
STATUTORY INSTRUMENTS

2004 No. 2152

CONSUMER PROTECTION

The Cosmetic Products (Safety) Regulations 2004

<i>Made</i>	- - - -	<i>17th August 2004</i>
<i>Laid before Parliament</i>		<i>19th August 2004</i>
<i>Coming into force</i>		
<i>for the purpose of</i>		
<i>regulations 7(2)(c) and 7(9)</i>		
<i>(b)</i>		<i>11th March 2005</i>
<i>for all other purposes</i>		<i>11th September 2004</i>

Whereas the Secretary of State has, in accordance with section 11(5) of the Consumer Protection Act 1987⁽¹⁾, 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 ⁽²⁾ for the purposes of section 2 of the European Communities Act 1972⁽³⁾ 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 and transitory provisions

1.—(1) These Regulations may be cited as the Cosmetic Products (Safety) Regulations 2004 and shall come into force on 11th September 2004 other than the provisions set out in paragraph (2) below.

(2) The following provisions of these Regulations shall come into force on 11th March 2005—

- (a) regulation 7(2)(c); and
- (b) regulation 7(9)(b).

⁽¹⁾ 1987 c. 43.

⁽²⁾ S.I. 1972/1811, S.I. 1975/1707 and S.I. 1993/2661.

⁽³⁾ 1972 c. 68.

(3) Schedules 3,4 and 6 to these Regulations shall have effect until 24th March 2005 with the insertion of the entries referred to in Part 1 of Schedule 1 to these Regulations as they appear in the Cosmetic Products (Safety) Regulations 2003⁽⁴⁾ in place of the corresponding entries in the Schedules to these Regulations and thereafter these entries shall have effect as they appear in the Schedules to these Regulations.

(4) The entries referred to in Part 2 of Schedule 1 to these Regulations shall not form part of Schedules 3, 4 and 6 to these Regulations until 24th March 2005.

Revocation

2. The Cosmetic Products (Safety) Regulations 2003 are hereby revoked.

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;

“alternative method” means a testing method which is listed in Schedule 12 to these regulations;

“approved supply list” shall have the same meaning as in regulation 2(1) of the CHIP Regulations;

“the CHIP Regulations” means in Great Britain the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 and in Northern Ireland the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2002 ;

“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](#)⁽⁵⁾, 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](#)⁽⁶⁾;

“the 1987 Act” means the Consumer Protection Act 1987;

“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;

(4) [S.I. 2003/835](#)

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

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

“the Directive” means Council Directive [76/768/EEC](#)(7) 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 amended from time to time;

“finished cosmetic product” means the cosmetic product in its final formulation as placed on the market and made available to the final consumer, or its prototype;

“market research experiment” means any activity 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;

“prototype” means a first model or design that has not been produced in batches and from which the finished cosmetic product is copied or finally developed;

“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.

(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.

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

(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, 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 column 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 cosmetic product 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 cosmetic product in question is supplied on or before the date specified in column 6 of that Part;
- (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⁽⁸⁾, 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) Subject to paragraph (8) below, no person shall supply a cosmetic product where the final formulation has been tested on animals in order that the cosmetic product might satisfy any requirements of these Regulations or the Directive using a method other than an alternative method where—

- (a) an alternative method is listed in column 4 of Part 1 or 2 of Schedule 12 to these Regulations; and
- (b) the final formulation is tested after the date given in column 5 of Part 1 or 2 of Schedule 12.

(8) No person shall supply a cosmetic product where the final formulation has been tested on animals in order that the cosmetic product might satisfy any requirements of these Regulations or the Directive using a method other than an alternative method after—

- (a) 11th March 2013 in relation to tests concerning repeated dose toxicity, reproductive toxicity and toxicokinetics; or
- (b) 11th March 2009 in relation to all other tests.

