requiring and receiving the information provided for in Articles 7.3, 7a.1 and 7a.4 of the Directive and granting and refusing requests for confidentiality pursuant to Article 4 of the Confidentiality Directive, and which is—
  - (i) a United Kingdom competent authority pursuant to paragraph (2) below; or
  - (ii) for the time being a competent authority of a Member State other than the United Kingdom, having been notified as a competent authority by the Member State concerned to the Commission pursuant to Articles 7.3 and 7a.5 of the Directive and Article 10 of the Confidentiality Directive.

(2) The United Kingdom competent authority shall be the Secretary of State provided that she may from time to time appoint such persons as she thinks fit to be a United Kingdom competent authority in addition to or in substitution for herself.

### **Product Information**

9.—(1) Subject to paragraph (6) below, where a cosmetic product is manufactured or supplied in the United Kingdom a responsible person shall for control purposes keep readily accessible to a United Kingdom competent authority at the address or registered office specified on the container or packaging of the cosmetic product in accordance with regulation 7(2)(a) above the following information—

- (a) the qualitative and quantitative composition of the product, except to the extent that the product is composed of any perfume or perfume composition, in which case the responsible person shall only be required to keep the name and code number of the perfume or perfume 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 which shall be in accordance with good manufacturing practice, that is to say that the cosmetic product shall be manufactured in such a way that under normal and reasonably foreseeable conditions of use it shall not endanger human health or safety;
- (d) assessment of the safety for human health of the finished product taking into consideration the general toxicological profile of each ingredient used, its chemical structure and its level of exposure;

- (e) the name and address of the person or persons, qualified in accordance with paragraph (3) below, responsible for the assessment referred to in sub-paragraph (d) above;
- (f) existing data on undesirable effects on human health resulting from use of the cosmetic product; and
- (g) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product.

(2) The assessment referred to in paragraph (1)(d) above shall be carried out in accordance with the principles of good laboratory practice referred to in Article 1 of Council Directive 87/18/EEC(a) on the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.

(3) The person referred to in paragraph (1)(e) above must be—

- (a) subject to paragraph (4) below, the holder of an appropriate European diploma within the meaning of section 4A of the Pharmacy Act 1954(b) or any other person who has the right, granted by a competent authority in a Member State, to take up and pursue the activities of a pharmaceutical chemist;
- (b) subject to paragraph (4) below, a person who is entitled to be registered under section 3(1) of the Medical Act 1983(c) as a fully registered medical practitioner and who has the right, granted by a competent authority in a Member State, to take up and pursue the activities of a doctor; or
- (c) the holder of a diploma within the meaning of regulation 2(1) of the European Communities (Recognition of Professional Qualifications) Regulations 1991(d) showing that the holder has the qualifications required to practise as a chartered biologist or that he has the qualifications required to practise as a chartered chemist or that he has the qualifications required to practise a profession equivalent to the profession of chartered biologist or chartered chemist in a Member State other than the United Kingdom.

(4) Any diploma or other evidence of qualification required for the purposes of paragraph (3)(a) or (b) above shall satisfy that requirement only if—

- (a) the education and training attested were received mainly within the European Community; or
- (b) the holder has spent at least three years in lawful pursuit in a Member State of the relevant profession, and such professional experience has been certified by a competent authority in a Member State (being a State which recognised a diploma or other evidence of qualification obtained in a non-Member State).

(5) Where the responsible person is the manufacturer or the person who first imports the cosmetic product into the Community he must possess appropriate experience or an appropriate level of professional qualification in accordance with the legislation and practice of the United Kingdom if it is the place of manufacture or first importation.

(6) Where the manufacturer manufactures a cosmetic product at two or more places within the Community, and one of those places is within the United Kingdom, the responsible person may choose a single place of manufacture within the Community where the information referred to in paragraph (1) above will be kept available, provided that, if requested by a United Kingdom competent authority, he informs the said authority of the location at which the said information is to be kept.

(7) Where the information referred to in paragraph (1) above is to be kept accessible to a United Kingdom competent authority it must be in English or a language readily understood by the said authority.

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(a) O.J. No. L15, 17.1.87, p. 29, implemented by the Notification of New Substances (Amendment) Regulations 1991 (S.I. 1991/1914). Article 1 was amended by Commission Directive 1999/11/EC (O.J. No. L77, 23.3.99, p. 8.), implemented by the Good Laboratory Practice Regulations 1999 (S.I. 1999/3106).

(b) 1954 c. 61.

(c) 1983 c. 54.

(d) S.I. 1991/824, to which there is an amendment not relevant to these Regulations.



**10.** Where the place of manufacture or initial importation into the Community of a type of cosmetic product is within the United Kingdom, the responsible person shall notify a United Kingdom competent authority of the address of the place of manufacture or, as the case may be, initial importation into the Community of that type of cosmetic product before its first supply in the Community.

**11.—(1)** A United Kingdom competent authority may, where difficulties are encountered in providing prompt and appropriate medical treatment, require that any holder of appropriate and adequate information on substances used in cosmetic products make such information available to it, where the difficulties referred to may be overcome or eased by the provision of the said information.

(2) Where the information referred to in paragraph (1) above is made available, the United Kingdom competent authority shall ensure that it is used solely for the purposes of the treatment referred to in paragraph (1) above.

**12.—(1)** Without prejudice to the provisions of regulations 4, 5, 9 and 11, a responsible person who for reasons of trade secrecy wishes not to include one or more cosmetic ingredients in the list of cosmetic ingredients referred to in regulation 7(1) above shall submit a request to that effect to the competent authority.

(2) In this regulation, “applicant” means a responsible person who submits a request for confidentiality.

(3) The applicant shall ensure that—

(a) the request for confidentiality includes the particulars laid down in Part I of Schedule 10; and

(b) any amendments to the particulars provided for in sub-paragraph (a) above are communicated as quickly as possible to the competent authority and, in particular, that all changes to the names of cosmetic products containing the cosmetic ingredient in respect of which confidentiality is or has been sought, are communicated to the competent authority at least 15 days before those cosmetic products are supplied under their new name.

(4) Within four months of the receipt of a request for confidentiality in respect of which the requirements of paragraph (3)(a) above are satisfied, the competent authority shall examine the request and inform the applicant in writing of its decision.

(5) If the competent authority decides to grant its approval to the applicant’s request it shall, in notifying the applicant of its decision, in accordance with paragraph (4) above, also notify him of the registration number which will replace the cosmetic ingredient in question in the list referred to in regulation 7(1), the said number to be allocated to the product in accordance with the procedure provided for in Part II of Schedule 10.

(6) If the competent authority decides to refuse to grant its approval to the applicant’s request it shall, in its notification of this refusal, include a statement of the reasons for refusal and a clear explanation of appeals procedures and their time limits.

(7) In exceptional cases the competent authority may inform the applicant in writing that a period of two months in addition to the four-month period referred to in paragraph (4) above is required for the examination of the request.

(8) Subject to paragraphs (9), (10), (11) and (12) below, a decision granting confidentiality shall be valid for a period of five years.

(9) An applicant may, by submitting a reasoned request to the competent authority, request that the period of confidentiality referred to in paragraph (8) above be extended.

(10) In the event of a reasoned request being submitted in accordance with paragraph (9) above, the competent authority shall deal with the request in accordance with paragraphs (4), (5) and (6) above.

(11) Any extension of the period of confidentiality shall not exceed three years.

(12) The competent authority may withdraw its approval to an applicant’s request for confidentiality if it considers this appropriate taking into account—

(a) any amendments to the particulars provided for in paragraph (3)(a) above which are communicated to it in accordance with paragraph (3)(b) above; and

(b) any new information which comes to its attention which makes it imperative, particularly for compelling reasons of public health, for it to so act, and in withdrawing its approval the competent authority shall comply with the provisions of paragraphs (4), (6) and (7) above.

#### **Contravention of regulation 9, 10 or 11**

**13.**—(1) Subject to paragraph (2) below, any contravention of a requirement of regulation 9, 10 or 11 shall be treated for all purposes as though it were a contravention of a requirement of safety regulations made under section 11 of the 1987 Act.

(2) The term of imprisonment to which a person guilty of an offence of contravening any requirement of regulation 9, 10 or 11 shall be liable on summary conviction shall not exceed three months.

#### **Enforcement**

**14.**—(1) No proceedings shall be brought and no enforcement action taken in respect of—

- (a) any failure to comply with regulations 4, 5, 7, 9, 10 and 11 in any case in which the cosmetic product is supplied for the purposes of exporting that product to any country which is not a Member State; or
- (b) any failure to comply with regulation 7(5)(a) in any case in which the enforcement authority is satisfied that the person supplying the cosmetic product reasonably believes that it will not be used in the United Kingdom.

(2) No proceedings shall be brought and no enforcement action taken in respect of any failure to comply with regulations 5(8), 5(9), 7(1), 7(2)(h), 7(5)(a) (in so far as it relates only to regulation 7(2)(h)), 7(5)(b), 7(6), 7(7) or 7(9) to (12) in the case of—

- (a) any supply of a cosmetic product before 31st December 1997 by the manufacturer in or importer into the United Kingdom or, in relation to a cosmetic product manufactured or imported into the United Kingdom on behalf of another person, by that other person, except for a supply by retail in which case no proceedings shall be brought and no enforcement action taken in respect of a supply before 31st December 1998; or
- (b) any other supply of a cosmetic product before 31st December 1998.

(3) For the purposes of this regulation, “enforcement action” means any action taken pursuant to or in connection with sections 13, 14, 16, 17, 28, 29, 30 or 31 of the 1987 Act.

**15.** Any test of goods purchased under section 28 or seized under section 29 of the 1987 Act (which relate to enforcement) by or on behalf of an enforcement authority for the purpose of ascertaining whether the provisions of these Regulations have been contravened shall in all cases be carried out in accordance with the provisions of paragraphs 2 to 5 of Schedule 11 and any test for which a method is specified in paragraph 6 of Schedule 11 shall be carried out in accordance with that method.

*Melanie Johnson,*  
Parliamentary Under Secretary of State for  
Competition, Consumers and Markets,  
Department of Trade and Industry

20th March 2003

SCHEDULE 1  
REVOCATIONS

Regulation 2

<i>(1)</i> <i>Regulations revoked</i>	<i>(2)</i> <i>References</i>
The Cosmetic Products (Safety) Regulations 1996	S.I. 1996/2925
The Cosmetic Products (Safety) (Amendment) Regulations 1997	S.I. 1997/2914
The Cosmetic Products (Safety) (Amendment) Regulations 1998	S.I. 1998/1727
The Cosmetic Products (Safety) (Amendment) Regulations 1999	S.I. 1999/1552
The Cosmetic Products (Safety) (Amendment) Regulations 2000	S.I. 2000/1679
The Cosmetic Products (Safety) (Amendment) (No. 2) Regulations 2000	S.I. 2000/2765

SCHEDULE 2

Regulation 3(1)

COMMUNITY INSTRUMENTS AMENDING COUNCIL DIRECTIVE  
76/768/EEC

1. Council Directive 82/368/EEC (O.J. No. L167, 15.6.82, p. 1).
2. Commission Directive 82/147/EEC (O.J. No. L63, 6.3.82, p. 26).
3. Commission Directive 83/191/EEC (O.J. No. L109, 26.4.83, p. 25).
4. Commission Directive 83/341/EEC (O.J. No. L188, 13.7.83, p. 15).
5. Council Directive 83/574/EEC (O.J. No. L332, 28.11.83, p. 38).
6. Commission Directive 83/496/EEC (O.J. No. L275, 8.10.83, p. 20).
7. Commission Directive 84/415/EEC (O.J. No. L228, 25.8.84, p. 31).
8. Commission Directive 85/391/EEC (O.J. No. L224, 22.8.85, p. 40).
9. Commission Directive 86/179/EEC (O.J. No. L138, 24.5.86, p. 40).
10. Commission Directive 86/199/EEC (O.J. No. L149, 3.6.86, p. 38).
11. Commission Directive 87/137/EEC (O.J. No. L56, 26.2.87, p. 20).
12. Commission Directive 88/233/EEC (O.J. No. L105, 26.4.88, p. 11).
13. Council Directive 88/667/EEC (O.J. No. L382, 31.12.88, p. 46).
14. Commission Directive 89/174/EEC (O.J. No. L64, 8.3.89, p. 10).
15. Council Directive 89/679/EEC (O.J. No. L398, 30.12.89, p. 25).
16. Commission Directive 90/121/EEC (O.J. No. L71, 17.3.90, p. 40).
17. Commission Directive 91/184/EEC (O.J. No. L91, 12.4.91, p. 59).
18. Commission Directive 92/8/EEC (O.J. No. L70, 17.3.92, p. 23).
19. Commission Directive 92/86/EEC (O.J. No. L325, 11.11.92, p. 18).
20. Commission Directive 93/47/EEC (O.J. No. L203, 13.8.93, p. 24).
21. Council Directive 93/35/EEC (O.J. No. L151, 23.6.93, p. 32).
22. Commission Directive 94/32/EC (O.J. No. L181, 15.7.94, p. 31).
23. Commission Directive 95/34/EC (O.J. No. L167, 18.7.95, p. 19).
24. Commission Directive 96/41/EC (O.J. No. L198, 8.8.96, p. 36).
25. Commission Directive 97/18/EC (O.J. No. L114, 1.5.97, p. 43).
26. Commission Directive 97/45/EC (O.J. No. L196, 24.7.97, p. 77).

27. Commission Directive 98/16/EC (O.J. No. L77, 14.3.98, p. 44).
28. Commission Directive 98/62/EC (O.J. No. L253, 15.9.98, p. 20).
29. Commission Directive 2000/6/EC (O.J. No. L56, 1.3.00, p. 42).
30. Commission Directive 2000/11/EC (O.J. No. L65, 14.3.00, p. 22).
31. Commission Directive 2000/41/EC (O.J. No. L145, 20.6.00, p. 25).
32. Commission Directive 2002/34/EC (O.J. No. L102, 18.4.02, p. 19).
33. Commission Directive 2003/1/EC (O.J. No. L5, 10.1.03, p. 14).
34. Commission Directive 2003/16/EC (O.J. No. L46, 20.2.03, p. 24).

### SCHEDULE 3

Regulations 5(2) and 6(1)

#### LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN

The alphabetical list set out in column 2 of this Schedule contains one or more of the names of each of the substances referred to in regulation 5(2); in certain cases a name is given of a group of substances, the names of particular examples of which are also given, and in such a case all substances comprised in the group are included, whether or not more specifically named.

The numbers given in columns 1, 3 and 4 are for information only. Those in column 3 are cross-references to other names listed for the same substances (except that where a name is that of a group of substances, the cross-references are to particular examples of that group, and any cross-reference in parenthesis is to the name of a group of substances within which the particular substance falls). Those in column 4 are cross-references to Annex II of the Directive, from which this Schedule is derived.

#### PART I

#### SUBSTANCES PROHIBITED WHEN USED OTHER THAN AS A FRAGRANCE INGREDIENT

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
1	Acenocoumarol (INN)	397	254
2	Acetonitrile	—	393
3	3-( <i>a</i> -Acetylbenzyl)-4-hydroxycoumarin and its salts	399, 762	203
4	2-Acetoxyethyltrimethylammonium hydroxide and its salts	6	2
5	2-Acetylamino-5-chlorobenzoxazole	163	1
6	Acetylcholine and its salts	4	2
7	Acetylene chlorides	250, 759	126
8	Acetylenic alcohols, their esters, ethers and salts	17	16
9	Acetyletyltetramethyltetralin (AETT)	342	362
10	7 $\alpha$ -Acetylthio-3-oxopregn-4-ene-17 $\alpha$ ,17 $\beta$ -propionolactone	652	4
11	Aconitine and its salts	—	12
12	<i>Aconitum napellus</i> L. (leaves, roots and galenical preparations)	—	11
13	<i>Adonis vernalis</i> L. and its preparations	—	13
14	Adrenaline	270, 315	14
15	Alkali pentacyanonitrosylferrate(2-)	605-6, 647-8,	255
16	<i>O</i> -Alkyldithiocarbonic acids, salts of	763	336
17	Alkyne alcohols, their esters, ethers and salts	8	16
18	Alloclamide (INN) and its salts	22	19
19	Allyl isothiocyanate	—	18

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
20	2-(4-Allyl-2-methoxyphenoxy)- <i>N,N</i> -diethylacetamide and its salts	—	224
21	<i>N</i> -Allylnormorphine, its salts and ethers	494	20
22	2-Allyloxy-4-chloro- <i>N</i> -[2-(diethylamino)-ethyl]benzamide and its salts	18	19
23	Alypine and its salts	45, 107	143
24	Ambenonium chloride (INN)	(529)	132
25	4-(or <i>p</i> -)Aminobenzoic acid esters	—	167
26	2-Amino-1,2-bis(4-methoxyphenyl)ethanol and its salts	—	29
27	Aminocaproic acid (INN) and its salts	31	7
28	2-Amino-5-chlorobenzoxazole	769	24
29	4-Amino- <i>N</i> -(2-diethylaminoethyl)benzamide, its salts and derivatives	610	25
30	Aminoheptane, its isomers and salts	751	25
31	6-Aminohexanoic acid and its salts	27	7
32	<i>α</i> -(Aminomethyl)-3,4-dihydroxybenzyl alcohol and its salts	519-520	257
33	4-Amino- <i>N</i> <sup>10</sup> -methylfolic acid	452	6
34	2-Amino-6-methylheptane and its salts	288, 525	28
35	2-Amino-4-methylhexane and its salts	289, 471	30
36	2-Amino-4-nitrophenol	—	383
37	2-Amino-5-nitrophenol	—	384
38	4-Amino-2-nitrophenol	—	412
39	4-(or <i>p</i> -)Aminosalicylic acid and its salts	—	31
40	Aminotoluenes, their isomers, salts and halogenated and sulphonated derivatives	719	32
41	Aminoxylenes, their isomers, salts and halogenated and sulphonated derivatives	765	33
42	Amitriptyline (INN) and its salts	284	146
43	<i>Ammi majus</i> and its galenical preparations	—	35
44	Amphetamine (INN), its salts and derivatives and salts of those derivatives	(681)	21
45	Amydracaine and its salts	23, 107	143
46	Amylene chloride	251	36
47	Amyl 4-dimethylaminobenzoate, mixed isomers	534	381
48	Amyl nitrites	—	247
49	Amylobarbitone and its salts	(69)	220
50	Amylocaine and its salts	282	50
51	<i>Anamirta cocculus L.</i> (fruit)	—	106
52	Substances with androgenic effect	—	37
53	Aniline, its salts and halogenated and sulphonated derivatives	—	22
54	Anthracene oil	—	38
55	Anti-androgens with steroid structure	—	390
56	Antibiotics	—	39
57	Antimony and its compounds	—	40
58	<i>Apocynum cannabinum L.</i> and its preparations	—	41
59	Apomorphine and its salts	697	42
60	Apronalide	420	216
61	Arecoline	482	238
62	Aristolochic acid and its salts	—	365
63	Arsenic and its preparations	—	43
64	<i>Atropa belladonna L.</i> and its preparations	—	44