(9) Subject to paragraph (10) below, no person shall supply a cosmetic product which contains any ingredients or combination of ingredients which have been tested on animals in order that the cosmetic product, ingredient or combination of ingredients might satisfy any requirements of these Regulations or the Directive using a method other than an alternative method where—

- (a) an alternative method is listed in column 4 of Part 1 or 2 of Schedule 12 to these Regulations; and
- (b) the ingredient or combination of ingredients is tested after the date given in column 5 of Part 1 or 2 of Schedule 12.

(10) No person shall supply a cosmetic product which contains any ingredients or combination of ingredients which have been tested on animals in order that the cosmetic product might satisfy any requirements of these Regulations or the Directive using a method other than an alternative method after—

- (a) 11th March 2013 in relation to tests concerning repeated dose toxicity, reproductive toxicity and toxicokinetics; or
- (b) 11th March 2009 in relation to all other tests.

(11) No person shall test a finished cosmetic product on animals where such testing is undertaken in order that the said product might satisfy any requirements of these Regulations or the Directive.

(12) Subject to paragraph (13) below, no person shall test any ingredient or combination of ingredients on animals in order to satisfy any requirement of these Regulations or the Directive using a method other than an alternative method where—

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

- (a) an alternative method is listed in column 4 of Part 1 or 2 of Schedule 12 to these Regulations; and
- (b) The ingredient or combination of ingredients is tested after the date given in column 5 of Part 1 or 2 of Schedule 12.

(13) No person shall test any ingredient or combination of ingredients on animals in order to satisfy any requirement of these Regulations or the Directive using a method other than an alternative method after 11th March 2009.

(14) The supply of any cosmetic product in respect of which a claim that the product or its ingredients have not been tested on animals appears on the packaging or in any document, notice, label, ring or collar accompanying or referring to the product is only permitted if—

- (a) the manufacturer and his supplier have not carried out any such tests on the finished product, its prototype or on any of the ingredients contained in the finished product or its prototype;
- (b) the manufacturer and his supplier have not commissioned any such tests on the finished product, its prototype or on any of the ingredients contained in the finished product or its prototype;
- (c) the cosmetic product contains no ingredients which have been tested on animals by others for the purpose of developing new cosmetic products.

(15) No person shall supply a cosmetic product containing any substances classified as carcinogenic, mutagenic or toxic for reproduction of category 1, 2 or 3 in the approved supply list unless the substance is listed in Schedule 13 to these Regulations.

(16) Paragraphs (14) and (15) above shall not apply to any cosmetic product placed on the market in a Member State before 11th September 2004.

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.

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 cosmetics 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 and other symbols (where appropriate) 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 before the end of 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 so to 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—
 - (i) not falling within sub-paragraph (b) above; and
 - (ii) which may cease to comply with the requirements of regulation 4 after the container in which the product is contained has been opened,the symbol given in Part II of Schedule 9 to these regulations together with an indication of the period of time after opening after which the cosmetic product is likely to cease to comply with the requirements of regulation 4;
- (d) 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;
- (e) 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;
- (f) 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;
- (g) 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), (d), (e) and (f) above);
- (h) 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
- (i) the function of the product unless this is clear from its presentation;

Provided that the requirements specified in sub-paragraphs (b), (c) and (h) 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 or the day, month and year in the order given in this paragraph.

(5) The particulars referred to—

(a) in paragraph (2)(b) to (g) and (i) above shall be in English, but this shall not prohibit the additional use of other languages;

(b) in paragraph (1) above shall be in a language easily understood by the consumer.

(6) Where it is impossible for practical reasons for the particulars referred to in paragraph (2)(c) to (g) 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 Part 1 of 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)(h) above to appear on the container and packaging, it shall be sufficient for the said particulars to appear only 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 (h) above, and in so far as any of the particulars referred to in paragraph (2)(b) to (g) and (i) 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 (h) 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 “aroma” except where the substance—

(i) is listed in column 2 of Schedule 4 to these regulations; and

(ii) is required to be mentioned by a requirement in column 5 of that Schedule;

(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 given 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” or the symbol “+/-” 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⁽⁹⁾.

(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 Part 1 of Schedule 9, which must appear on the packaging; and where it is impracticable for reasons of size and 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 consumer in which the cosmetic product is exposed for sale.

(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)(d) to (g) above shall appear on an enclosed leaflet and an indication shall appear on both the containers and 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.

(15) Paragraphs 7(2)(c) and 7(9)(b) above shall not apply to cosmetic products placed on the market in the Community prior to 11th March 2005.

Responsible Persons and Competent Authorities

8.—(1) For the purposes of regulations 9 (except regulation 9(5) and (6)), 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—

(9) An ingredient’s CTFA name is the name given to it by the Cosmetics, Toiletries and Fragrances Association (CTFA) and listed in the tenth edition of the International Cosmetic Ingredient Dictionary and Handbook (ISBN 1-882621-34-4) published in 2004 by The Cosmetic Toiletry and Fragrance Association. 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 fourth edition of The Colour Index published by the Society of Dyers and Colourists and the American Society of Textile Chemists and Colourists (available by on-line subscription at <http://www.colour-index.org/>). 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.).

- (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 person 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 (8) below, where a cosmetic product is manufactured or supplied in the United Kingdom a responsible person shall for control purposes keep easily 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) an assessment of the safety for human health of the finished product taking into consideration the matters specified in paragraph (2) below;
- (e) a specific assessment of the safety for human health of the finished product taking into consideration the matters specified in paragraph (2) below in respect of cosmetic products intended for use on children under the age of 3 and for cosmetic products intended exclusively for use in external intimate hygiene;
- (f) the name and address of the person or persons, qualified in accordance with paragraph (5) below, responsible for the assessments referred to in sub-paragraphs (d) and (e) above;
- (g) existing data on undesirable effects on human health resulting from use of the cosmetic product;
- (h) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product; and
- (i) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety evaluation of the product or its ingredients, including any

animal testing performed to meet the legislative or regulatory requirements of countries which are not Member States;

(2) The assessments referred to in paragraphs (1)(d) and (1)(e) above shall be carried out in accordance with the principles of good laboratory practice referred to in Article 1 of European Parliament and Council Directive 2004/10/EC⁽¹⁰⁾ on the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances and shall take particular account of the following—

- (a) the general toxicological profile of each ingredient used;
- (b) the chemical structure of each ingredient;
- (c) the level of exposure of each ingredient;
- (d) the specific exposure characteristics of the areas on which the cosmetic product will be applied; and
- (e) the specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

(3) Subject to paragraph (4) below and without prejudice to the protection in particular of commercial secrecy and of intellectual property rights where a cosmetic product is manufactured or supplied in the United Kingdom a responsible person shall ensure that the information specified in paragraphs (1)(a) and (1)(g) above shall be made easily accessible to the public by any appropriate means.

(4) For the purposes of paragraph (3) above, the quantitative information required under paragraph (1)(a) shall be limited to information relating to dangerous substances covered by Directive 67/548/EEC as amended.

(5) The person referred to in paragraph (1)(f) must be—

- (a) subject to paragraph (6) below, the holder of an appropriate European diploma within the meaning of section 4A of the Pharmacy Act 1954⁽¹¹⁾ 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 (6) below, a person who is entitled to be registered under section 3(1) of the Medical Act 1983⁽¹²⁾ 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⁽¹³⁾ 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.

(6) Any diploma or other evidence of qualification required for the purposes of paragraph (5)(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

⁽¹⁰⁾ O.J. No. L50, 20.2.2004, p. 44, implemented by the Good Laboratory Practice (Codification Amendment Etc.) Regulations (S.I. 2004/994).

⁽¹¹⁾ 1954 c. 61.

⁽¹²⁾ 1983 c. 54.

⁽¹³⁾ S.I. 1991/824, to which there is an amendment not relevant to these Regulations.

authority in a Member State (being a State which recognised a diploma or other evidence of qualification obtained in a non-Member State).