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
65	Atropine, its salts and derivatives	—	45
66	Azacyclonol (INN) and its salts	305	286
67	Azamethonium bromide (INN)	(473)	121
68	Barbitone and its salts	(69)	220
69	Barbiturates	various	220
70	Barium salts (except barium sulphate, barium sulphide under the condition laid down in Part I of Schedule 4 for alkaline earth sulphides, and lakes, salts and pigments prepared from those colouring agents identified in column 1 of Schedule 5 by “*” immediately after the name or colour index number)	—	46
71	Bemegrade (INN) and its salts	337, 338	183
72	Benactyzine (INN)	258	157
73	Bendrofluazide and its derivatives	74, 89	53
74	Bendroflumethiazide (INN) and its derivatives	73, 89	53
75	Benzamine and its salts	744	51
76	Benzatropine (INN) and its salts	301	158
77	Benzazepines, their salts and derivatives	88	49
78	Benzene	—	47
79	Benzene-1,2-diol	152, 630	408
80	Benzene-1,2,3-triol	631	409
81	2-Benzhydroxyethyl dimethylamine and its salts	296	339
82	Benzidine	243	26
83	Benzilium bromide (INN)	93	60
84	2-Benziloyloxymethyl-1,1-dimethylpyrrolidinium methyl sulphate	602	239
85	Benzimidazolone	86, 267	48
86	Benzimidazol-2(3 <i>H</i> )-one	85, 267	48
87	Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol (except natural content of essences)	211	357
88	Benzodiazepines, their salts and derivatives	77	49
89	Benzothiadiazine and its derivatives	73, 74	53
90	Benzoyl peroxide	—	382
91	3-( <i>N</i> -Benzylhydrazinocarbonyl)-5-methylisoxazole	415	52
92	Benzylideneacetone	567	356
93	3-Benzylloxy-1,1-diethylpyrrolidine hydrobromide	83	60
94	4-Benzylloxyphenol	(391), 487	178
95	2-[Benzyl- <i>N</i> -2-pyridyl]amino]ethyl dimethylamine	626, 748	347
96	Bergapten(e) (except natural content of essences). In sun protection and in bronzing products, furocoumarins content shall be below 1 mg/kg	(357)	358
97	Beryllium and its compounds	—	54
98	Betamethasone (INN)	(361)	300
99	Betoxycaine (INN) and its salts	257	23
100	BHC (ISO) ( <i>gamma</i> -BHC)	370, 372, 428	195
101	Bietamiverine (INN)	261	287
102	1,6-Bis(2-chloroethylamino)-1,6-dideoxymannitol and its salts	436	89
103	2-[Bis(2-chloroethyl)amino]-1-oxa-3-aza-2-phosphacyclohexane 2-oxide and its salts	106, 231	88
104	<i>N,N</i> -Bis(2-chloroethyl)methylamine and its salts	159, 492	87

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
105	<i>N,N</i> -Bis(2-chloroethyl)methylamine <i>N</i> -oxide and its salts	493	86
106	<i>N,N</i> -Bis(2-chloroethyl)-1,3,2-oxazaphosphinan-2-ylamine <i>P</i> -oxide and its salts	103, 231	88
107	1,1-Bis(dimethylaminomethyl)propyl benzoate and its salts	23, 45	143
108	Bis(hydroxyalkyl)amines, not further <i>N</i> -substituted	255, 274, 643	411
109	2,2-Bis(hydroxymethyl)butan-1-ol trinitrate	616	206
110	2,6-Bis( $\beta$ -hydroxyphenethyl)-1-methylpiperidine and its salts	430	219
111	3,3-Bis(4-hydroxyphenyl)phthalide	560	417
112	Bis(8-hydroxyquinolinium) sulphate, except for the uses provided for in entry number 51 in Part 1 of Schedule 4	(401, 533)	395
113	Bithionol (INN)	708	352
114	Bretylum tosilate (INN) (Bretylum tosylate)	117	56
115	Bromine, elemental	—	55
116	Bromisoval (INN)	119	58
117	<i>p</i> -Bromobenzylethyldimethylammonium <i>p</i> -toluenesulphonate	114	56
118	2-Bromo-2-ethylbutyrylurea	148	57
119	2-Bromo-3-methylbutyrylurea	116	58
120	1- <i>p</i> -Bromophenyl-1-(2-pyridyl)-3-dimethylaminopropane and its salts	121	59
121	Brompheniramine (INN) and its salts	120	59
122	Brucine	—	62
123	Butanilcaine (INN) and its salts	466	90
124	Butobarbitone and its salts	(69)	220
125	Butopiprine (INN) and its salts	127	288
126	2-Butoxy- <i>N</i> -(2-diethylaminoethyl)-cinchoninamide and its salts	190	129
127	2-Butoxyethyl phenyl(piperidino)acetate and its salts	125	288
128	1-Butyl-3-( <i>N</i> -crotonoylsulphanilyl)urea	—	108
129	4-Butyl-1,2-diphenylpyrazolidine-3,5-dione	566	67
130	4- <i>tert</i> -Butyl-3-methoxy-2,6-dinitrotoluene	490	414
131	4-Butyl-1-phenylpyrazolidine-3,5-dione	486	64
132	1-Butyl-3-( <i>p</i> -methylbenzenesulphonyl)urea	718	65
133	1-Butyl-3-sulphanilylurea	149	66
134	4-Butylthiobenzhydryl 2-(dimethylamino)ethyl sulphide	142	140
135	1- <i>tert</i> -Butyl-3,4,5-trimethyl-2,6-dinitrobenzene	491	422
136	Cadmium and its compounds	—	68
137	Calabar bean	588	281
138	Calciferol	317, (761)	335
139	Cantharides, <i>Cantharis vesicatoria</i>	650	69
140	Cantharidin	379	70
141	Captan (ISO)	737	370
142	Captodiame (INN)	134	140
143	Caramiphen (INN) and its salts	570	169
144	<i>N</i> -(3-Carbamoyl-3,3-diphenylpropyl)- <i>N,N</i> -diisopropylmethylammonium salts	419	156
145	Carbazole, nitroderivatives of	510	72
146	Carbon disulphide	—	73
147	Carbon tetrachloride	693	315

(1)	(2)	(3)	(4)
<i>Number in this Schedule</i>	<i>Name of substance</i>	<i>Cross-reference to this Schedule</i>	<i>Cross-reference to Annex II of the Directive</i>
148	Carbromal (INN)	118	57
149	Carbutamide (INN)	133	66
150	Carisoprodol (INN)	480	235
151	Catalase	—	74
152	Catechol	79, 630	408
153	Cells, tissues or products of human origin	—	416
154	Cephaeline and its salts	—	75
155	<i>Chenopodium ambrosioides</i> (essential oil)	—	76
156	Cherry laurel water	621	291
157	Chloral hydrate	735	77
158	Chlorine	—	78
159	Chlormethine (INN) and its salts	104, 492	87
160	Chlormezanone (INN)	174	91
161	4-Chlorobenzene-1,3-disulfonamide	193	85
162	5-Chloro-1,3-benzoxazol-2(3 <i>H</i> )-one	185	82
163	<i>N</i> -5-Chlorobenzoxazol-2-ylacetamide	5	1
164	2-Chloro-4-dimethylamino-6-methylpyrimidine	168, 216,	83
165	2-Chloro-9-[3-(dimethylamino)-propylidene]thioxanthene ( <i>cis</i> -form) and its salts	182	84
166	Chloroethane	328	96
167	Chloroform	736	366
168	2-Chloro-6-methylpyrimidin-4-yl dimethylamine	164, 216	83
169	Chlorophacinone (ISO)	175	93
170	1-( <i>p</i> -Chloro- $\infty$ -phenylbenzyl)-4-(2-hydroxyethoxyethyl)piperazine	402	240
171	2-(4-Chlorophenyl)-1-[4-(2-diethyl aminoethoxy)]phenyl-1- <i>p</i> -tolylethanol	747	92
172	4-[4-(4-Chlorophenyl)-4-hydroxypiperidin-1-yl]-1-(4-fluorophenyl)butan-1-one	369	185
173	2-(4-Chlorophenyl)-3-methylbutane-2,3-diol	554	95
174	2-(4-Chlorophenyl-3-methyl-1,3-thiazinan-4-one 1,1-dioxide	160	91
175	2[2-(4-Chlorophenyl)-2-phenylacetyl]indane-1,3-dione	169	93
176	2-[1-(4-Chlorophenyl)-1-phenylethoxy]ethyl-(dimethyl)amine	179	94
177	Chloropicrin	738	325
178	3-(4-Chloro-3-sulphamoylphenyl)-3-hydroxyisoindolin-1-one	183, 184	262
179	Chlorphenoxamine (INN)	176	94
180	Chlorpromazine (INN)	(561)	320
181	Chlorpropamide (INN)	617	79
182	Chlorprothixene (INN) and its salts	165	84
183	Chlortalidone (INN)	178, 184	262
184	Chlorthalidone	178, 184	262
185	Chlorzoxazone (INN)	162	82
186	Cholecalciferol	(761)	335
187	Choline salts and their esters	—	168
188	Chromium, chromic acid and salts of the acid	—	97
189	Chrysoidine citrate hydrochloride	565	81
190	Cinchocaine (INN) and its salts	126	129
191	Cincophen (INN), its salts and derivatives and salts of those derivatives	580	8



(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
192	<i>Claviceps purpurea Tul.</i> , its alkaloids and galenical preparations	318	98
193	Clofenamide (INN)	161	85
194	Clofenotane (INN)	734	123
195	Coal tar, crude and refined	218	420
196	Cobalt benzenesulphonate	—	101
197	Cocculin	592	282
198	Colchicine, its salts and derivatives	—	102
199	Colchicoside and its derivatives	—	103
200	<i>Colchicum autumnale L.</i> and its galenical preparations	—	104
201	Colouring agent CI 12075 and its lakes, pigments and salts	—	397
202	Colouring agent CI 12140	—	378
203	Colouring agent CI 13065	—	387
204	Colouring agent CI 15585	—	401
205	Colouring agent CI 26105	—	379
206	Colouring agent CI 42535	—	388
207	Colouring agents CI 42555, 42555:1 and 42555:2	—	380
208	Colouring agent CI 42640	—	386
209	Colouring agent CI 45170 and CI 45170:1	—	398
210	Colouring agent CI 61554	—	389
211	Coniferyl benzoate (except natural content of essences)	87	357
212	Coniine	618	290
213	<i>Conium maculatum L.</i> (fruit, powder, galenical preparations)	—	99
214	Convallatoxin	—	105
215	Coumetarol (INN)	454	225
216	Crimidine (ISO)	164, 168	83
217	<i>Croton tiglium</i> (oil)	—	107
218	Crude and refined coal tars	195	420
219	Curare and curarine	—	109
220	Curarizants, synthetic	—	110
221	1-(3-Cyano-3,3-diphenylpropyl)-4-ethoxycarbonyl-4-phenylpiperidinium chloride	297	80
222	Cyclarbamate (INN)	230	122
223	Cyclizine (INN) and its salts	302	159
224	Cyclobarbitone and its salts	(69)	220
225	Cyclocoumarol	268	234
226	2- <i>a</i> -Cyclohexylbenzyl( <i>N,N,N',N'</i> -tetraethyl)trimethylenediamine	555	112
227	2-Cyclohexyl-3,5-dimethylphenol and its salts	229	113
228	Cyclohexyl-3-( <i>p</i> -methylbenzenesulphonyl)urea	364	100
229	Cyclomenol (INN) and its salts	227	113
230	Cyclopentane-1,1-dimethanol dicarbanilate	222	122
231	Cyclophosphamide (INN) and its salts	103, 106	88
232	<i>Datura stramonium L.</i> and its galenical preparations	54	301
233	DDT (ISO) ( <i>pp'</i> -DDT)	194, 734	123
234	Deanol aceglumate (INN)	279	3
235	Decamethonium bromide (INN)	(236)	214
236	Decamethylenebis(trimethylammonium) salts	235	214
237	Dextromethorphan (INN) and its salts	457	226
238	Dextropropoxyphene (INN)	281	116

(1)	(2)	(3)	(4)
<i>Number in this Schedule</i>	<i>Name of substance</i>	<i>Cross-reference to this Schedule</i>	<i>Cross-reference to Annex II of the Directive</i>
239	<i>O, O'</i> -Diacetyl- <i>N</i> -allyl- <i>N</i> -normorphine	—	117
240	2,4-Diaminoanisole and its salts	455, 461	376
241	2,5-Diaminoanisole and its salts	456, 460	377
242	1,2-Diaminobenzene and its salts	573	363
243	<i>p,p'</i> -Diaminodiphenyl	82	26
244	2-(2,4-Diaminophenyl)ethanol and its salts	—	407
245	1,4:3,6-Dianhydrosorbitol 2,5-dinitrate	422	148
246	5-( <i>a,B</i> -Dibromophenethyl)-5-methylhydantoin	—	119
247	Dibromosalicylanilides	248, 443	351
248	Dibromsalan (INN)	(247)	351
249	Dichloroethanes	330, 335	125
250	Dichloroethylenes	7, 759	126
251	2,3-Dichloro-2-methylbutane	46	36
252	Dichlorosalicylanilides	—	349
253	Dicoumarin	254, 469	231
254	Dicoumarol (INN)	253, 469	231
255	Diethanolamine	(108, 643)	411
256	2-(Diethylaminoethoxy)ethyl- <i>a</i> -phenylpiperidine-1-acetate dimethiodide	601	137
257	2-Diethylaminoethyl 3-amino-4-butoxybenzoate and its salts	99	23
258	2-Diethylaminoethyl benzilate	72	157
259	2-Diethylaminoethyl 4-ethoxybenzoate and its salts	411, 538	179
260	2-Diethylaminoethyl 3-hydroxy-4-phenylbenzoate and its salts	—	128
261	2-Diethylaminoethyl phenyl(piperidino)acetate	101	287
262	3-Diethylaminopropyl cinnamate	—	130
263	Diethyl 4-nitrophenyl phosphate	536	170
264	<i>O, O</i> -Diethyl <i>O</i> -4-nitrophenyl phosphorothioate	537	131
265	Difenclozazine (INN)	569	270
266	Digitaline and all heterosides of <i>Digitalis purpurea L.</i>	—	134
267	4,5-Dihydrobenzimidazol-4-one	85, 86	48
268	3,4-Dihydro-2-methoxy-2-methyl-4-phenyl-2 <i>H</i> ,5 <i>H</i> -pyrano[3,2- <i>c</i> ]-[1]-benzopyran-5-one	225	234
269	Dihydrotachysterol (INN)	-	342
270	3,4-Dihydroxy- <i>a</i> -(methylaminomethyl)benzyl alcohol	14, 315	14
271	4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene)dicoumarin	-	207
272	1-(3,4-Dihydroxyphenyl)-2-ethylaminopropan-1-ol and its salts	294	136
273	1-(3,4-Dihydroxyphenyl)-2-isopropylaminoethanol	418, 421	17
274	Diisopropanolamine	(108, 643)	411
275	5,5'-Di-isopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihydroiodide	413	361
276	Dimethoxane	286	368
277	4-[2-(3,4-Dimethoxyphenyl)ethyl]-1-(2-chlorophenyl)piperazine and its salts	438	141
278	Dimethylamine	-	142
279	2-Dimethylaminoethyl <i>N</i> -acetylglutamate	234	3
280	2-Dimethylaminoethyl <i>p</i> -butylaminobenzoate and its salts	690	63
281	(+)-4-Dimethylamino-3-methyl-1,2-diphenyl-2-propionyloxybutane	238	116

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
282	1-Dimethylaminomethyl-1-methylpropyl benzoate and its salts	50	50
283	2-Dimethylaminopropiophenone and its salts	445	145
284	3-(3-Dimethylaminopropylidene)-1,2:4,5-dibenzocyclohepta-1,4-diene and its salts	42	146
285	1,1-Dimethylbiguanide and its salts	447	147
286	2,6-Dimethyl-1,3-dioxan-4-yl acetate	276	368
287	Dimethylformamide	-	355
288	1,5-Dimethylhexylamine and its salts	34, 525	28
289	1,3-Dimethylpentylamine and its salts	35, 471	30
290	Dimethyl sulfoxide (INN)	—	338
291	Dimevamide (INN) and its salts	298	153
292	Dinitrophenol isomers	—	151
293	Dioxane	—	343
294	Dioxethedrin (INN) and its salts	272	136
295	2,5-Dioxo-3,3-diethyl-5-methylpiperidine and its salts	483	133
296	Diphenhydramine (INN) and its salts	81	339
297	Diphenoxylate hydrochloride (INNM)	221	80
298	2,2-Diphenyl-4-dimethylaminovaleramide and its salts	291	153
299	5,5-Diphenyl-4-imidazolidone	—	160
300	4-Diphenylmethoxy-1-methylpiperidine and its salts	306	154
301	3-Diphenylmethoxytropane and its salts	76	158
302	1-Diphenylmethyl-4-methylpiperazine and its salts	223	159
303	1,2-Diphenyl-4-(2-phenylsulphinylethyl)-pyrazolidine-3,5-dione	664	155
304	<i>a,a</i> -Diphenyl-2-piperidinemethanol and its salts	600	285
305	<i>a,a</i> -Diphenyl-4-piperidinemethanol and its salts	66	286
306	Diphenylpyraline (INN) and its salts	300	154
307	2,5-Dipropoxy-3,6-bis(ethyleneimino)-1,4-benzoquinone	410	152
308	4-Dipropylsulphamoylbenzoic acid	609	161
309	Disulfiram (INN)	702, 713	162
310	Dithio-2,2'-bis(pyridine 1-oxide) 1,1' (additive with trihydrated magnesium sulphate)	628	396
311	Doxylamine (INN) and its salts	579	176
312	Emetine, its salts and derivatives	—	163
313	Endrin (ISO)	373	196
314	Ephedrine and its salts	—	164
315	Epinephrine (INN)	14, 270	14
316	1,2-Epoxybutane	—	400
317	Ergocalciferol (INN)	138 (761)	335
318	Ergot and its alkaloids	192	98
319	Eserine and its salts	589	166
320	Ethionamide (INN)	336	319
321	Ethoheptazine (INN) and its salts	476	173
322	Ethopropazine and its salts	(561)	320
323	4-Ethoxyphenol	(391)	178
324	4-Ethoxy- <i>m</i> -phenylenediamine and its salts	—	406
325	2-Ethylamino-5-phenyloxazolin-4-one	345	180
326	Ethyl bis(4-hydroxycoumarinyl)acetate and salts of the acid	327	204
327	Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl)acetate and salts of the acid	326	204

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
328	Ethyl chloride	166	96
329	Ethyl 1,3-dimethyl-4-phenylazepane-4-carboxylate and its salts	446	171
330	Ethylene dichloride	(249)	125
331	Ethylene oxide	—	182
332	2-Ethyl-2,3-epoxyhexamide and its derivatives	530	165
333	Ethyl <i>p</i> -fluorophenyl sulphone	348	189
334	Ethyl 1-(2-hydroxy-2-phenylethyl)-4-phenylpiperidine-4-carboxylate and its salts	532	172
335	Ethylidene dichloride	(249)	125
336	3-Ethylisothionicotinamide	320	319
337	3-Ethyl-3-methylglutarimide and its salts	71, 338	183
338	4-Ethyl-4-methylpiperidine-2,6-dione and its salts	71, 337	183
339	2-Ethyl-3-methylvaleramide	755	184
340	Ethylphenacemide	556, 568	272
341	2-Ethyl-2-phenylglutarimide and its salts	362	181
342	3'-Ethyl-5',6',7',8'-tetrahydro-5',5',8',8'-tetramethyl-2'-acetonephthone	9	362
343	Ethyl urocanate	(406)	418
344	Fenadiazole (INN)	528	208
345	Fenozolone (INN)	325	180
346	Fenylramidol (INN)	578, 582	274
347	Fluanisone (INN)	351	187
348	Fluoresone (INN)	333	189
349	4'-Fluoro-4-[4-hydroxy-4-( <i>a,a,a</i> -trifluoro- <i>m</i> -tolyl)piperino]butyrophenone	741	188
350	6-Fluoro-16-methyl-11 $\beta$ ,17 $\alpha$ ,21-trihydroxypregna-1,4-diene-3,20-dione	535	186
351	1-(4-Fluorophenyl)-4-[4-(2-methoxyphenyl)-1-piperazinyl]butan-1-one	347	187
352	5-Fluoropyrimidine-2,4-dione	353	190
353	Fluorouracil (INN)	352	190
354	Fluphenazine (INN)	(561)	320
355	Furazolidone (INN)	513	252
356	Furfuryltrimethylammonium salts	358	192
357	Furocoumarins (except natural content of essences). In sun protection and in bronzing products, furocoumarins content shall be below 1 mg/kg	96, 462, 623, 746	358
358	Furtrethonium iodide (INN)	(356)	192
359	Galantamine (INN)	—	193
360	Gallamine triethiodide (INN)	518	329
361	Glucocorticoids	98	300
362	Glutethimide (INN) and its salts	341	181
363	Glycerol trinitrate	514, 615	253
364	Glycyclamide (INN)	228	100
365	Gold salts	—	296
366	Guaifenesin (INN)	459	230
367	Guanethidine (INN) and its salts	368	259
368	<i>N</i> -(2-Guanidinoethyl)azocane and its salts	367	259
369	Haloperidol (INN)	172	185
370	HCH (ISO) ( <i>gamma</i> -HCH)	100, 372, 428	195
371	HETP	378	316

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
372	1,2,3,4,5,6-Hexachlorocyclohexane	100, 370, 428	195
373	(1 <i>R</i> ,4 <i>S</i> ,5 <i>R</i> ,8 <i>S</i> )-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4:5,8-dimethanonaphthalene	313	196
374	Hexachloroethane	—	197
375	3,3',4,4',6,6'-Hexachloro-2,2'-methylenediphenol	376	371
376	Hexachlorophene (INN)	375	371
377	(1 <i>R</i> ,4 <i>S</i> ,5 <i>R</i> ,8 <i>S</i> )-1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-1,4:5,8-dimethanonaphthalene	416	198
378	Hexaethyl tetraphosphate	371	316
379	(1 <i>R</i> ,2 <i>S</i> )-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride	140	70
380	(3 <i>S</i> ,5a <i>R</i> ,9b <i>S</i> )-3,3a,4,5,5a,9b-Hexahydro-3,5a,9-trimethylnaphtho[1,2- <i>b</i> ]furan-2,8dione	639	217
381	Hexamethonium bromide (INN)	(382)	124
382	<i>N</i> - <i>N'</i> -Hexamethylenebis(trimethylammonium) salts	381	124
383	Hexapropymate (INN)	619	115
384	Hydrastine, hydrastinine and their salts	—	199
385	Hydrazides and their salts	—	200
386	Hydrazine, its derivatives and their salts	—	201
387	2-Hydrazino-octane and its salts	523	202
388	Hydrocyanic acid and its salts	390, 409, 604	111
389	Hydrofluoric acid, its normal salts, complexes and hydrofluorides (except those listed in Part I of Schedule 4)	—	191
390	Hydrogen cyanide and its salts	388, 409, 604	111
391	Hydroquinone monobenzyl, monoethyl and monomethyl ethers	487	178
392	7-[2-Hydroxy-3-(2-hydroxyethyl- <i>N</i> -methylamino)propyl]theophylline	764	135
393	[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl] acetic acid and its salts	742	5
394	3-[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]propionic acid and its salts	716	9
395	2-Hydroxy-3-(2-methoxyphenyl)propyl carbamate	450	205
396	1-Hydroxymethyl-1-cyclohexylacetic acid, sodium salt	646	114
397	4-Hydroxy-3-[1-(4-nitrophenyl)-3-oxobutyl]coumarin	1	254
398	8-Hydroxy-5-nitroquinoline and its salts	517	209
399	4-Hydroxy-3-(3-oxo-1-phenylbutyl)coumarin and its salts	3, 762	203
400	11a-Hydroxypregn-4-ene-3,20-dione and its esters	—	385
401	Hydroxy-8-quinoline and its sulphate, except for the uses provided for in entry number 51 in Part I of Schedule 4	112, 533, 633	395
402	Hydroxyzine (INN)	170	240
403	Hyoscine, its salts and derivatives	641	295
404	Hyoscyamine, its salts and derivatives	—	210
405	<i>Hyoscyamus niger</i> L. (leaves, seeds, powder and galenical preparations)	—	211
406	3-Imidazol-4-ylacrylic acid and its ethyl ester	343, 753	418
407	2-Imino-5-phenyloxazolidin-4-one and its salts	540	212
408	Imperatorin	465	34

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
409	Inorganic cyanides	(388, 390), 604	111
410	Inproquone (INN)	307	152
411	Intracaine and its salts	259, 538	179
412	Iodine	—	213
413	Iodothymol	275	361
414	Ipecacuanha ( <i>Cephaelis ipecacuanha</i> Brot. and related species) (roots, powder and galenical preparations)	—	215
415	Isocarboxazid (INN)	91	52
416	Isodrin	377	198
417	Isometheptene (INN) and its salts	463	228
418	Isoprenaline (INN)	273, 421	17
419	Isopropamide iodide (INN)	(144)	156
420	(2-Isopropylpent-4-enoyl)urea	60	216
421	Isoproterenol	273, 418	17
422	Isosorbide dinitrate (INN)	245	148
423	<i>Juniperus sabina</i> L. (leaves, essential oil and galenical preparations)	—	294
424	<i>Laurus nobilis</i> L. (oil from seeds)	—	359
425	Lead and its compounds (except lead acetate subject to the restrictions laid down in entry number 55 in Part I of Schedule 4)	—	289
426	Levophacetoperane and its salts	597	284
427	Lidocaine (INN) (Lignocaine)	—	399
428	Lindane	100, 370, 372	195
429	<i>Lobelia inflata</i> L. and its galenical preparations	—	218
430	Lobeline (INN) and its salts	110	219
431	LSD	(433, 434)	127
432	Lupinidine and its salts	651	299
433	Lysergic acid diethylamide and its salts	431, 434	127
434	Lysergide (INN) and its salts	431, 433	127
435	Malononitrile	—	149
436	Mannomustine (INN) and its salts	102	89
437	Mecamylamine (INN)	701	229
438	Mefeclozazine (INN) and its salts	277	141
439	Mephenesin (INN) and its esters	721	322
440	Meprobamate (INN)	481	236
441	Mercury and its compounds (except those listed in Part I of Schedule 6)	—	221
442	Mescaline and its salts	743	222
443	Metabromsalan (INN)	(247)	351
444	Metaldehyde	603	223
445	Metamfepramone (INN) and its salts	283	145
446	Metethoheptazine (INN) and its salts	329	171
447	Metformin (INN) and its salts	285	147
448	Methapyrilene (INN) and its salts	627	144
449	Metheptazine (INN) and its salts	468	174
450	Methocarbamol (INN)	395	205
451	Methohexitone and its salts	(69)	220
452	Methotrexate (INN)	33	6
453	2-[4-Methoxybenzyl- <i>N</i> -(2-pyridyl)amino]-ethylidimethylamine maleate	625	346
454	1-Methoxy-2,2-bis(4-hydroxy-3-coumarinyl)ethane	215	225

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
455	1-Methoxy-2,4-diaminobenzene and its salts	240, 461	376
456	1-Methoxy-2,5-diaminobenzene and its salts	241, 460	377
457	(+)-3-Methoxy- <i>N</i> -methylnorphinan and its salts	237	226
458	4-Methoxyphenol	(391)	178
459	3-(2-Methoxyphenoxy)propane-1,2-diol	366	230
460	2-Methoxy- <i>p</i> -phenylenediamine and its salts	241, 456	377
461	4-Methoxy- <i>m</i> -phenylenediamine and its salts	240, 455	376
462	Methoxypsoralens (except natural content of essences). In sun protection and in bronzing products, furocoumarins content shall be below 1 mg/kg	(357)	358
463	6-Methylamino-2-methylhept-2-ene and its salts	417	228
464	2-Methyl-1,2-bis(3-pyridyl)propan-1-one	484	292
465	9-(3-Methylbut-2-enyloxy)furo-[3,2- <i>g</i> ]chromen-7-one	408	34
466	2-Methyl-6-chloroanilide of <i>n</i> -butylaminoacetic acid and its salts	123	90
467	1-Methyl-2,4-diaminobenzene and its salts	477	364
468	Methyl 1,2-dimethyl-4-phenylazepane-4-carboxylate and its salts	449	174
469	3,3-Methylenebis-(4-hydroxycoumarin)	253, 254	231
470	2-Methylheptylamine and its salts	—	227
471	4-Methyl-2-hexylamine and its salts	35, 289	30
472	1-Methylimidazole-2-thiol	474, 707	233
473	<i>N,N'</i> -[(Methylimino)diethylene] bis- (ethyl)dimethylammonium salts	67	121
474	1-Methyl-2-mercaptoimidazole	472, 707	233
475	Methylphenidate (INN) and its salts	575	175
476	1-Methyl-4-phenyl-4-carbethoxyhexa-methyleneimine and its salts	321	173
477	4-Methyl- <i>m</i> -phenylenediamine and its salts	467	364
478	2-Methyl- <i>m</i> -phenylenediamine	—	413
479	3-Methyl-2-phenylmorpholine, its derivatives and salts	558	232
480	2-Methyl-2-propyl-1-isopropylcarbamoxyloxy-3- carbamoxyloxypropane	150	235
481	2-Methyl-2-propyltrimethylene dicarbamate	440	236
482	<i>N</i> -Methyl-1,2,5,6-tetrahydro-3-nicotinic acid methyl ester	61	238
483	Methyprylon (INN) and its salts	295	133
484	Metyrapone (INN)	464	292
485	Minoxidil (INN), its salts and derivatives	599	372
486	Mofebutazone (INN)	131	64
487	Monobenzene (INN)	94, (391)	178
488	Morpholine and its salts	—	344
489	Moskene	546	421
490	Musk ambrette	130	414
491	Musk tibetene	135	422
492	Mustine and its salts	104, 159	87
493	Mustine <i>N</i> -oxide and its salts	105	86
494	Nalorphine (INN), its salts and ethers	21	20
495	Naphazoline (INN) and its salts	501	244
496	2-Naphthol	497	241
497	$\beta$ -Naphthol	496	241
498	1- and 2-Naphthylamines and their salts	499	242
499	$\alpha$ - and $\beta$ -Naphthylamines and their salts	498	242

(1)	(2)	(3)	(4)
<i>Number in this Schedule</i>	<i>Name of substance</i>	<i>Cross-reference to this Schedule</i>	<i>Cross-reference to Annex II of the Directive</i>
500	3-(1-Naphthyl)-4-hydroxycoumarin	—	243
501	2-(1-Naphthylmethyl)-2-imidazoline and its salts	495	244
502	Narcotics, natural and synthetic: All substances listed in Tables I and II of the Single Convention on Narcotic Drugs 1961 (Treaty Series No. 34 (1965), Cmnd. 2631)	—	306
503	Narcotine and its salts	521	258
504	Neodymium and its salts	—	309
505	Neostigmine and its salts	—	245
506	Nicotine and its salts	—	246
507	Nitrites, inorganic (except sodium nitrite)	—	248
508	Nitrobenzene	—	249
509	Nitrocresols and their alkali metal salts	—	250
510	Nitroderivatives of carbazole	145	72
511	Nitrofurantoin (INN)	512	251
512	<i>N</i> -(5-Nitro-2-furfurylidene)-1-aminohydantoin	511	251
513	3-(5-Nitrofurfurylideneamino)oxazolidin-2-one	355	252
514	Nitroglycerine	363, 615	253
515	Nitrosamines	—	410
516	Nitrostilbenes, their homologues and derivatives	—	256
517	Nitroxoline (INN) and its salts	398	209
518	<i>N,N,N,N',N',N',N'',N'',N''</i> -Nonaethyl-2,2',2''-(benzene-1,2,3-triyltrioxy)-tris(ethanaminium) triiodide	360	329
519	Noradrenaline and its salts	32, 520	257
520	Norepinephrine (INN) and its salts	32, 519	257
521	Noscapine (INN) and its salts	503	258
522	Nux vomica and its preparations	(661)	305
523	Octamoxin (INN) and its salts	387	202
524	Octamylamine (INN) and its salts	—	267
525	Octodrine (INN) and its salts	34, 288	28
526	Oestrogens	—	260
527	Oleandrin	—	261
528	2-(1,3,4-Oxadiazol-2-yl)phenol	344	208
529	[Oxaly]bis(iminoethylene)]bis[( <i>o</i> -chlorobenzyl)diethylammonium] salts	24	132
530	Oxamide (INN) and its derivatives	332	165
531	2-Oxo-3-isobutyl-9,10-dimethoxy-1,2,3,4,6,7-hexahydro-11b <i>H</i> -benzo[ <i>a</i> ]quinolizine and its salts	688	139
532	Oxpheneridine (INN) and its salts	334	172
533	Oxyquinoline and its sulphate, except for the uses provided for in entry number 51 in Part I of Schedule 4	112, 401, 633	395
534	Padimate A	47	381
535	Paramethasone (INN)	350	186
536	Paraoxon	263	170
537	Parathion (ISO)	264	131
538	Parethoxycaine (INN) and its salts	259, 411	179
539	Pelletierine and its salts	598	263
540	Pemoline (INN) and its salts	407	212
541	Pentachloroethane	—	264
542	Pentaerythritol chloral	552	266
543	Pentaerythritol tetranitrate	544, 551	265
544	Pentaerythrityl tetranitrate (INN)	543, 551	265
545	Pentamethonium bromide (INN)	(547)	120
546	1,1,3,3,5-Pentamethyl-4,6-dinitroindane	489	421



(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
547	<i>N,N'</i> -Pentamethylenebis(trimethyl-ammonium) salts	545	120
548	Pentobarbitone and its salts	(69)	220
549	Perchloroethylene	692	314
550	Perphenazine (INN) and its salts	(561)	320
551	PETN	543, 544	265
552	Petrichloral (INN)	542	266
553	Phenacemide (INN)	564	269
554	Phenaglycodol (INN)	173	95
555	Phenetamine	226	112
556	Pheneturide (INN)	340, 568	272
557	Phenindone (INN)	574	271
558	Phenmetrazine (INN), its derivatives and salts	479	232
559	Phenobarbitone and its salts	(69)	220
560	Phenolphthalein (INN)	111	417
561	Phenothiazine (INN) and its compounds	various	320
562	Phenprobamate (INN)	576	71
563	Phenprocoumon (INN)	577	273
564	<i>N</i> -Phenylacetylurea	553	269
565	4-Phenylazophenylene-1,3-diamine citrate hydrochloride	189	81
566	Phenylbutazone (INN)	129	67
567	4-Phenylbut-3-en-2-one	92	356
568	(2-Phenylbutyryl)urea	340, 556	272
569	<i>N</i> -[2-( <i>a</i> -Phenyl- <i>p</i> -chlorobenzyl)-ethyl]morpholine	265	270
570	1-Phenylcyclopentanecarboxylic acid diethylaminoethyl ester and its salts	143	169
571	2-Phenylcyclopropylamine ( <i>trans</i> -form) and its salts	722	324
572	1-Phenyl-2,3-dimethyl-4-isopropylpyrazol-5-one	620	138
573	<i>o</i> -Phenylenediamine and its salts	242	363
574	2-Phenylindan-1,3-dione	557	271
575	<i>α</i> -Phenyl-2-piperidineacetic acid methyl ester and its salts	475	175
576	3-Phenylpropyl carbamate	562	71
577	3-( <i>a</i> -Phenylpropyl)-4-hydroxycoumarin	563	273
578	1-Phenyl-2-(2-pyridylamino)ethanol	346, 582	274
579	2-[1-Phenyl-1-(2-pyridyl)ethoxy]-ethyl dimethylamine and its salts	311	176
580	2-Phenylquinoline-4-carboxylic acid, its salts and derivatives and salts of those derivatives	191	8
581	6-Phenyl-2,4,7-triaminopteridine and its salts	725	275
582	Phenyramidol	346, 578	274
583	Phosphides, metal	—	279
584	Phosphorus	—	279
585	4-Phosphoryloxy- <i>N,N</i> -dimethyltryptamine	622	278
586	3-Phthalimidopiperidine-2,6-dione and its salts	704	280
587	Phthalylsulphathiazole (INN) and its salts	(678)	307
588	<i>Physostigma venenosum</i> Balf.	137	281
589	Physostigmine and its salts	319	166
590	<i>Phytolacca</i> spp and their preparations	—	374
591	Picric acid	745	268
592	Picrotoxin	197	282
593	Pilocarpine and its salts	—	283