(7) 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.

(8) 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.

(9) 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.

(10) Paragraphs 9(1)(e), 9(1)(i), 9(2)(d) and 9(2)(e) above shall not apply in respect of cosmetic products placed on the market in the Community prior to 11th September 2004.

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 12, 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 names.

(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 these Regulations with the exception of regulations 5(7) to 5(13)

13.—(1) Subject to paragraph (2) below, any contravention of a requirement of these regulations with the exception of regulations 5(7)-5(13) 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 under regulations 9, 10 or 11 shall be liable on summary conviction shall not exceed three months.

Contravention of Regulations 5(7) to 5(13)

14.—(1) Any person who contravenes regulation 5(7), 5(8), 5(9), 5(10), 5(11), 5(12) or 5(13) or causes or permits another person to contravene those regulations, shall be guilty of an offence.

(2) Any person guilty of an offence under paragraph (1) above shall be liable, on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment not exceeding three months and, on conviction on indictment, to a fine or to imprisonment not exceeding six months.

(3) Where an offence under paragraph (1) committed by a body corporate is proved—

- (a) to have been committed with the consent or connivance of an officer, or
- (b) to be attributable to any neglect on his part,

the officer as well as the body corporate shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

(4) In paragraph (3), “officer” in relation to a body corporate, means a director, manager, secretary or other similar officer of the body, or a person purporting to act in any such capacity.

(5) If the affairs of the body corporate are managed by its members, paragraph (3) shall apply in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(6) Where an offence under paragraph (1) committed by a partnership in Scotland is proved—

- (a) to have been committed with the consent and connivance of the partner, or
- (b) to be attributable to any neglect on his part,

the partner as well as the partnership shall be guilty of that offence and liable to be proceeded against and punished accordingly.

(7) In paragraph (6), partner includes a person purporting to act as a partner.

15. For the purposes of enforcing regulations 5(7), 5(8), 5(9), 5(10), 5(11), 5(12) and 5(13), those regulations shall be treated as if they were safety regulations made under section 11 of the 1987 Act provided that section 12 of that Act shall not apply.

Enforcement

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

- (a) any failure to comply with regulations 4, 5 (with the exception of 5(11) and 5(12)), 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 contravention of regulation 5(7) of the Cosmetic Products (Safety) Regulations 2003⁽¹⁴⁾ once these regulations have come into force.

(3) No proceedings shall be brought and no enforcement action taken in respect of any contravention or failure to comply with these Regulations insofar as an entry in Part 2 of Schedule 1 to these Regulations is concerned in respect of a new substance in such an entry or where the cosmetic product in question complied with the entry as it appeared before 24th March 2005 and where the cosmetic product in question was—

- (i) placed on the market before 24th March 2005; and
- (ii) supplied before 24th September 2005.

(4) 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.

17. 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 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.

Proceedings

18. No proceedings for an offence under these Regulations shall be commenced after—

(14) [SI 2003/835](#) revoked by these regulations

- (a) the end of the period of three years beginning with the date of the commission of the offence, or
 - (b) the end of the period of one year beginning with the date of the discovery of the offence by the prosecutor,
- whichever is earlier.

17th August 2004

Gerry Sutcliffe,
Parliamentary Under Secretary of State for
Employment Relations, Competition and
Consumers
Department of Trade and Industry

SCHEDULE 1

Regulations 1(3), 1(4) and 16(3)

PART 1

Schedules 3,4 and 6 to these Regulations shall have effect until 24th March 2005 with the insertion of the entries set out in Part 1 of this Schedule as they appear in the Cosmetic Products (Safety) Regulations 2003(15) in place of the corresponding entries in the those Schedules to these Regulations.