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
594	<i>Pilocarpus jaborandi</i> Holmes and its galenical preparations	—	311
595	Pipazetate (INN) and its salts	596	118
596	2-(2-Piperidinoethoxy)ethyl 10-thia-1,9-diazaanthracene-9-carboxylate and its salts	595	118
597	<i>a</i> -Piperidin-2-ylbenzyl acetate, laevorotatory <i>threo</i> -form and its salts	426	284
598	1-(2-Piperidyl)propan-2-one and its salts	539	263
599	6-(Piperidiny)-2,4-pyrimidinediamine 3-oxide, its salts and derivatives	485	372
600	Pipradrol (INN) and its salts	304	285
601	Piprocuarium iodide (INN)	256	137
602	Poldine metilsulfate (INN) (Poldine methylsulphate)	84	239
603	Polyacetaldehyde	444	223
604	Potassium cyanide	(388, 390, 409)	111
605	Potassium nitroferricyanide	(15), 606	255
606	Potassium nitroprusside	(15), 605	255
607	Pramocaine (INN)	608	405
608	Pramoxine	607	405
609	Probenecid (INN)	308	161
610	Procainamide (INN) its salts and derivatives	29	25
611	Prochlorperazine (INN) and its salts	(561)	320
612	Progestogens	—	194
613	Promazine (INN) and its salts	(561)	320
614	Promethazine (INN) and its salts	(561)	320
615	Propane-1'2,3-triyl trinitrate	363, 514	253
616	Propatylnitrate (INN)	109	206
617	1-Propyl-3-(4-chlorobenzenesulphonyl)urea	181	79
618	2-Propylpiperidine	212	290
619	1-(2-Propynyl)cyclohexyl carbamate	383	115
620	Propyphenazone (INN)	572	138
621	<i>Prunus laurocerasus</i> L.	156	291
622	Psilocybine (INN)	585	278
623	Psoralen (except natural content of essences). In sun protection and in bronzing products, furocoumarins content shall be below 1 mg/kg	(357)	358
624	<i>Pyrethrum album</i> L. and its galenical preparations	—	345
625	Pyrianisamine maleate	453	346
626	Pyribenzamine	95, 748	347
627	2-( <i>N</i> -2-Pyridyl- <i>N</i> -2-thienylamino)ethyl-dimethylamine and its salts	448	144
628	Pyrithione disulphide + magnesium sulphate	310	396
629	Pyrithione sodium (INNM)	—	369
630	Pyrocatechol	79, 152	408
631	Pyrogallol	80	409
632	Quinalbarbitone and its salts	(69)	220
633	Quinolin-8-ol except for the uses provided for in entry number 51 in Part I of Schedule 4	(401, 533)	395

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
634	Radioactive substances (within the meaning of Article 1 of Council Directive 96/29/Euratom(a) laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation)	—	293
635	<i>Rauwolfia serpentina</i> alkaloids and their salts	636	15
636	Reserpine (INN) and its salts	(635)	15
637	Retinoic acid and its salts	724, 760	375
638	Safrole (except natural content of essences in cases where the concentration of such safrole in the cosmetic product does not exceed— (a) in the case of oral hygiene or dental products other than toothpaste intended specifically for children, 50 mg/kg; or (b) in the case of products other than oral hygiene or dental products, 100 mg/kg)	—	360
639	<i>a</i> -Santonin	380	214
640	<i>Schoenocaulon officinale</i> Lind. (seeds and galenical preparations)	—	332
641	Scopolamine, its salts and derivatives	403	295
642	Secbutobarbitone and its salts	(69)	220
643	Secondary dialkanolamines	108, 255, 274	411
644	Selenium and its compounds (except when permitted under the restrictions laid down in Part I of Schedule 4)	—	297
645	Sodium cyanide	(388, 390, 409)	111
646	Sodium hexacyclonate (INN)	396	114
647	Sodium nitroferricyanide	(15), 648	255
648	Sodium nitroprusside	(15), 647	255
649	<i>Solanum nigrum</i> L. and its galenical preparations	-	298
650	Spanish Fly	139	69
651	Sparteine (INN) and its salts	432	299
652	Spirolactone (INN)	10	4
653	Squill and its preparations	752	330
654	Stramonium and its preparations	232	301
655	Strontium lactate	—	402
656	Strontium nitrate	—	403
657	Strontium polycarboxylate	—	404
658	Strophanthines and their aglucones and their respective derivatives	—	302
659	<i>Strophanthus</i> species and their galenical preparations	—	303
660	Strychnine and its salts	—	304
661	<i>Strychnos</i> species and their galenical preparations	522	305
662	Succinonitrile	—	150
663	Succinylsulphathiazole and its salts	(678)	307
664	Sulfinpyrazone (INN)	303	155
665	Sulphacetamide and its salts	(678)	307
666	Sulphadiazine and its salts	(678)	307
667	Sulphadimethoxine and its salts	(678)	307
668	Sulphadimidine and its salts	(678)	307
669	Sulphafurazole and its salts	(678)	307

(a) O.J. No. L159, 29.6.96, p. 1.

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
670	Sulphaguanidine and its salts	(678)	307
671	Sulphamethizole and its salts	(678)	307
672	Sulphamethoxazole and its salts	(678)	307
673	Sulphamethoxydiazine and its salts	(678)	307
674	Sulphamethoxypyridazine and its salts	(678)	307
675	Sulphanilamide and its salts	(678)	307
676	Sulphapyridine and its salts	(678)	307
677	Sulphathiazole and its salts	(678)	307
678	Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the -NH <sub>2</sub> groups) and their salts	665-677	307
679	Sulthiame	680, 699	308
680	Sultiame (INN)	679, 699	308
681	Sympathomimetic 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	44	21
682	Tefazoline (INN) and its salts	698	237
683	Tellurium and its compounds	—	312
684	TEPP (ISO)	696	276
685	2-(4- <i>tert</i> -Butyl-2,6-dimethylbenzyl)-2-imidazoline and its salts	766	313
686	4- <i>tert</i> -Butylphenol	—	340
687	4- <i>tert</i> -Butylpyrocatechol	—	341
688	Tetrabenazine (INN) and its salts	531	139
689	Tetrabromosalicylanilides	—	350
690	Tetracaine (INN) and its salts	280	63
691	2,3,7,8-Tetrachlorodibenzo- <i>p</i> -dioxin	—	367
692	Tetrachloroethylene	549	314
693	Tetrachloromethane	147	315
694	Tetrachlorosalicylanilides	—	348
695	Tetraethylammonium bromide	703	61
696	Tetraethyl pyrophosphate	684	276
697	( <i>R</i> )-5,6,6a,7-Tetrahydro-6-methyl-4 <i>H</i> -dibenzo[ <i>de,g</i> ]quinoline-10,11-diol and its salts	59	42
698	2-(5,6,7,8-Tetrahydro-1-naphthylmethyl)-2-imidazoline and its salts	682	237
699	4-(Tetrahydro-2 <i>H</i> -1,2-thiazin-2-yl)-benzenesulphonamide <i>S,S</i> -dioxide	679, 680	308
700	Tetrahydrozoline and its salts	-	394
701	<i>N</i> ,2,3,3-Tetramethyl-2-nocamphanamine	437	229
702	Tetramethylthiuram disulphide	713	162
703	Tetrylammonium bromide (INN)	695	61
704	Thalidomide (INN) and its salts	586	280
705	Thallium and its compounds	—	317
706	<i>Thevetia neriifolia</i> Juss., glycoside extract	—	318
707	Thiamazole (INN)	472, 474	233
708	2,2'-Thiobis(4,6-dichlorophenol)	113	352
709	Thiopentone and its salts	(69)	220
710	Thioridazine (INN) and its salts	(561)	320
711	Thiotepa (INN)	726	310
712	Thiourea and its derivatives (except those listed in Part I of Schedule 4)	—	321

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
713	Thiram (ISO)	702	162
714	Thiuram disulphides	—	354
715	Thiuram monosulphides	—	353
716	Thyropropic acid (INN) and its salts	394	9
717	Tolboxane (INN)	720	177
718	Tolbutamide (INN)	132	65
719	Toluidines, their isomers, salts and halogenated and sulphonated derivatives	40	32
720	<i>p</i> -Tolylboric acid ester of 2-methyl-2-propylpropane-1,3-diol	717	177
721	3- <i>o</i> -Tolyloxypropane-1,2-diol	(439)	322
722	Tranlycypromine (INN) and its salts	571	324
723	Tretamine (INN)	727	328
724	Tretinoin (INN) and its salts	637, 760	375
725	Triamterene (INN) and its salts	581	275
726	Tri(aziridin-1-yl)phosphine sulphide	711	310
727	2,4,6-Tri(aziridin-1-yl)-1,3-triazine	723	328
728	2,2,2-Tribromoethanol	(729)	326
729	Tribromoethyl alcohol	728	326
730	Tribromsalan (INN)	731	373
731	3,4',5-Tribromosalicylanilide	730	373
732	Trichlormethine (INN) and its salts	749	327
733	Trichloroacetic acid	—	10
734	1,1,1-Trichloro-2,2-bis(4-chlorophenyl)ethane	194, 233	123
735	2,2,2-Trichloroethane-1,1-diol	157	77
736	Trichloromethane	167	366
737	<i>N</i> -(Trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide	141	370
738	Trichloronitromethane	177	325
739	Tricresyl phosphate	750	277
740	Trifluoperazine (INN) and its salts	(561)	320
741	Trifluperidol (INN)	349	188
742	3,3',5-Triiodothyroacetic acid and its salts	393	5
743	3,4,5-Trimethoxyphenethylamine and its salts	442	222
744	2,2,6-Trimethyl-4-piperidyl benzoate and its salts	75	51
745	2,4,6-Trinitrophenol	591	268
746	Trioxysalen (INN) (except natural content of essences). In sun protection and in bronzing products, furocoumarins content shall be below 1 mg/kg	(357)	358
747	Triparanol (INN)	171	92
748	Tripelennamine (INN)	95, 626	347
749	Tris(2-chloroethyl)amine	732	327
750	Tritolyl phosphate	739	277
751	Tuaminoheptane (INN), its isomers and salts	30	27
752	<i>Urginea scilla Stern.</i> and its galenical preparations	653	330
753	Urocanic acid	(406)	418
754	Vaccines, toxins and serums listed in the Annex to Council Directive No. 75/319/EEC(a)	—	323
755	Valnoctamide (INN)	339	184
756	Veratrine, its salts and galenical preparations	—	331

(a) O.J. No. L147, 9.6.75, p. 13.

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
757	<i>Veratrum spp</i> and their preparations	—	333
758	Vinyl chloride monomer	—	334
759	Vinylidene chloride	(7,250)	126
760	Vitamin A acid and its salts	637, 724	375
761	Vitamins D <sub>2</sub> and D <sub>3</sub>	138, 186, 317	335
762	Warfarin (ISO) and its salts	3, 399	203
763	Xanthates	16	336
764	Xanthinol	392	135
765	Xylidines, their isomers, salts and halogenated and sulphonated derivatives	41	33
766	Xylometazoline (INN) and its salts	685	313
767	Yohimbine and its salts	—	337
768	Zirconium and its compounds (except aluminium zirconium chloride hydroxide complexes and aluminium zirconium chloride hydroxide glycine complexes under the conditions laid down in Part I of Schedule 4 and zirconium lakes, salts and pigments prepared from those colouring agents identified in column 1 of Part I of Schedule 5 by “*” immediately after the name or colour index number)	—	391
769	Zoxazolamine (INN)	28	24

## PART II

### SUBSTANCES PROHIBITED WHEN USED AS A FRAGRANCE INGREDIENT

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
1	Alanroot oil ( <i>Inula helenium</i> )	—	423
2	Benzyl cyanide	31	424
3	Cyclamen alcohol	22	425
4	Decahydro-6-isopropyl-2-naphthol	21	441
5	Diethyl maleate	—	426
6	Dihydrocoumarin	8	427
7	6,7-Dihydrogeraniol	10	429
8	3,4-Dihydroxycoumarin	6	427
9	2,4-Dihydroxy-3-methylbenzaldehyde	—	428
10	3,7-Dimethyl-2-octen-1-ol	7	429
11	4,6-Dimethyl-8- <i>tert</i> -butylcoumarin	—	430
12	Dimethyl citraconate	—	431
13	7,11-Dimethyl-4,6,10-dodecatrien-3-one	—	432
14	6, 10-Dimethyl-3,5,9-undecatrien-2-one	—	433
15	Diphenylamine	—	434
16	Ethyl acrylate	—	435
17	Fig leaf absolute ( <i>Ficus carica</i> )	—	436
18	<i>trans</i> -2-Heptenal	—	437
19	<i>trans</i> -2-Hexenal diethyl acetal	—	438
20	<i>trans</i> -2-Hexenal dimethyl acetal	—	439
21	Hydroabietyl alcohol	—	440
22	6-Isopropyl-2-decahydronaphthalenol	4	441

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
23	3-(4-Isopropylphenyl)-2-methylpropan-1-ol	3	425
24	7-Methoxycoumarin	—	442
25	4-(4-Methoxyphenyl)-3-butene-2-one	—	443
26	1-(4-Methoxyphenyl)-1-penten-3-one	—	444
27	Methyl <i>trans</i> -2-butenolate	—	445
28	7-Methylcoumarin	—	446
29	Methyleugenol (except for normal content in the natural essences used and provided that the concentration does not exceed: (a) 0.01 per cent in fine fragrance; (b) 0.004 per cent in eau de toilette; (c) 0.002 per cent in fragrance cream; (d) 0.001 per cent in rinse-off products; and (e) 0.0002 per cent in other leave-on products and oral hygiene products)	—	451
30	5-Methyl-2,3-hexanedione	—	447
31	2-Pentylidenecyclohexanone	—	448
32	2-Phenylacetonitrile	2	424
33	3,6,10-Trimethyl-3,5,9-undecatrien-2-one	—	449
34	Verbena oil ( <i>Lippia citriodora</i> Kunth.)	—	450

**SCHEDULE 4**

Regulations 5(2), 6(1) and 7(2)

**LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO RESTRICTIONS**

In this Schedule, the matters specified in columns 3, 4, 5 and 6 which apply to a particular substance are those set out to the right of its name as mentioned in column 2; and the matters specified in columns 4, 5 and 6 which apply in any particular case are those set out to the right of the matter specified in column 3 which applies in that case. The substance may not be used except for the purposes or contained other than in the types of product specified in column 3. The concentration of the substance in a product may not exceed the limit specified in column 4; where the names of two or more substances are mentioned in a single item as set out in column 2 and a product contains more than one of those substances, the limit specified in column 4 is the limit for all of those substances taken together; and where a product is intended to be mixed with another product in specified proportions before use, the level of concentration shall be calculated by reference to the mixture. Other requirements are specified in column 5. In column 4 of this Schedule, the percentage concentration is measured by reference to mass (m/m) unless a contrary intention appears.

Names which appear in square brackets in column 2 are the International Nomenclature Cosmetic Ingredient names of the substances in question given in the inventory of ingredients employed in cosmetic products drawn up in accordance with the provisions of the Directive and contained in Commission Decision 96/335/EC(a).

**PART I**

**SUBSTANCES LISTED IN ANNEX III, PART 1 OF THE DIRECTIVE AS SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN**

(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>	(5) <i>Other requirements</i>	(6) <i>Required information</i>
1a	Boric acid, borates, and tetraborates	Talcum powder	5 per cent	Not to be used in products intended for children under three years old Not to be used in products intended for peeling or irritated skin if the concentration of free soluble borate exceeds 1.5 per cent calculated as boric acid	Not to be used for bathing children under three years old Do not use on peeling or irritated skin (Only required if the concentration of free soluble borate exceeds 1.5 per cent calculated as boric acid)
	Oral hygiene products	Oral hygiene products	0.1 per cent	Not to be used in products intended for children under three years old	Do not swallow Not to be used for children under three years old
	Other products (excluding bath products and hair waving products)	Other products (excluding bath products and hair waving products)	3 per cent	Not to be used in products intended for children under three years old Not to be used in products intended for peeling or irritated skin if the concentration of free soluble borate exceeds 1.5 per cent calculated as boric acid	Not to be used for children under three years old Do not use on peeling or irritated skin (Only required if the concentration of free soluble borate exceeds 1.5 per cent calculated as boric acid)

(a) O.J. No. L132, 1.6.1996, p. 1.



(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
1b	Tetraborates	Bath products Hair waving products	The above-mentioned percentages are calculated as boric acid 18 per cent 8 per cent The above-mentioned percentages are calculated as boric acid	Not to be used in products for children under three years old	Not to be used for bathing children under three years old
2a	Thioglycolic acid and its salts	(a) Hair waving or straightening products for general use (b) Hair waving or straightening products for professional use (c) Depilatories (d) Other hair-care products which are removed after application	8 per cent ready for use 11 per cent ready for use 5 per cent ready for use 2 per cent ready for use	pH 7 to 9.5 pH 7 to 9.5 pH 7 to 12.7 pH 7 to 9.5	Contains thioglycolate. Follow the instructions. Keep out of reach of children Contains thioglycolate. Follow the instructions. Keep out of reach of children. For professional use only Contains thioglycolate. Follow the instructions. Keep out of reach of children Contains thioglycolate. Follow the instructions. Keep out of reach of children
			The above-mentioned percentages are calculated as thioglycolic acid	(a), (b), (c) and (d): The directions for use must incorporate the following: —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), (b) and (d) only)	

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
2b	Thioglycolic acid esters	(a) Hair waving or straightening products for general use (b) Hair waving or straightening products for professional use	8 per cent ready for use  11 per cent ready for use	pH 6 to 9.5  pH 6 to 9.5	Contains thioglycolate. Follow the instructions. Keep out of reach of children 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 per cent	—	For professional use only
4	Ammonia	All purposes and products	6 per cent calculated as NH <sub>3</sub>	—	Contains ammonia (not required when concentration is not more than 2 per cent)
5	Tosylchloramide sodium (INN) [Chloramine-T]	All purposes and products	0.2 per cent	—	—
6	Chlorates of alkali metals	Toothpaste Other uses	5 per cent 3 per cent	—	—
7	Dichloro-methane	All purposes and products	35 per cent (and when mixed with 1,1,1-trichloroethane, total concentration must not exceed 35 per cent)	Purity of the dichloromethane must be not less than 99.8 per cent	—

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
8	<i>m</i> - and <i>p</i> -Phenylenediamines, their <i>N</i> -substituted derivatives and their salts; <i>N</i> -substituted derivatives of <i>o</i> -phenylenediamines (see Note 1), with the exception of those derivatives listed elsewhere in this Schedule	Oxidizing colouring agents for hair-dyeing for general use	6 per cent calculated as a free base, subject to the provisions of "Combination Rule A" set out below	—	Contains phenylenediamines. Can cause an allergic reaction. Do not use to dye eyelashes or eyebrows
9	Methylphenylenediamines (other than 4-methyl- <i>m</i> -phenylenediamine and its salts), their <i>N</i> -substituted derivatives and their salts (Toluenediamines (other than toluene-1, 3-diamine and its salts), their <i>N</i> -substituted derivatives and their salts)	Oxidizing colouring agents for hair-dyeing for professional use	6 per cent calculated as a free base, subject to the provisions of "Combination Rule A" set out below	—	Contains phenylenediamines. For professional use only. Can cause an allergic reaction. Wear suitable gloves
10	Diaminophenols	Oxidizing colouring agents for hair-dyeing for professional use	10 per cent calculated as a free base, subject to the provisions of "Combination Rule A" set out below	—	Contains phenylenediamines. Can cause an allergic reaction. Do not use to dye eyelashes or eyebrows
		Oxidizing colouring agents for hair-dyeing for professional use	10 per cent calculated as a free base, subject to the provisions of "Combination Rule A" set out below	—	Contains diaminophenols. Can cause allergic reaction. Do not use to dye eyelashes or eyebrows
		Oxidizing colouring agents for hair-dyeing for professional use	10 per cent calculated as a free base, subject to the provisions of "Combination Rule A" set out below	—	Contains diaminophenols. For professional use only. Can cause allergic reaction. Wear suitable gloves

Note 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 authorised for each of them does not exceed 1.

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
11	Dichlorophen (INN) [Dichlorophene]	All purposes and products	0.5 per cent	—	Contains dichlorophen
12	Hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide including hydrogen peroxide-urea (hydrogen peroxide-carbamide) and zinc peroxide	(a) Hair-care preparations (b) Skin-care preparations (c) Nail hardening preparations (d) Oral hygiene products	12 per cent of H <sub>2</sub> O <sub>2</sub> present or released 4 per cent of H <sub>2</sub> O <sub>2</sub> present or released 2 per cent of H <sub>2</sub> O <sub>2</sub> present or released 0.1 per cent of H <sub>2</sub> O <sub>2</sub> present or released 5 per cent	— — — — —	(a): Wear suitable gloves (a)(b)(c): Contains hydrogen peroxide. Avoid contact with eyes. Rinse eyes immediately if product comes into contact with them —
13	Formaldehyde (see also Part I of Schedule 6)	Nail hardeners	5 per cent	—	Contains formaldehyde. Protect cuticles with grease or oil. (Not required when concentration is not more than 0.05 per cent)
14	Hydroquinone	Oxidizing colouring agent for hair dyeing for general use	0.3 per cent subject to the provisions of "Combination Rule B" set out below	—	Contains hydroquinone. Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them Contains hydroquinone. For professional use only. Rinse eyes immediately if product comes into contact with them
15a	Potassium hydroxide and sodium hydroxide	Nail cuticle solvent  Hair straightener for general use  Hair straightener for professional use  pH adjuster for depilatories  Other uses as pH adjuster	5 per cent calculated as sodium hydroxide (see Note 2) 2 per cent calculated as sodium hydroxide (see Note 2) 4.5 per cent calculated as sodium hydroxide (see Note 2) —	— — — — pH value not to exceed 12.7 pH value not to exceed 11	Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children For professional use only. Avoid contact with eyes. Can cause blindness Keep out of reach of children Avoid contact with eyes

Note 2: The concentration of sodium, potassium or lithium hydroxide is expressed as a percentage of sodium hydroxide. In cases of mixtures, the sum must not exceed the limits given in column (4).

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
15b	Lithium hydroxide	Hair straightener for general use	2 per cent calculated as sodium hydroxide (see Note 2)	—	Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children
15c	Calcium hydroxide	Hair straightener for professional use	4.5 per cent calculated as sodium hydroxide (see Note 2)	—	For professional use only. Avoid contact with eyes. Can cause blindness
		pH adjuster for depilatories	—	pH value not to exceed 12.7	Contains alkali. Keep out of reach of children. Avoid contact with eyes
		Other uses as pH adjuster (for rinse-off products only)	—	pH value not to exceed 11	—
		Hair straighteners containing two components: calcium hydroxide and aguanidine salt	7 per cent by weight of calcium hydroxide	—	Contains alkali. Avoid contact with eyes. Keep out of reach of children. Can cause blindness
		pH adjuster for depilatories	—	pH value not to exceed 12.7	Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children
16	$\alpha$ -Naphthol [1-Naphthol] and its salts	Other uses e.g. pH adjuster processing aid	—	pH value not to exceed 11	—
		Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	Can cause allergic reaction
17	Sodium nitrite	Rust inhibitor	0.2 per cent	Do not use with secondary and/or tertiary amines or other substances forming nitrosamines	—
18	Nitromethane	Rust inhibitor	0.3 per cent	—	—
19	Phenol and its alkali salts	Soaps and shampoos	1 per cent calculated as phenol	—	Contains phenol

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
20	ENTRY DELETED				
21	Quinine and its salts	Shampoos	0.2 per cent calculated as quinine base	—	—
		Hair lotions	0.5 per cent calculated as quinine base	—	—
22	Resorcinol	Oxidizing colouring agent for hair dyeing for general use	5 per cent subject to the provisions of "Combination Rule B" set out below	—	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
		Oxidizing colouring agent for hair dyeing for professional use	5 per cent subject to the provisions of "Combination Rule B" set out below	—	Contains resorcinol. For professional use only. Rinse eyes immediately if product comes into contact with them
		Hair lotions and shampoos	0.5 per cent subject to the provisions of "Combination Rule B" set out below	—	Contains resorcinol
23a	Alkali sulphides	Depilatories	2 per cent calculated as sulphur	pH value not to exceed 12.7	Keep out of reach of children. Avoid contact with eyes
23b	Alkaline earth sulphides	Depilatories	6 per cent calculated as sulphur	pH value not to exceed 12.7	Keep out of reach of children. Avoid contact with eyes
24	Water-soluble zinc salts with the exception of zinc 4-hydroxybenzenesulphonate	All purposes and products	1 per cent calculated as zinc	—	—
25	Zinc 4-hydroxybenzenesulphonate [Zinc phenolsulfonate]	Deodorants, antiperspirants and astringent lotions	6 per cent calculated as percentage of anhydrous substance	—	Avoid contact with eyes
26	Ammonium monofluorophosphate	Oral hygiene products	0.15 per cent calculated as fluorine. When mixed with other fluorine compounds the total fluorine concentration must not exceed 0.15 per cent	—	Contains ammonium monofluorophosphate
27	Sodium monofluorophosphate	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains sodium monofluorophosphate

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
28	Potassium monofluorophosphate	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains potassium monofluorophosphate
29	Calcium monofluorophosphate	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains calcium monofluorophosphate
30	Calcium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains calcium fluoride
31	Sodium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains sodium fluoride
32	Potassium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains potassium fluoride
33	Ammonium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains ammonium fluoride
34	Aluminium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains aluminium fluoride
35	Stannous fluoride	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains stannous fluoride
36	Hexadecylammonium fluoride [Cetylamine hydrofluoride]	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains hexadecylammonium fluoride
37	3-( <i>n</i> -Hexadecyl- <i>N</i> -2-hydroxyethylammonio)-propylbis(2-hydroxyethyl)ammonium difluoride [Stearyl trihydroxyethyl propylenediamine dihydrofluoride]	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains 3-( <i>n</i> -hexadecyl- <i>N</i> -2-hydroxyethylammonio)-propylbis(2-hydroxyethyl)ammonium difluoride
38	<i>N,N',N''</i> -Tris(polyoxyethylene)- <i>N</i> -hexadecylpropyl-enediamine dihydrofluoride [Palmityl trihydroxyethyl propylenediamine dihydrofluoride]	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains <i>N,N',N''</i> -tris (polyoxyethylene)- <i>N</i> -hexadecylpropylenediamine dihydrofluoride

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
39	Octadecenylammonium fluoride	Oral hygiene products	As for ammonium mono-fluorophosphate	—	Contains octadecenylammonium fluoride
40	Sodium fluorosilicate	Oral hygiene products	As for ammonium mono-fluorophosphate	—	Contains sodium fluorosilicate
41	Potassium fluorosilicate	Oral hygiene products	As for ammonium mono-fluorophosphate	—	Contains potassium fluorosilicate
42	Ammonium fluorosilicate	Oral hygiene products	As for ammonium mono-fluorophosphate	—	Contains ammonium fluorosilicate
43	Magnesium fluorosilicate	Oral hygiene products	As for ammonium mono-fluorophosphate	—	Contains magnesium fluorosilicate
44	1,3-Bis(hydroxymethyl)-imidazolidene-2-thione [Dimethylol ethylene thiourea]	Hair care preparations	As for ammonium mono-fluorophosphate 2 per cent	Not to be used in aerosol dispensers	Contains 1,3-bis(hydroxymethyl)imidazolidene-2-thione
45	Benzyl alcohol (See also Part I of Schedule 6)	Nail care preparations	2 per cent	pH value as applied must be less than 4	Contains 1,3-bis(hydroxymethyl)imidazolidene-2-thione
46	6-Methylcoumarin	Solvent, perfumes and flavourings	—	—	—
47	Nicomethanol hydrofluoride	Oral hygiene products	0.003 per cent	—	Contains nicomethanol hydrofluoride
48	Silver nitrate	Oral hygiene products	As for ammonium mono-fluorophosphate	—	Contains silver nitrate. Rinse eyes immediately if product comes into contact with them
49	Selenium disulphide [Selenium sulfide]	Products to dye eyelashes or eyebrows	4 per cent	—	Contains selenium disulphide. Avoid contact with eyes or damaged skin
	Anti-dandruff shampoos		1 per cent	—	



(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
50	Aluminium zirconium chloride hydroxide complexes $Al_xZr(OH)_yCl_z$ and aluminium zirconium chloride hydroxide glycine complexes	Anti-perspirants	20 per cent as anhydrous aluminium zirconium chloride hydroxide, 5.4 per cent as zirconium	The ratio of the number of aluminium atoms to that of zirconium atoms must be between 2 and 10 The ratio of the number of (Al + Zr) atoms to chlorine atoms must be between 0.9 and 2.1 Not to be used in aerosol dispensers (sprays)	Do not apply to irritated or damaged skin
51	Quinolin-8-ol and bis-(8-hydroxyquinolinium sulphate) (See also Part I of Schedule 3) [Oxyquinoline and Oxyquinoline sulfate]	Stabilizer for hydrogen peroxide in rinse-off hair care preparations	0.3 per cent calculated as base	—	—
52	Methanol	Stabilizer for hydrogen peroxide in non rinse-off hair care preparations Denaturant for ethanol and isopropyl alcohol	0.03 per cent calculated as base 5 per cent calculated as a percentage of ethanol and isopropyl alcohol	—	—
53	Etidronic acid and its salts (1-hydroxyethylidene-diphosphonic acid and its salts)	Hair care	1.5 per cent expressed as etidronic acid	—	—
54	1-Phenoxy-propan-2-ol (See also Part I of Schedule 6) [Phenoxy-isopropanol]	Soap Products rinsed off after use	0.2 per cent expressed as etidronic acid 2 per cent	—	Prohibited in oral hygiene products

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
55	Lead acetate	Only for hair dyeing	0.6 per cent calculated as lead	—	Contains lead acetate. Keep away from children. Avoid all contact with the eyes. Wash hands after use. Do not use to dye eyelashes, eyebrows or moustaches. If irritation develops discontinue use
56	Magnesium fluoride	Dental hygiene products	0.15 per cent calculated as fluorine. When mixed with other fluorine compounds the total fluorine concentration must not exceed 0.15 per cent	—	Contains magnesium fluoride
57	Strontium chloride hexahydrate	(a) Toothpaste	3.5 per cent calculated as strontium. When mixed with other permitted strontium compounds the total strontium content must not exceed 3.5 per cent	—	Contains strontium chloride. Frequent use by children is not advisable
58	Strontium acetate hemihydrate	(b) Shampoo and face care products	2.1 per cent calculated as strontium. When mixed with other permitted strontium compounds the total strontium content must not exceed 2.1 per cent	—	Contains strontium acetate. Use by children is not advisable

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
59	Talc: hydrated magnesium silicate	(a) Powdery products intended to be used for children under three years of age (b) other products	—	—	(a): Keep powder away from children's nose and mouth
60	Fatty acid dialkanolamides	All purposes and products	Maximum dialkanolamine content: 0.5 per cent	Do not use with nitrosating systems. Maximum dialkanolamine content: 5 per cent (applies to raw materials). Maximum <i>N</i> -nitroso-dialkanolamine content: 50 µg/kg (applies to raw materials). Keep in nitrite-free containers	—
61	Monoalkanolamines	All purposes and products	Maximum dialkanolamine content: 0.5 per cent	Do not use with nitrosating systems. Minimum purity: 99 per cent. Maximum dialkanolamine content: 0.5 per cent (applies to raw materials). Maximum <i>N</i> -nitrosodialkanolamine content: 50 µg/kg (applies to raw materials). Keep in nitrite-free containers	—
62	Trialkanolamines	(a) non-rinse-off (b) other products	(a) 2.5 per cent —	(a) (b): Do not use with nitrosating systems. Minimum purity: 99 per cent. Maximum dialkanolamine content: 0.5 per cent (applies to raw materials). Maximum <i>N</i> -nitroso-dialkanolamine content: 50 µg/kg (applies to raw materials). Keep in nitrite-free containers	—
63	Strontium hydroxide	pH-regulator in depilatory products	3.5 per cent calculated as strontium	pH value not to exceed 12.7	Keep out of reach of children. Avoid contact with the eyes

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
64	Strontium peroxide	Rinse-off hair care preparations for professional use	4.5 per cent 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
65	Benzalkonium chloride (INN), bromide and saccharinate (eg. Cetalkonium chloride, Stearalkonium chloride, Cetearalkonium bromide)	Hair care products rinsed off after use	3 per cent calculated as benzalkonium chloride	In the finished product the concentration of benzalkonium chloride, bromide and saccharinate with an alkyl chain-length of C <sub>14</sub> or less must not exceed 0.1 per cent calculated as benzalkonium chloride	Avoid contact with the eyes
66	Polyacrylamides	Other products Body-care leave-on products Other cosmetic products	0.1 per cent calculated as benzalkonium chloride — —	Maximum residual acrylamide content 0.1 mg/kg Maximum residual acrylamide content 0.5 mg/kg	Avoid contact with the eyes — —

PART II  
SUBSTANCES LISTED IN ANNEX III, PART 2 OF THE DIRECTIVE AS SUBSTANCES PROVISIONALLY ALLOWED

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information	(7) Permitted for supply until
1	C.I. Basic Blue 7	Non-oxidising colouring agents for hair dyeing	0.2 per cent	—	Can cause allergic reaction	30.9.2004
2	2-Amino-3-nitrophenol and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	3 per cent 3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	Can cause allergic reaction Can cause allergic reaction	30.9.2004
3	4-Amino-3-nitrophenol and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	3 per cent 3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	Can cause allergic reaction Can cause allergic reaction	30.9.2004
4	Naphthalene-2,7-diol and its salts	Oxidising colouring agents for hair dyeing	1 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.5 per cent	—	30.9.2004
5	3-Aminophenol and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	Can cause allergic reaction	30.9.2004
6	3, 4-Dimethylpyridine-2, 6-diol and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	Can cause allergic reaction Can cause allergic reaction	30.9.2004

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information	(7) Permitted for supply until
7	4-(3-Hydroxypropyl)- amino-3-nitrophenol and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	5.2 per cent 2.6 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 2.6 per cent —	Can cause allergic reaction Can cause allergic reaction	30.9.2004
8	6-Nitropyridine-2,5- diamine and its salts	Non-oxidising colouring agent for hair dyeing	3 per cent	—	Can cause allergic reaction	30.9.2004
9	HC Blue No. 11 and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	3 per cent 2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	Can cause allergic reaction Can cause allergic reaction	30.9.2004
10	2-(2-Nitro- <i>p</i> -toluidino)- ethanol and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	2 per cent 1 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	Can cause allergic reaction Can cause allergic reaction	30.9.2004
11	2-(2-Hydroxyethyl- amino)-4,6-dinitro- phenol and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	3 per cent 2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	Can cause allergic reaction Can cause allergic reaction	30.9.2004
12	4-Methylaminophenol and its salts	Oxidising colouring agent for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	Can cause allergic reaction	30.9.2004
13	2-(2,4-Diamino-5- methylphenoxy)ethanol and its salts	Oxidising colouring agent for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	Can cause allergic reaction	30.9.2004

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information	(7) Permitted for supply until
14	HC Violet No. 2 and its salts	Non-oxidising colouring agent for hair dyeing	2 per cent	—	—	30.9.2004
15	2(2,6-Dinitro- <i>p</i> -anisidino)ethanol and its salts	Non-oxidising colouring agent for hair dyeing	3 per cent	—	Can cause allergic reaction	30.9.2004
16	HC Blue No. 12 and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	1.5 per cent 1.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.75 per cent	Can cause allergic reaction Can cause allergic reaction	30.9.2004
17	4-Ethoxy-6-methyl- <i>m</i> -phenylenediamine and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	Can cause allergic reaction	30.9.2004
18	4,4'-(Trimethylene-dioxy)di- <i>m</i> -phenylenediamine and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	Can cause allergic reaction	30.9.2004
19	3-Amino-2,4-dichlorophenol and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	Can cause allergic reaction	30.9.2004
20	3-Methyl-1-phenyl-5-pyrazolone and its salts	Oxidising colouring agents for hair dyeing	0.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.25 per cent	—	30.9.2004