<i>Substance</i>	<i>Reference number or entry number</i>	<i>Schedule and Part number in the Cosmetic Products (Safety) Regulations 2003</i>
Benzoyl peroxide	90	Schedule 3, Part 1
Hydroquinone monobenzyl, monoethyl and monomethyl ethers	391	Schedule 3, Part 1
4-Methoxyphenol	458	Schedule 3, Part 1
Secondary dialkanolamines	643	Schedule 3, Part 1
Hydroquinone	14	Schedule 4, Part 1
Fatty acid dialkanolamides	60	Schedule 4, Part 1
Monoalkanolamines	61	Schedule 4, Part 1
Trialkanolamines	62	Schedule 4, Part 1
1,2-Dibromo-2,4-dicyanobutane [Methyldibromo glutaronitrile]	36	Schedule 6, Part 1

PART 2

Subject to regulation 1(3), the entries referred to in Part 2 of this Schedule shall not form part of the Schedules referred to in column 3 below until 24th March 2005.

<i>Substance</i>	<i>Reference number or entry number</i>	<i>Schedule and Part number in these Regulations</i>
Secondary alkyl- and alkanolamines and their salts	643	Schedule 3, Part 1
Hydroquinone monobenzyl and monoethyl ethers	391	Schedule 3, Part 1
Hydroquinone	14	Schedule 4, Part 1
Fatty acid dialkylamides and dialkanolamides	60	Schedule 4, Part 1
Monoalkylamines,	61	Schedule 4, Part 1

(15) [S.I. 2003/835](#).

<i>Substance</i>	<i>Reference number or entry number</i>	<i>Schedule and Part number in these Regulations</i>
Monoalkanolamines and their salts		
Trialkylamines, trialkanolamines and their salts	62	Schedule 4, Part 1
2,4-Diamino-pyrimidine-3-oxide (CAS No 74638-76-9)	93	Schedule 4, Part 1
Benzoyl peroxide	94	Schedule 4, Part 1
Hydroquinone methyl ether	95	Schedule 4, Part 1
1,2-Dibromo-2,4-dicyanobutane [Methyldibromo glutaronitrile]	36	Schedule 6, Part 1

SCHEDULE 2

Regulation 3(1)

1. Council Directive [82/368/EEC](#) (N.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. 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. 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. 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 [90/12/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](#) (OJ 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 [2003/1/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).
35. Commission Directive [2003/15/EC](#) (O.J. No. L66, 11.3.03, p.26).
36. Commission Directive [2003/80/EC](#) (O.J. No. L224, 6.9.2003, p.27).
37. Commission Directive [2003/83/EC](#) (O.J. No. L238, 25.9.03, p.23)

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 references given in columns 3 and 4 are for information only. Those in column 3 are cross-references to other names listed for the same substance (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 substances falls).

Regulation 1(3) provides that until 24th March 2005 entries 90, 391, 458 and 643 shall be inserted into Part 1 of this Schedule as they appear Part 1, Schedule 3 to the Cosmetic Products (Safety) Regulations 2003. From 24th March 2005 the above entries shall have effect as they appear in Part 1 of this Schedule.

PART 1

SUBSTANCES PROHIBITED IN ALL COSMETIC PRODUCTS

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
1	Acenocoumarol (INN)	397	254
2	Acetonitrile	—	393
3	3-(α -Acetonylbenzyl)-4-hydroxycoumarin and its salts	399, 762	203
4	2-Acetoxethyltrimethylammonium 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	Acetylethyltetramethylterephthalin (AETT)	342	362
10	7 α -Acetylthio-3-oxopregn-4-ene-17 α ,17 β -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	O-Alkyldithiocarbonic acids, salts of	763	336
17	Alkyne alcohols, their esters, ethers and salts	8	16

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
18	Alloclamide (INN) and its salts	22	18
19	Allyl isothiocyanate	—	18
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	Amбеноний chloride (INN)	(529)	132
25	4-(or p-)Aminobenzonic 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	α -(Aminomethyl)-3,4-dihydroxybenzyl alcohol and its salts	519-520	257
33	4-Amino- N^{10} -methylfolic acid	452	6

<i>(1)</i> <i>Number in this</i> <i>Schedule</i>	<i>(2)</i> <i>Name of substance</i>	<i>(3)</i> <i>Cross-reference to</i> <i>this Schedule</i>	<i>(4)</i> <i>Cross-reference</i> <i>to Annex II of the</i> <i>Directive</i>
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

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(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
49	Amylobarbitone and its salts	(69)	220
50	Amylocaine and its salts	282	50
51	<i>Anamirta cocculus</i> L. (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</i> L. 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</i> L. and its preparations	—	44
65	Antropine, 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

<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
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	Bemegride (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-Benzhydryloxyethyldimethylamine and its salts	296	339
82	Benzidine	243	26
83	Benzilium bromide (INN)	93	60

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(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
84	2-Benziloyloxymethyl-1,1-dimethylpyrrolidinium methyl sulphate	602	239
85	Benzimidazolone	86, 267	48
86	Benzimidazol-2(3H)-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	ENTRY DELETED		
91	3-(N-Benzylhydrazinocarbonyl)-5-methylisoxazole	415	52
92	Benzylideneacetone	567	356
93	3-Benzyloxy-1,1-diethylpyrrolidine hydrobromide	83	60
94	4-Benzyloxyphenol	(391), 487	178
95	2-[Benzyl-N-(2-pyridyl)amino]ethyldimethylamine	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

<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
100	BHC (ISO) (<i>gamma</i> -BHC)	370, 372, 428	195
101	Bietammiverine (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
105	<i>N,N</i> -Bis(2-chloroethyl)methylamine <i>N</i> -oxide and its salts	493	86
106	<i>N,N</i> -Bis(2chloroethyl)-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)amine 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(β -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	(401, 533)	395

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
	in entry number 51 in Part 1 of Schedule 4		
113	Bithionol (INN)	708	352
114	Bretylum tosylate (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	Butopirine (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

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
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> -methylenzenesulphonyl)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	Captodiamine (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
148	Carbromal (INN)	118	57
149	Carbutamide (INN)	133	66

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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-9-[3- 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	737	366
168	2-Chloro-6- methylpyrimidin-4- yldimethylamine	164, 216	83
169	Chlorophacinone (ISO)	175	93

<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
170	1-(<i>p</i> -Chloro- α -phenylbenzyl)-4-(2-hydroxyethoxyethyl)piperazine	402	240
171	2-(4-Chlorophenyl)-1-[4-2-diethyl-aminoethoxyl]]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-hydroxyisindolin-1-one	183, 184	262
179	Chlorphenoxamine (INN)	176	94
180	Chlorpromazine (INN)	(561)	320
181	Chlorpropamide (INN)	617	79
182	Chlorprohixene (INN) and its salts	165	84
183	Chlortalidone (INN)	178, 184	262
184	Chlorthalidone	178, 184	262
185	Chlorzoxazone (INN)	162	82

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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
192	<i>Claviceps purpurea</i> Tul., 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</i> L, 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

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
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</i> L. (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

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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</i> L. 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	Decamethylene-bis(trimethylammonium) salts	235	214
237	Dextromethorphan (INN) and its salts	457	226
238	Dextropropoxyphene (INN)	281	116
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

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
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-(α,β -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-Diethylaminoethoxyethyl α -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-	—	128

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	phenylbenzoate and its salts		
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	Difencloxadine INN)	569	270
266	Digitaline and all heterosides of <i>Digitalis purpurea</i> L.	—	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	Dihydrotachacysterol (INN)	—	342
270	3,4-Dihydroxy- α -(methylaminomethyl)benzyl alcohol	14, 315	14
271	4,4'-Dihydroxy-3,3'-(3-methylthiopropylideneI)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

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
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 N-acetylglutamate	234	3
280	2-Dimethylaminoethyl p-butylaminobenzoate and its salts	690	63
281	(+)-4- Dimethylamino-3- methyl-1,2- diphenyl-2- propionyloxybutane	238	116
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