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information	(7) Permitted for supply until
21	5-(2-Hydroxyethyl-amine)- <i>o</i> -cresol and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	Can cause allergic reaction	30.9.2004
22	3,4-Dihydro-2 <i>H</i> -1,4-benzoxazin-6-ol and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	Can cause allergic reaction	30.9.2004
23	Naphthalene-1,7-diol and its salts	Oxidising colouring agents for hair dyeing	1 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.5 per cent	Can cause allergic reaction	30.9.2004
24	HC Yellow No. 10 and its salts	Non-oxidising colouring agents for hair dyeing	0.2 per cent	—	—	30.9.2004
25	2,6-Dimethoxy-3,5-pyridinediamine and its salts	Oxidising colouring agents for hair dyeing	0.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.25 per cent	Can cause allergic reaction	30.9.2004
26	HC Orange No. 2 and its salts	Non-oxidising colouring agents for hair dyeing	1 per cent	—	—	30.9.2004
27	HC Violet No. 1 and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	0.5 per cent 0.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.25 per cent	—	30.9.2004



(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information	(7) Permitted for supply until
28	2-(3-Methylamino-4-nitrophenoxy)ethanol and its salts	Non-oxidising colouring agents for hair dyeing	1 per cent	—	—	30.9.2004
29	2-(2-Methoxy-4-nitroanilino)ethanol and its salts	Non-oxidising colouring agents for hair dyeing	1 per cent	—	—	30.9.2004
30	2-(4-Amino-2-chloro-5-nitroanilino)ethanol and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	2 per cent 1 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent In combination with hydrogen peroxide the maximum use concentration upon application is 1.25 per cent	—	30.9.2004
31	HC Red No. 13	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	2.5 per cent 2.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.25 per cent	—	30.9.2004
32	Naphthalene-1,5-diol and its salts	Oxidising colouring agents for hair dyeing	1 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.5 per cent	—	30.9.2004
33	2,2'-[2-Hydroxy-trimethylenebis(4-aminophenyl)imino]diethanol and its salts	Oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	Can cause allergic reaction	30.9.2004
34	2-Aminophenol and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	—	30.9.2004

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information	(7) Permitted for supply until
35	5-Amino- <i>o</i> -cresol and its salts	Oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	—	30.9.2004
36	2-(2,4-Diamino-phenoxy)ethanol and its salts	Oxidising colouring agents for hair dyeing	4 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 2 per cent	—	30.9.2004
37	2-Methylresorcinol and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	—	30.9.2004
38	4-Amino- <i>m</i> -cresol and its salts	Oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	—	30.9.2004
39	2-Amino-4-hydroxyethyl-aminoanisole and its salts	Oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	—	30.9.2004
40	3,4-Diaminobenzoic acid and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	—	30.9.2004

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information	(7) Permitted for supply until
41	6-Amino- <i>o</i> -cresol and its salts	Oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	—	30.9.2004
42	2-Aminomethyl- <i>p</i> -aminophenol and its salts	Oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	—	30.9.2004
43	4-Amino-2-(2-hydroxyethylaminomethyl) phenol and its salts	Oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	—	30.9.2004
44	<i>N</i> -(2-Hydroxyethyl)-3,4-methylenedioxylaniline and its salts	Oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	—	30.9.2004
45	C.I. Acid Black 52 and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	—	30.9.2004
46	2-Nitro- <i>p</i> -phenylenediamine and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	0.3 per cent 0.3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.15 per cent	—	30.9.2004

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information	(7) Permitted for supply until
47	HC Blue No. 2 and its salts	Non-oxidising colouring agents for hair dyeing	2.8 per cent	—	—	30.9.2004
48	4-(2-Hydroxyethylamino)-3-nitrophenol and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	6 per cent 6 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 3 per cent	—	30.9.2004
49	2-(4-Nitrophenylamino)-ethylurea and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	0.5 per cent 0.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.25 per cent	—	30.9.2004
50	HC Red No. 10 + HC Red No. 11 and their salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	2 per cent 1 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	—	30.9.2004
51	HC Yellow No. 6 and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	2 per cent 1 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	—	30.9.2004
52	HC Yellow No. 12 and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	1 per cent 0.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.5 per cent	—	30.9.2004
53	HC Blue No. 10 and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	—	30.9.2004

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information	(7) Permitted for supply until
54	HC Blue No. 9 and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	2 per cent 1 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	—	30.9.2004
55	2-Chloro-6-ethylamino-4-nitrophenol and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	3 per cent 3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.5 per cent	—	30.9.2004
56	2-Amino-6-chloro-4-nitrophenol and its salts	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	2 per cent 2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	—	30.9.2004
57	C.I. Basic Blue 26	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	0.5 per cent 0.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.25 per cent	—	30.9.2004
58	C.I. Acid Red 33	Non-oxidising colouring agents for hair dyeing	2 per cent	—	—	30.9.2004
59	C.I. Food Red 1	Non-oxidising colouring agents for hair dyeing	2 per cent	—	—	30.9.2004
60	C.I. Basic Violet 14	Oxidising colouring agents for hair dyeing Non-oxidising colouring agents for hair dyeing	0.3 per cent 0.3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.15 per cent	—	30.9.2004

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information	(7) Permitted for supply until
61	1- <i>tert</i> -Butyl-3,5-dimethyl-2,4,6-trinitrobenzene (musk xylene)	All cosmetic products, with the exception of oral care products	1 per cent in fine fragrance 0.4 per cent in eau de toilette 0.03 per cent in other products	—	—	30.9.2004
62	4- <i>tert</i> -Butyl-2,6-dimethyl-3,5-dinitroacetophenone (musk ketone)	All cosmetic products, with the exception of oral care products	1.4 per cent in fine fragrance 0.56 per cent in eau de toilette 0.042 per cent in other products	—	—	30.9.2004

#### Combination Rules

- A. Where a cosmetic product contains two or more substances to which this Combination Rule applies, the concentration in the product of each of those substances shall be such that the sum of the relevant quotients for those substances (as defined in Rule C below) shall not exceed 1.
- B. Where a cosmetic product contains the substances to which this Combination Rule applies, the concentration in the product of each of those substances shall be such that the sum of the relevant quotients for those substances (as defined in Rule C below) shall not exceed 2; but the concentration of each substance shall not in any event exceed the limit specified for the substance in respect of the product in column 4 above.
- C. The relevant quotient for each substance is the actual concentration of the substance in the product divided by the maximum concentration specified for the substance in respect of the product in Column 4 of this Schedule.

LIST OF COLOURING AGENTS WHICH COSMETIC PRODUCTS MUST NOT CONTAIN  
EXCEPT COLOURING AGENTS INTENDED SOLELY TO COLOUR HAIR AND EXCEPT  
SUBJECT TO RESTRICTIONS

In this Schedule the colouring agents referred to in regulation 5(2)(d) are—

- (i) those identified in column 1 either by name or by colour index number (the colour index numbers being those specified in the third edition of The Colour Index published in 1971 by the Society of Dyers and Colourists);
- (ii) lakes or salts of these colouring agents which do not use substances prohibited under Schedule 3.

In the case of colouring agents identified by the addition of (\*) to the name or colour index number, the insoluble barium, strontium and zirconium lakes, salts and pigments of these colouring agents shall also be permitted. They must pass the test for insolubility which will be determined by the procedure laid down in Article 8 of the Directive.

Colouring agents whose number is preceded by the letter 'E' in accordance with the EEC Directive of 23rd October 1962 on the approximation of the rules of member States concerning foodstuffs and colouring matter(a), as amended(b), adapted(c) and replaced in part(d) must fulfil the purity requirements laid down in those Directives.

## PART I

COLOURING AGENTS LISTED IN ANNEX IV, PART 1 OF THE DIRECTIVE AS  
COLOURING AGENTS WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT  
SUBJECT TO THE RESTRICTIONS LAID DOWN

**Field of application**

In column 3 of this Schedule, the entry "X" in a sub-column means that the colouring agent must not be used other than as follows—

- Sub-column 1 = Colouring agents allowed in all cosmetic products;
- Sub-column 2 = Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes, in particular eye make-up and eye make-up remover;
- Sub-column 3 = Colouring agents allowed exclusively in cosmetic products except cosmetic products intended to come into contact with the mucous membranes;
- Sub-column 4 = Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

(1) <i>Name or colour index number</i>	(2) <i>Colour</i>	(3) <i>Type of product Field of application</i>				(4) <i>Other requirements</i>
		<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	
10006	Green				X	
10020	Green			X		
10316*	Yellow		X			
11680	Yellow			X		
11710	Yellow			X		
11725	Orange				X	
11920	Orange	X				
12010	Red			X		

(a) O.J. No. 115, 11.11.62, p. 2645.

(b) Council Directives Nos. 65/469/EEC, 67/653/EEC, 68/419/EEC, 70/358/EEC, 76/399/EEC, 78/144/EEC, 81/20/EEC and 85/7/EEC (O.J. Nos. L178, 26.10.65, p. 2793; L263, 30.10.67, p. 4; L309, 24.12.68, p. 24; L157, 18.7.70, p. 36; L108, 26.4.76, p. 19; L44, 15.2.78, p. 20; L43, 14.2.81, p. 11; L2, 3.1.85, p. 22).

(c) Annexes I and VII to the Act of Accession of 22nd January 1972, as adjusted by the Council Decision of 1st January 1973 (O.J. No. L2, 1.1.73, p.1).

(d) Council Directive 94/36/EC (O.J. No. L237, 10.9.94, p. 13) and Commission Directive 95/45/EC (O.J. No. L226, 22.9.95, p. 1).

(1) <i>Name or colour index number</i>	(2) <i>Colour</i>	(3) <i>Type of product Field of application</i>				(4) <i>Other requirements</i>
		<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	
12085*	Red	X				3 per cent maximum concentration in the finished product
12120	Red				X	
12150	Red	X				
12370	Red				X	
12420	Red				X	
12480	Brown				X	
12490	Red	X				
12700	Yellow				X	
13015	Yellow	X				E 105
14270	Orange	X				E 103
14700	Red	X				
14720	Red	X				E 122
14815	Red	X				E 125
15510*	Orange	X				
15525	Red	X				
15580	Red	X				
15620	Red				X	
15630*	Red	X				3 per cent maximum concentration in the finished product
15800	Red			X		
15850*	Red	X				
15865*	Red	X				
15880	Red	X				
15980	Orange	X				E 111
15985*	Yellow	X				E 110
16035	Red	X				
16185	Red	X				E 123
16230	Orange			X		
16255*	Red	X				E 124
16290	Red	X				E 126
17200*	Red	X				
18050	Red			X		
18130	Red				X	
18690	Yellow				X	
18736	Red				X	
18820	Yellow				X	
18965	Yellow	X				
19140*	Yellow	X				E 102



(1) <i>Name or colour index number</i>	(2) <i>Colour</i>	(3) <i>Type of product Field of application</i>				(4) <i>Other requirements</i>
		<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	
20040	Yellow				X	Maximum 3,3'-dimethylbenzidine concentration in the colouring agent: 5 mg/kg
20170	Orange			X		
20470	Black				X	
21100	Yellow				X	Maximum 3,3'-dichlorobenzidine concentration in the colouring agent: 5 mg/kg
21108	Yellow				X	Maximum 3,3'-dichlorobenzidine concentration in the colouring agent: 5 mg/kg
21230	Yellow			X		
24790	Red				X	
26100	Red			X		Purity criteria: aniline ≤ 0.2 per cent, 2-naphthol ≤ 0.2 per cent, azobenzene-4-amine ≤ 0.1 per cent, 1-phenylazo-2-naphthol ≤ 3 per cent, 1-[2-(phenylazo)phenylazo]-2-naphthol ≤ 2 per cent
27290*	Red				X	
27755	Black	X				E 152
28440	Black	X				E 151
40215	Orange				X	
40800	Orange	X				
40820	Orange	X				E 160e
40825	Orange	X				E 160f
40850	Orange	X				E 161g
42045	Blue			X		
42051*	Blue	X				E 131
42053	Green	X				
42080	Blue				X	
42090	Blue	X				
42100	Green				X	
42170	Green				X	
42510	Violet			X		
42520	Violet				X	Maximum concentration in the finished product: 5 mg/kg
42735	Blue			X		
44045	Blue			X		
44090	Green	X				E 142
45100	Red				X	

(1) <i>Name or colour index number</i>	(2) <i>Colour</i>	(3) <i>Type of product Field of application</i>				(4) <i>Other requirements</i>
		<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	
45190	Violet				X	
45220	Red				X	
45350	Yellow	X				6 per cent. maximum concentration in the finished product
45370*	Orange	X				Not more than 1 per cent 2-(6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl)benzoic acid and 2 per cent 2-(bromo-6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl)benzoic acid
45380*	Red	X				as immediately above
45396	Orange	X				When used in lipstick, the colouring agent is allowed only in free acid form and in a maximum concentration of 1 per cent
45405	Red		X			Not more than 1 per cent 2-(6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl)benzoic acid and 2 per cent 2-(bromo-6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl)benzoic acid
45410*	Red	X				as immediately above
45425	Red	X				Not more than 1 per cent 2-(6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl)benzoic acid and 3 per cent 2-(iodo-6-hydroxy-3-oxo-3 <i>H</i> -xanthen-9-yl)benzoic acid
45430*	Red	X				as immediately above, E 127
47000	Yellow			X		
47005	Yellow	X				E 104
50325	Violet				X	
50420	Black			X		
51319	Violet				X	
58000	Red	X				
59040	Green			X		
60724	Violet				X	
60725	Violet	X				
60730	Violet			X		
61565	Green	X				
61570	Green	X				
61585	Blue				X	
62045	Blue				X	
69800	Blue	X				E 130

(1) <i>Name or colour index number</i>	(2) <i>Colour</i>	(3) <i>Type of product Field of application</i>				(4) <i>Other requirements</i>
		<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	
69825	Blue	X				
71105	Orange			X		
73000	Blue	X				
73015	Blue	X				E 132
73360	Red	X				
73385	Violet	X				
73900	Violet				X	
73915	Red				X	
74100	Blue				X	
74160	Blue	X				
74180	Blue				X	
74260	Green		X			
75100	Yellow	X				
75120	Orange	X				E 160b
75125	Yellow	X				E 160d
75130	Orange	X				E 160a
75135	Yellow	X				E 161d
75170	White	X				
75300	Yellow	X				E 100
75470	Red	X				E 120
75810	Green	X				E 140 and E 141
77000	White	X				E 173
77002	White	X				
77004	White	X				
77007	Blue	X				
77015	Red	X				
77120	White	X				
77163	White	X				
77220	White	X				E 170
77231	White	X				
77266	Black	X				
77267	Black	X				
77268:1	Black	X				E 153
77288	Green	X				Free from chromate ions
77289	Green	X				Free from chromate ions
77346	Green	X				
77400	Brown	X				
77480	Brown	X				E 175
77489	Orange	X				E 172
77491	Red	X				E 172
77492	Yellow	X				E 172
77499	Black	X				E 172

(1) <i>Name or colour index number</i>	(2) <i>Colour</i>	(3) <i>Type of product Field of application</i>				(4) <i>Other requirements</i>
		<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	
77510	Blue	X				Free from cyanide ions
77713	White	X				
77742	Violet	X				
77745	Red	X				
77820	White	X				E 174
77891	White	X				E 171
77947	White	X				
Acid Red 195	Red			X		
Aluminium, zinc, magnesium and calcium stearates	White	X				
Anthocyanins	Red	X				E 163
Beetroot red	Red	X				E 162
Bromocresol green	Green				X	
Bromothymol blue	Blue				X	
Caramel	Brown	X				E 150
Capsanthin, capsorubin	Orange	X				E 160c
Lactoflavin	Yellow	X				E 101

## PART II

COLOURING AGENTS LISTED IN ANNEX IV, PART 2 OF THE DIRECTIVE AS  
COLOURING AGENTS WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT  
SUBJECT TO THE RESTRICTIONS LAID DOWN AND WHERE COSMETIC PRODUCT  
SUPPLIED BEFORE A CERTAIN DATE

### Field of application

In column 3 of this Schedule, the entry "X" in a sub-column means that the colouring agent must not be used other than as follows—

Sub-column 1 = Colouring agents allowed in all cosmetic products;

Sub-column 2 = Colouring agents allowed in all cosmetic products except those intended to be applied in the vicinity of the eyes, in particular eye make-up and eye make-up remover;

Sub-column 3 = Colouring agents allowed exclusively in cosmetic products intended not to come into contact with the mucous membranes;

Sub-column 4 = Colouring agents allowed exclusively in cosmetic products intended to come into contact only briefly with the skin.

<i>(1)</i> <i>Name or colour</i> <i>index number</i>	<i>(2)</i> <i>Colour</i>	<i>(3)</i> <i>Type of product</i> <i>Field of application</i>				<i>(4)</i> <i>Other</i> <i>requirements</i>	<i>(5)</i> <i>Cosmetic product</i> <i>supplied until</i>
		<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>		

Note: There are no entries in this Part at the date that these Regulations are made.

SCHEDULE 6

Regulations 5(2) and 7(2)

**LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO RESTRICTIONS**

In this Schedule, the matters specified in columns 3, 4, 5 and 6 which apply to a particular substance are those set out to the right of its name as mentioned in column 2; and the matters specified in columns 4, 5 and 6 which apply in any particular case are those set out to the right of the matter specified in column 3 which applies in that case. The substance may not be used or contained other than in the types of product specified in column 3. The concentration of the substance, when it is used as a preservative, in a product may not exceed the limit set out in column 4. Where a product is intended to be mixed with another product in specified proportions before use, the level of concentration shall be calculated by reference to the mixture. Other requirements are specified in column 5.

In column 4 of this Schedule, "A" indicates that the concentration of the substance in a product may exceed the limit set out in that column provided that—

- (a) the presence of any excess of the substance in a product over the concentration so set out is not for the primary purpose of inhibiting the development of micro-organisms; and
- (b) the purpose for which any such excess is present in the product is apparent from the labelling of the product.

In this Schedule—

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

In column 4 of this Schedule, the percentage concentration is measured by reference to mass (m/m) unless a contrary intention appears.

All preservative substances containing formaldehyde or any substances named in this Schedule which release formaldehyde must be labelled with the warning "contains formaldehyde" when the concentration of formaldehyde in the final product exceeds 0.05 per cent.

Names which appear in square brackets in column 2 of this Schedule are the INCI names of the substances in question given in the inventory of ingredients employed in cosmetic products drawn up in accordance with the provisions of the Directive and contained in Commission Decision 96/335/EC(a).

PART I

**PRESERVATIVES LISTED IN ANNEX VI, PART 1 OF THE DIRECTIVE AS PRESERVATIVES WHICH COSMETIC PRODUCTS MAY NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN**

(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>	(5) <i>Other requirements</i>	(6) <i>Required information</i>
1	Benzoic acid, its salts and esters	All products	0.5 per cent (expressed as acid)	A —	—
2	Propionic acid and its salts	All products	2 per cent (expressed as acid)	A —	—
3	Salicylic acid and its salts	All products	0.5 per cent (expressed as acid)	A	Not to be used for children under three years of age (solely for children under three years of age except for shampoos)
				A	Not to be used for children under three years of age (solely for children under three years of age which might be used for children under three years of age and which remain in prolonged contact with the skin)

(a) O.J. No. L132, 1.6.96, p. 1.

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
4	Sorbic acid (hexa-2,4-dienoic acid) and its salts	All products	0.6 per cent (expressed as acid)	A —	—
5	Formaldehyde and para-formaldehyde	For oral hygiene	0.1 per cent (expressed as free formaldehyde)	Not to be used in aerosol dispensers (sprays)	—
		Except for oral hygiene (see also Part I of Schedule 4)	0.2 per cent (expressed as free formaldehyde)		
6	ENTRY DELETED				
7	Biphenyl-2-ol [ <i>o</i> -phenylphenol] and its salts	All products	0.2 per cent (expressed as the phenol)	A —	—
8	Pyrithione zinc (INN) [Zinc pyrithione]	Products rinsed off after use	0.5 per cent	A Not to be used in oral hygiene products	—
9	Inorganic sulphites and hydrogen sulphites	All products	0.2 per cent (expressed as free SO <sub>2</sub> )	A —	—
10	Sodium iodate	Products rinsed off after use	0.1 per cent	—	—
11	Chlorobutanol (INN)	All products	0.5 per cent	Not to be used in aerosol dispensers (sprays)	Contains chlorobutanol
12	4-Hydroxybenzoic acid and its salts and esters [the Parabens]	All products	0.4 per cent (expressed as acid) for 1 ester, 0.8 per cent (expressed as acid) for mixtures of esters	A —	—
13	3-Acetyl-6-methylpyran-2,4(3 <i>H</i> )-dione [Dehydroacetic acid] and its salts	All products	0.6 per cent (expressed as acid)	Not to be used in aerosol dispensers (sprays)	—
14	Formic acid and its sodium salt	All products	0.5 per cent (expressed as acid)	A —	—
15	3,3'-Dibromo-4,4'-hexamethylenedioxydibenzamide [Dibromohexamidine] and its salts (including isethionate)	All products	0.1 per cent	—	—
16	Thiomersal (INN) [Thimerosal]	Eye make-up and eye make-up remover	0.007 per cent calculated as mercury. When mixed with other authorised mercury compounds total mercury concentration must not exceed 0.007 per cent	—	Contains thiomersal

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
17	Phenylmercuric salts (including borate)	Eye make-up and eye make-up remover	0.007 per cent calculated as mercury. When mixed with other authorised mercury compounds total mercury concentration must not exceed 0.007 per cent	—	Contains phenylmercuric compounds
18	Undec-10-enoic acid [Undecylenic acid] and its salts	All products	0.2 per cent (expressed as acid)	A —	—
19	Hexetidine (INN)	Products rinsed off after use	0.1 per cent	A —	—
20	5-Bromo-5-nitro-1,3-dioxane	Products rinsed off after use	0.1 per cent	Avoid formation of nitrosamines	—
21	ENTRY DELETED				
22	2,4-Dichlorobenzyl alcohol [Dichlorobenzyl alcohol]	All products	0.15 per cent	A —	—
23	Triclocarban (INN)	All products	0.2 per cent	A Purity criteria: 3,3',4,4'-tetrachloroazobenzene < 1 mg/kg	—
24	4-Chloro- <i>m</i> -cresol [ <i>p</i> -Chloro- <i>m</i> -cresol]	Not to be used in products intended to come into contact with mucous membranes	0.2 per cent	A —	—
25	Triclosan (INN)	All products	0.3 per cent	A —	—
26	4-Chloro-3,5-xyleneol [Chloroxylenol]	All products	0.5 per cent	A —	—
27	3,3'-Bis(1-hydroxymethyl-2,5-dioximidazolidin-4-yl)-1,1'-methyleneurea [Imidazolidinyl urea]	All products	0.6 per cent	A —	—
28	Poly(1-hexamethylenebiguanide hydrochloride) [Polyaminopropyl biguanide]	All products	0.3 per cent	A —	—
29	ENTRY DELETED				
30	Hexamethylenetetramine (Methenamine (INN)) [Methenamine]	All products	0.15 per cent	A —	—



(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
31	Methenamine 3-chloroallylochloride (INN/M) [Quaternium-15]	All products	0.2 per cent	—	—
32	1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one (Climbazole (INN)) [Climbazole]	All products	0.5 per cent	A —	—
33	1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione [DMDM Hydantoin]	All products	0.6 per cent	A —	—
34	Benzyl alcohol (See also Part I of Schedule 4)	All products	1.0 per cent	A —	—
35	1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2-pyridone and its monoethanolamine salt [Piroctone olamine]	Products rinsed off after use Other products	1.0 per cent 0.5 per cent	A — A —	— —
36	1,2-Dibromo-2,4-dicyanobutane [Methyldibromo glutaronitrile]	All products	0.1 per cent	Not to be used in cosmetic sunscreen products at a concentration exceeding 0.025 per cent	—
37	6,6-Dibromo-4,4-dichloro-2,2'-methylenediphenol [Bromochlorophen]	All products	0.1 per cent	A —	—
38	4-Isopropyl- <i>m</i> -cresol [ <i>o</i> -Cymen-5-ol]	All products	0.1 per cent	—	—
39	Mixture of 5-chloro-2-methylisothiazol-3(2 <i>H</i> )-one and 2-methylisothiazol-3(2 <i>H</i> )-one with magnesium chloride and magnesium nitrate [Methylchloroisothiazolinone and Methylisothiazolinone]	All products	0.0015 per cent of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol-3(2 <i>H</i> )-one to 2-methylisothiazol-3(2 <i>H</i> )-one	—	—

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
40	2-Benzyl-4-chlorophenol [Chlorophene]	All products	0.2 per cent	—	—
41	2-Chloroacetamide [Chloroacetamide]	All products	0.3 per cent	—	Contains chloroacetamide
42	Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride	All products	0.3 per cent	A	—
43	1-Phenoxypropan-2-ol [Phenoxyisopropanol] (see also Part I of Schedule 4)	Products rinsed off after use	1.0 per cent	—	—
44	Alkyl (C12-C22)-trimethylammonium bromide and chloride (Cetrimonium bromide (INN) and Cetrimonium chloride (INN))	All products	0.1 per cent	A	—
45	4,4-Dimethyl-1,3-oxazolidine [Dimethyloxazolidine]	All products	0.1 per cent	The pH of the finished product must not be lower than 6	—
46	1-[1,3-Bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea [Diazolidinyl urea]	All products	0.5 per cent	—	—
47	Hexamine (INN) (4,4'-(Hexamethylenedioxy)-dibenzamidine) and its salts, including isethionate and <i>p</i> -hydroxybenzoate	All products	0.1 per cent	A	—
48	Glutaraldehyde (pentane-1,5-dial) [Glutaral]	All products	0.1 per cent	Prohibited in aerosols (sprays)	Contains glutaraldehyde (where glutaraldehyde concentration in the finished product exceeds 0.05 per cent)
49	5-Ethyl-3,7-dioxo-1-azabicyclo[3.3.0]octane [7-Ethylbicyclo-oxazolidine]	All products	0.3 per cent	Prohibited in oral hygiene products and in products intended to come into contact with mucous membranes	—
50	Chlorphenesin (INN) [Chlorphenesin]	All products	0.3 per cent	—	—

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information
51	Sodium N-hydroxymethyl-glycinate [Sodium hydroxymethylglycinate]	All products	0.5 per cent	—	—
52	Silver chloride deposited on titanium dioxide	Not to be used in products for children under three years of age, in oral hygiene products and in products intended for application around the eyes and on the lips	0.004 per cent, calculated as silver chloride	The ratio of titanium dioxide to silver chloride shall be 4:1 by mass	—
53	Benzethonium chloride (INN) [Benzethonium chloride]	Products rinsed off after use	0.1 per cent	—	—
54	Benzalkonium chloride, bromide and saccharinate	All products	0.1 per cent calculated as benzalkonioium chloride	A —	Avoid contact with eyes
55	Benzylhemiformal	Products rinsed off after use	0.15 per cent	—	—
56	3-Iodoprop-2-ynyl butylcarbamate [Iodopropynyl butylcarbamate]	Not to be used in oral hygiene and lip products	0.05 per cent	—	Contains iodine (Only required where the 3-iodoprop-2-ynyl butylcarbamate concentration in products intended to remain on the skin exceeds 0.02 per cent)

PART II

PRESERVATIVES LISTED IN ANNEX VI, PART 2 OF THE DIRECTIVE AS PRESERVATIVES WHICH COSMETIC PRODUCTS MAY NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN AND WHERE SUPPLIED BEFORE A CERTAIN DATE

(1) Reference Number	(2) Name of substance	(3) Purpose of substance or type of product	(4) Maximum concentration of substance in product	(5) Other requirements	(6) Required information	(7) Permitted for supply until
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Note: There are no entries in this Part at the date that these Regulations are made.

SCHEDULE 7

Regulations 5(2) and 7(2)

**LIST OF UV FILTERS WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO RESTRICTIONS**

In this Schedule, the matters specified in columns 3, 4 and 5 which apply to a particular substance are those set out to the right of its name as mentioned in column 2. The concentration of the substance in a product may not exceed the limit specified in column 3. Where a product is intended to be mixed with another product in specified proportions before use, the level of concentration shall be calculated by reference to the mixture. Other requirements are specified in column 4. In column 3 of this Schedule, the percentage concentration is measured by reference to mass (m/m) unless a contrary intention appears.

Names which appear in square brackets in column 2 are the International Nomenclature Cosmetic Ingredient names of the substances in question given in the inventory of ingredients employed in cosmetic products drawn up in accordance with the provisions of the Directive and contained in Commission Decision 96/335/EC(a).

PART I

**UV FILTERS LISTED IN ANNEX VII, PART 1 OF THE DIRECTIVE AS UV FILTERS WHICH COSMETIC PRODUCTS MAY NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN**

(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Maximum concentration of substance in product</i>	(4) <i>Other requirements</i>	(5) <i>Required information</i>
1	4-Aminobenzoic acid [PABA]	5 per cent	—	—
2	<i>N,N,N</i> -Trimethyl-4-(2-oxoborn-3-ylidenemethyl)anilinium methyl sulphate [Camphor benzalkonium methosulfate]	6 per cent	—	—
3	Homosalate (INN)	10 per cent	—	—
4	Oxybenzone (INN) [Benzophenone-3]	10 per cent	—	Contains oxybenzone. (Not required when concentration is not more than 0.5 per cent, and when the substance is only intended to protect the product.)
5	ENTRY DELETED.			
6	2-Phenylbenzimidazole-5-sulphonic acid [Phenylbenzimidazole sulfonic acid] and its potassium, sodium and triethanolamine salts	8 per cent (expressed as acid)	—	—

(a) O. J. No. L132, 1.6.96, p.1.

(1) Reference Number	(2) Name of substance	(3) Maximum concentration of substance in product	(4) Other requirements	(5) Required information
7	3,3'(1,4-Phenylenedimethylene)-bis(7,7-dimethyl-2-oxobicyclo[2.2.1]hept-1-ylmethanesulfonic acid) [Terephthalidene dicamphor sulfonic acid] and its salts	10 per cent (expressed as acid)	—	—
8	1-(4- <i>tert</i> -Butylphenyl)-3-(4-methoxyphenyl)propane-1,3-dione (Avobenzene (INN)) [Butyl methoxy dibenzoylmethane]	5 per cent	—	—
9	$\alpha$ -(2-Oxoborn-3-ylidene)toluene-4-sulphonic acid [Benzylidene camphor sulfonic acid] and its salts	6 per cent (expressed as acid)	—	—
10	2-Ethylhexyl 2-cyano-3,3-diphenylacrylate [Octocrylene]	10 per cent (expressed as acid)	—	—
11	Polymer of N-[(2 and 4)-(2-oxoborn-3-ylidene)methyl]benzylacrylamide [Polyacrylamidomethyl benzylidene camphor]	6 per cent	—	—
12	2-Ethylhexyl 4-methoxycinnamate [Octyl methoxycinnamate]	10 per cent	—	—
13	Ethoxylated ethyl-4-aminobenzoate [PEG-25 PABA]	10 per cent	—	—
14	Isopentyl 4-methoxycinnamate [Isoamyl <i>p</i> -methoxycinnamate]	10 per cent	—	—
15	Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriumino)tribenzoate [Octyl triazone]	5 per cent	—	—
16	2-(2 <i>H</i> -Benzotriazol-2-yl)-4-methyl-6-[2-methyl-3-[1,3,3,3-tetramethyl-1-(trimethylsilyloxy)disiloxan-1-yl]propyl]phenol [Drometrizole trisiloxane]	15 per cent	—	—

(1) Reference Number	(2) Name of substance	(3) Maximum concentration of substance in product	(4) Other requirements	(5) Required information
17	Bis(2-ethylhexyl) 4,4'-[6- <i>tert</i> -butylcarbamoylethylidene]-1,3,5-triazine-2,4-diyldimino]dibenzoate	10 per cent	—	—
18	3-(4-Methylbenzylidene)bornan-2-one [4-Methylbenzylidene camphor]	4 per cent	—	—
19	3-Benzylidenebornan-2-one [3-Benzylidene camphor]	2 per cent	—	—
20	2-Ethylhexyl salicylate [Octyl salicylate]	5 per cent	—	—
21	2-Ethylhexyl 4-dimethylaminobenzoate [Octyl dimethyl PABA]	8 per cent	—	—
22	2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid [Benzophenone-4] and its sodium salt [Benzophenone-5] (Sulisobenzone (INN) and Sulisobenzone sodium (INN))	5 per cent (expressed as acid)	—	—
23	2,2'-Methylenebis[6-(2 <i>H</i> -benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol]	10 per cent	—	—
24	<i>di</i> Sodium 2,2'-(1,4-phenylene)bis(1 <i>H</i> -benzimidazole-4,6-disulfonate)	10 per cent (expressed as acid)	—	—
25	5,5'-Bis(2-ethylhexyloxy)-2,2'-(6- <i>p</i> -methoxyphenyl)-1,3,5-triazine-2,4-diyldiphenol	10 per cent	—	—
26	<i>a</i> -(Trimethylsilyl)- <i>n</i> -(trimethylsilyloxy)poly-[dimethylsilylene]- <i>co</i> -[oxy(methyl)(2- <i>p</i> -[2,2-bis(ethoxycarbonyl)-vinyl]-phenoxy]-1-methylenecetyl)silylene]- <i>co</i> -[oxy(methyl)(2- <i>p</i> -[2,2-bis(ethoxycarbonyl)vinyl]-phenoxy]prop-1-enyl)silylene] where there are usually 60 polymeric units, of which the first part of the copolymer provides 56 (Dimethicodithyl/Benzalmonate)	10 per cent	—	—
27	Titanium dioxide.	25 per cent	—	—

PART II

UV FILTERS LISTED IN ANNEX VII, PART 2 OF THE DIRECTIVE AS UV FILTERS WHICH COSMETIC PRODUCTS MAY NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN AND WHERE SUPPLIED BEFORE A CERTAIN DATE

(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Maximum concentration of substance in product</i>	(4) <i>Other requirements</i>	(5) <i>Required information</i>	(6) <i>UV filter supplied until</i>

Note: There are no entries in this Part at the date that these Regulations are made.

## SCHEDULE 8

Regulation 5(5)

### METHODS OF MANUFACTURE OF TALLOW DERIVATIVES

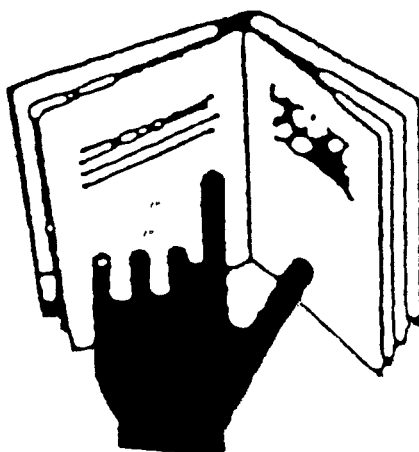
The following are the methods of manufacture referred to in regulation 5(5)—

- (a) transesterification or hydrolysis at at least 200°C, 40 bars (40,000 hPa) for 20 minutes (glycerol and fatty acids and esters);
- (b) saponification with sodium hydroxide solution,  $c(\text{NaOH}) = 12 \text{ mol/l}$  (glycerol and soap)—
  - (i) batch process: at 95°C for three hours; or
  - (ii) transesterification or hydrolysis at a temperature of at least 200°C and at an appropriate corresponding pressure, for 20 minutes (glycerol, fatty acids and fatty acid esters).

## SCHEDULE 9

Regulations 7(6) and (11)

### SYMBOL IN ANNEX VIII OF THE DIRECTIVE WHICH IS REQUIRED FOR THE PURPOSES OF REGULATION 7(6) AND (11)



## SCHEDULE 10

Regulation 12

### PART I

#### PARTICULARS TO BE INCLUDED WITH A REQUEST FOR CONFIDENTIALITY

1. The name or trade name and address or registered office of the applicant.
2. Precise identification of the cosmetic ingredient for which confidentiality is requested, namely—
  - (a) where they exist, the CAS, EINECS and colour index numbers, the chemical name, the IUPAC name, the INCI name, the European Pharmacopoeia name, the International Non-proprietary Name as recommended by the World Health Organization and the common name as provided for in the common ingredients nomenclature;
  - (b) the European List of Notified Chemical Substances (ELINCS) name and the official number allocated to it if it has been notified pursuant to Council Directive 67/548/EEC and an indication of the decision to approve or refuse any request for confidentiality made under Article 19 of that Directive;
  - (c) where the names or numbers referred to in sub-paragraphs (a) and (b) above do not exist, for example in the case of certain ingredients of natural origin, the name of the base material, the name of the part of the plant or animal used and the names of the cosmetic ingredient's compounds, such as solvents.
3. The evaluation of the safety for human health of the cosmetic ingredient as used in the finished cosmetic product or products taking into account the cosmetic ingredient's toxicological profile, chemical structure and the level of exposure as specified in regulation 9(1)(d) and carried out in accordance with the requirements of regulation 9(2) and (3).
4. The envisaged use of the cosmetic ingredient and in particular the different categories of cosmetic products in which it will be used.
5. A detailed justification of why confidentiality is sought addressing for example—
  - (a) the fact that the identity of the cosmetic ingredient or its function in the cosmetic product to be supplied has not been described in the literature accompanying the cosmetic product and is unknown to other manufacturers or suppliers of cosmetic products;



- (b) the fact that the information is not yet in the public domain even though a patent application has been lodged for the cosmetic ingredient or its use;
- (c) the fact that if the information were known it would be easily reproducible, to the detriment of the applicant.

6.—(a) If known, the name of each cosmetic product which is to contain the cosmetic ingredient and if different names are to be used in other member States, precise details of each one of them.

- (b) If the name of a cosmetic product is not yet known, it may be communicated at a later date, but at least 15 days before the cosmetic product is supplied.
- (c) If the cosmetic ingredient is used in several products, one request shall suffice, provided that the cosmetic products are clearly indicated to the competent authority.

7. A statement setting out whether a request has been submitted to the competent authority of any other member State in respect of the cosmetic ingredient for which confidentiality is sought and particulars on the outcome of any such request.

## PART II

### PROCEDURE FOR GRANT OF REGISTRATION NUMBER

1. The registration number referred to in regulation 12(5) shall consist of seven digits, the first two corresponding to the year of approval of confidentiality, the second two to the code assigned to each Member State, as referred to in paragraph 2 below, and the final three digits assigned by the competent authority.

- 2. The code allocated to the United Kingdom is 06.

## SCHEDULE 11

Regulation 15

### SAMPLING AND TESTING

1. In this Schedule—

“Annex A” means the Annex to Commission Directive No. 80/1335/EEC(a) as amended by Commission Directive No. 87/143/EEC(b);

“Annex B” means the Annex to Commission Directive No. 82/434/EEC(c) as amended by Commission Directive No. 90/207/EEC(d);

“Annex C” means the Annex to Commission Directive No. 83/514/EEC(e);

“Annex D” means the Annex to Commission Directive No. 85/490/EEC(f);

“Annex E” means the Annex to Commission Directive No. 93/73/EEC(g);

“Annex F” means the Annex to Commission Directive No. 95/32/EC(h);

“Annex G” means the Annex to Commission Directive No. 96/45/EC(i);

“purchase” means purchase for the purpose of carrying out a test.

2. An enforcement authority intending to purchase a cosmetic product shall purchase a sufficient laboratory sample, as defined in paragraph 2.3 of Part I of Annex A, for the purpose of Annex A; and, for the purposes of the definition of “total sample” in paragraph 2.2 of Part I of Annex A; samples shall be regarded as having the same batch number if—

- (a) the means of identifying the batch referred to in regulation 7(2)(g) above shows that they were manufactured in the same batch;
- (b) in the case of a product not manufactured in a batch, the reference referred to in regulation 7(2)(g) above shows that they are derived from the same unit of production; or
- (c) in the case of a product which does not comply with the requirements of regulation 7(2)(g) above, the officer effecting the purchase has reasonable cause to believe that they were manufactured in the same batch or are derived from the same unit of production, as the case may be.

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(a) O.J. No. L383, 31.12.80, p. 27.

(b) O.J. No. L57, 27.2.87, p. 56.

(c) O.J. No. L185, 30.6.82, p. 1.

(d) O.J. No. L108, 28.4.90, p. 92.

(e) O.J. No. L291, 24.10.83, p. 9.

(f) O.J. No. L295, 7.11.85, p. 30.

(g) O.J. No. L231, 14.9.93, p. 34.

(h) O.J. No. L178, 28.7.95, p. 20.

(i) O.J. No. L213, 2.7.96, p. 8.

3. The immediate container, if any, of a cosmetic product purchased by an enforcement authority shall not have been opened by, on behalf of or at the request of the enforcement authority before the purchase takes place and the container shall not thereafter be opened except in accordance with paragraph 5.3 of Part I of Annex A and paragraph 1.2 of Part II of Annex A.

4. As soon as an enforcement authority has purchased a cosmetic product, the officer effecting the purchase shall—

(a) either—

(i) place a seal on the product's container or outer packaging; or

(ii) place the product in a container and forthwith place a seal on that container, in such a way that the product's immediate container cannot be opened or (in the case of a product which was not in a container when it was purchased) the product cannot be touched without (in either case) the seal being broken in such a manner that it would be apparent thereafter that it had been broken, and

(b) attach to the product a label indicating—

(i) the name of the product,

(ii) the date, time and place at which the product was purchased,

(iii) his own name, and

(iv) the name of the enforcement authority making the purchase.

5.—(1) Subject to sub-paragraph (2) below, the provisions of Part I of Annex A, other than paragraphs 3.1, 3.2 and 4, and of Part II of Annex A, other than paragraph 1.4, shall be complied with in the sampling of cosmetic products and the laboratory preparation of test portions.

(2) Where, because of the way in which a cosmetic product is put up for sale, it is not practicable for Part II of Annex A to be complied with, it shall be prepared for testing in accordance with good analytical practice, and the person so preparing it shall record in writing the method of preparation which he has used.

6.—(1) Any test to determine whether a cosmetic product contains a significant amount of free sodium hydroxide or free potassium hydroxide shall be carried out in accordance with paragraphs 1 to 4 of Part III of Annex A.

(2) Any test to determine the amount of free sodium hydroxide or free potassium hydroxide in a hair straightener product or a nail cuticle solvent product shall be carried out in accordance with paragraphs 1, 2, 3 and 5 of Part III of Annex A.

(3) Any test to determine whether a hair-care product contains oxalic acid or any alkaline salt of oxalic acid or to determine the amount of such a substance in a hair-care product shall, subject to the limitation specified in the second sentence of paragraph 1 of Part IV of Annex A, be carried out in accordance with the said Part IV.

(4) Any test to determine the amount of chloroform in toothpaste shall, subject to the limitation specified in the second sentence of paragraph 1 of Part V of Annex A, be carried out in accordance with the said Part V.

(5) Any test to determine the amount of zinc chloride, zinc sulphate or zinc 4-hydroxybenzene-sulphonate by virtue of their zinc contents in a cosmetic product shall be carried out in accordance with Part VI of Annex A and Commission Directive 87/143/EEC(a), and shall take into account paragraph 11 of Part VII of Annex A.

(6) Any test to determine whether a cosmetic product contained in an aerosol dispenser or a cream, emulsion, lotion, gel or oil intended to be applied to the skin contains 4-hydroxybenzene-sulphonic acid, or to determine the amount of that acid in such a product, shall be carried out in accordance with Part VII of Annex A.

(7) Any test to determine whether a hair-care product contains persulphate, bromate or hydrogen peroxide shall be carried out in accordance with Part A of Part I of Annex B.

(8) Any test to determine whether a hair-care product contains barium peroxide shall be carried out in accordance with Part B of Part I of Annex B.

(9) Any test to determine the amount of hydrogen peroxide in a hair-care product shall be carried out in accordance with Part C of Part I of Annex B.

(10) Any test to determine whether a hair-dye contains any of the oxidation colourants specified in paragraph 1 of Part II of Annex B, or to determine the amount of such a substance in a hair-dye, shall be carried out in accordance with the said Part II.

(11) Any test to determine whether a cosmetic product contains nitrite, or to determine the amount of that substance in a cosmetic product, shall be carried out in accordance with Part III of Annex B.

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(a) O.J. No. L57, 27.2.87, p. 56.

(12) Any test to determine whether a cosmetic product contains free formaldehyde, or to determine the amount of that substance in a cosmetic product, shall be carried out in accordance with Part IV of Annex B.

(13) Any test to determine the amount of resorcinol in a shampoo or hair lotion shall, subject to the limitation specified in the second sentence of paragraph 1 of Part V of Annex B, be carried out in accordance with the said Part V.

(14) Any test to determine the amount of methanol in relation to ethanol or propan-2-ol in a cosmetic product shall be carried out in accordance with Part VI of Annex B.

(15) Any test to determine the amount of dichloromethane or 1,1,1-trichloroethane in a cosmetic product shall be carried out in accordance with paragraphs 1 to 10 of that part of Annex C which is headed "Determination of dichloromethane and 1,1,1-trichloroethane".

(16) Any test to determine whether a cosmetic product contains quinolin-8-ol or bis(8-hydroxyquinolinium) sulphate, or to determine the amount of such a substance in a cosmetic product, shall be carried out in accordance with paragraphs 1 to 9 of that part of Annex C which is headed "Identification and determination of quinolin-8-ol and bis(8-hydroxyquinolinium) sulphate".

(17) Any test to determine the amount of ammonia in a cosmetic product shall be carried out in accordance with paragraphs 1 to 8 of that part of Annex C which is headed "Determination of ammonia".

(18) Any test to determine whether a cosmetic product contains nitromethane, or to determine the amount of that substance in a cosmetic product, shall be carried out in accordance with paragraphs 1 to 7 of that part of Annex C which is headed "Identification and determination of nitromethane".

(19) Any test to determine whether a hair-waving, hair-straightening or depilatory product contains mercaptoacetic acid (thioglycolic acid), or to determine the amount of that substance in such a product, shall be carried out in accordance with paragraphs 1 to 6 of that part of Annex C which is headed "Identification and determination of mercaptoacetic acid in hair-waving, hair-straightening and depilatory products".

(20) Any test to determine whether a cosmetic product contains hexachlorophene (INN) shall be carried out in accordance with paragraphs 1 to 7 of Part A of that part of Annex C which is headed "Identification and determination of hexachlorophene".

(21) Any test to determine the amount of hexachlorophene (INN) in a cosmetic product shall be carried out in accordance with paragraphs 1 to 9 of Part B of that part of Annex C which is headed "Identification and determination of hexachlorophene".

(22) Any test to determine the amount of tosylchloramide sodium (INN) in a cosmetic product shall be carried out in accordance with paragraphs 1 to 9 of that part of Annex C which is headed "Quantitative determination of tosylchloramide sodium (INN) (chloramine-T)".

(23) Any test to determine the total amount of fluorine in dental creams shall be carried out in accordance with paragraphs 1 to 8 of that part of Annex C which is headed "Determination of total fluorine in dental creams".

(24) Any test to determine whether a cosmetic product contains organomercury compounds shall be carried out in accordance with paragraphs 1 to 4 of Part A of that part of Annex C which is headed "Identification and determination of organomercury compounds".

(25) Any test to determine the amount of organomercury compounds in a cosmetic product shall be carried out in accordance with paragraphs 1 to 7 of Part B of that part of Annex C which is headed "Identification and determination of organomercury compounds".

(26) Any test to determine the amount of alkali sulphides or alkaline earth sulphides in a cosmetic product shall be carried out in accordance with paragraphs 1 to 8 of that part of Annex C which is headed "Determination of alkali and alkaline earth sulphides".

(27) Any test for the identification and determination of the amount of glycerol 1-(4-aminobenzoate) in a cosmetic product shall be carried out in accordance with that part of Annex D which is headed "Identification and determination of glycerol 1-(4-aminobenzoate)".

(28) Any test to determine the amount of chlorobutanol (INN) in a cosmetic product shall be carried out in accordance with that part of Annex D which is headed "Determination of chlorobutanol".

(29) Any test for the identification and determination of the amount of quinine in a cosmetic product shall be carried out in accordance with that part of Annex D which is headed "Identification and determination of quinine".

(30) Any test for the identification and determination of inorganic sulphites and hydrogen sulphites in a cosmetic product shall be carried out in accordance with that part of Annex D which is headed "Identification and determination of inorganic sulphites and hydrogen sulphites".

(31) Any test for the identification and determination of chlorates of the alkali metals in a cosmetic product shall be carried out in accordance with that part of Annex D which is headed "Identification and determination of chlorates of the alkali metals".

(32) Any test for the identification and determination of sodium iodate in a cosmetic product shall be carried out in accordance with that part of Annex D which is headed "Identification and determination of sodium iodate".

(33) Any test for the identification and determination of silver nitrate in a cosmetic product shall be carried out in accordance with that part of Annex E which is headed "Identification and determination of silver nitrate in cosmetic products".

(34) Any test for the identification and determination of selenium disulphide in anti-dandruff shampoos shall be carried out in accordance with that part of Annex E which is headed "Identification and determination of selenium disulphide in anti-dandruff shampoos".

(35) Any test for the determination of soluble barium and soluble strontium in pigments in the form of salts or lakes shall be carried out in accordance with that part of Annex E which is headed "Determination of soluble barium and strontium in pigments in the form of salts or lakes".

(36) Any test for the identification and determination of benzyl alcohol in a cosmetic product shall be carried out in accordance with that part of Annex E which is headed "Identification and determination of benzyl alcohol in cosmetic products".

(37) Any test for the identification of zirconium and the determination of zirconium, aluminium and chlorine in non-aerosol anti-perspirants shall be carried out in accordance with that part of Annex E which is headed "Identification of zirconium, and determination of zirconium, aluminium and chlorine in non-aerosol anti-perspirants".

(38) Any test for the identification and determination of hexamidine, dibromohexamidine, dibromopropamidine and chlorhexidine in a cosmetic product shall be carried out in accordance with that part of Annex E which is headed "Identification and determination of hexamidine, dibromohexamidine, dibromopropamidine and chlorhexidine".

(39) Any test for the identification and determination of benzoic acid, 4-hydroxybenzoic acid, sorbic acid, salicylic acid and propionic acid in a cosmetic product shall be carried out in accordance with that part of Annex F which is headed "Identification and determination of benzoic acid, 4-hydroxybenzoic acid, sorbic acid, salicylic acid and propionic acid in cosmetic products".

(40) Any test for the identification and determination of hydroquinone, hydroquinone monomethyl ether, hydroquinone monoethyl ether and hydroquinone monobenzyl ether (monobenzone) in a cosmetic product shall be carried out in accordance with that part of Annex F which is headed "Identification and determination of hydroquinone, hydroquinone monomethyl ether, hydroquinone monoethyl ether and hydroquinone monobenzyl ether in cosmetic products".

(41) Any test for the identification and determination of 2-phenoxyethanol, 1-phenoxypropan-2-ol, and methyl, ethyl, propyl, butyl and benzyl 4-hydroxybenzoate in a cosmetic product shall be carried out in accordance with Annex G.

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations revoke and re-enact the Cosmetic Products (Safety) Regulations 1996 (S.I. 1996/2625 as amended by S.I. 1997/2914, S.I. 1998/1727, S.I. 1999/1552, S.I. 2000/1679 and S.I. 2000/2765; together “the 1996 Regulations”). The 1996 Regulations give effect to Council Directive 76/768/EEC (O.J. No. L262, 27.9.76, p. 169) on the approximation of the laws of the Member States relating to cosmetic products, as amended by the Community instruments listed in Schedule 2 to these Regulations.

These Regulations also give effect for the first time to Commission Directive 2002/34/EC (O.J. No. L102, 18.4.02, p.19) as follows—

- (a) in Schedule 1 to the 1996 Regulations (now Schedule 3 to these Regulations) relating to substances which cosmetic products (as defined in regulation 3(1)) of these Regulations) must not contain—
  - (i) by amending entry 631 (now entry 634) relating to radioactive substances; and
  - (ii) by inserting, as a new Part II to that Schedule, 29 new substances which cosmetic products must not contain when used as a fragrance ingredient;
- (b) in Part I of Schedule 2 to the 1996 Regulations (now Schedule 4 to these Regulations) relating to substances which cosmetic products must not contain except subject to the restrictions laid down—
  - (i) by amending entries 8, 15b, 15c and 16 regarding *m*- and *p*-phenylenediamines, lithium hydroxide, calcium hydroxide and [1-*n*]aphthol respectively;
  - (ii) by inserting a new entry 66 regarding polyacrylamides;
- (c) in Part II of Schedule 2 to the 1996 Regulations (now Schedule 4 to these Regulations) relating to substances provisionally allowed, by inserting 62 new substances; and
- (d) in Part I of Schedule 5 to the 1996 Regulations (now Schedule 7 to these Regulations) relating to UV filters (as defined in regulation 3(1) of these Regulations) which cosmetic products may not contain except subject to the restrictions laid down, by inserting new entries 26 and 27 regarding dimethicodiethylbenzalmalonate and titanium dioxide respectively.

In addition, the Regulations give effect for the first time to Commission Directive 2003/1/EC (O.J. No. L5, 10.1.03, p. 14) by substituting a new regulation 5(3) concerning specified risk material in relation to bovine, ovine and caprine animals. Regulation 5(3) prohibits the supply of a cosmetic product which contains any such specified risk material.

Furthermore, the Regulations give effect for the first time to Commission Directive 2003/16/EC (O.J. No. L46, 20.2.03, p. 24) by extending from 28th February 2003 to 30th September 2004 the date in column 7 of Part II of Schedule 4 to the Regulations by which substance numbers 61 and 62 are permitted to be used.

The Colour Index referred to in these Regulations may be obtained from the Society of Dyers and Colourists, PO Box No. 244, Perkin House, 88 Grattan Road, Bradford BDI 2JB.

The ninth edition of the International Cosmetic Ingredient Dictionary Handbook referred to in these Regulations may be obtained from Micelle Press, 12 Ullswater Crescent, Weymouth, Dorset DT3 5HE.

“A full regulatory impact assessment report of the effect that these Regulations would have on the costs to business, together with a Transposition Note, is freely available to the public from the Consumer and Competition Policy Directorate, Department of Trade and Industry, 4th Floor, 1 Victoria Street, London SW1H 0ET. Copies of the report have also been placed in the libraries of both Houses of Parliament.”