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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 (INN)	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-Diphenylmethoxytropene 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	α,α -Diphenyl-2-piperidinemethanol and its salts	600	285

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
305	α,α -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

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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
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	Ethylphenacetamide	556, 568	272

<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
341	2-Ethyl-2-phenylglutarimide and its salts	362	181
342	3'-Ethyl-5',6',7',8'-tetrahydro-5',5',8',8'-tetramethyl-2'-acetone	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-(α,α,α -trifluoro- <i>m</i> -tolyl)piperino]butyrophenone	741	188
350	6-Fluoro-16-methyl-11 β ,17 α ,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	96, 462, 623, 746	358

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	shall be below 1 mg/ kg		
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
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>)-1,2,3,4,10,11,12- Hexachloro-6,7- epoxy-1,4,4a,5,6,7,8,8a- octahydro-1,4:5,8 dimethanonaphthalene	373	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>)-1,2,3,4,10,11,12- Hexachloro-1,4,4a,5,8,8a-	377	198

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
	hexahydro-1,4:5,8- dimethanonaphthalene		
378	Hexaethyl tetraphosphate	371	316
379	(1R,2S)- Hexahydro-1,2- dimethyl-3,6- epoxyphthalic anhydride	140	70
380	(3S,5aR,9bS)-3,3a,4,5,5a,6,9b- Hexahydro-3,5a,9- trimethylnaphtho[1,2- b]furan-2,8-dione	380	217
381	Hexamethonium bromide (INN)	(382)	124
382	N-N'- 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

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391	Hydroquinone monobenzyl and monoethyl ethers	487	178
392	7-[2-Hydroxy-3-(2-hydroxyethyl-N-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	11 α -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

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
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
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</i> <i>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

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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

<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
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-N-(2-pyridyl)amino]-ethyl dimethylamine maleate	625	346
454	1-Methoxy-2,2-bis(4-hydroxy-3-coumarinyl)ethane	215	225
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-N-methylmorphinan and its salts	237	226
458	ENTRY DELETED		
459	3-(2-Methoxyphenoxy)propane-1,2-diol	366	230

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<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
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

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
472	1-Methylimidazole-2-thiol	474, 707	233
473	<i>N,N'</i> [Methylimino]diethylene]bis- (ethyltrimethylammonium) 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- isopropylcarbamoyloxy-3- carbamoyloxypropane	150	235
481	2-Methyl-2- propyltrimethylene dicarbamate	440	236
482	<i>N</i> -Methyl-1,2,5,6- tetrahydro-3-nicotine acid methyl ester	61	238
483	Methypylon (INN) and its salts	295	133
484	Metirapone (INN)	464	292
485	Minoxidil (INN), its salts and derivatives	599	372
486	Mofebutazone (INN)	131	64
487	Monobenzone (INN)	94, (391)	178
488	Morpholine and its salts	—	344

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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	β -Naphthol	496	241
498	1-and 2-Naphthylamines and their salts	499	242
499	α -and β -Naphthylamines and their salts	498	242
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

<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
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''</i> -N,N-diethyl-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

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<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
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	[Oxalylbis(iminoethylen-2-yl)bis[(<i>o</i> -chlorobenzyl)diethylammonium] salts	24	132
530	Oxanamide (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

<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
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
547	<i>N,N'</i> -Pentamethylenebis(trimethylammonium) 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

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(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
567	4-Phenylbut-3-en-2-one	92	356
568	(2-Phenylbutyryl)urea	340, 556	272
569	<i>N</i> -[2-(α -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	α -Phenyl-2-piperidineacetic acid methyl ester and its salts	475	175
576	3-Phenylpropyl carbamate	562	71
577	3-(α -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

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
581	6-Phenyl-2,4,7-triaminopteridine and its salts	725	275
582	Phenylamidol	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
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	95	118
597	α -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

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599	6-(Piperidiny)-2,4-pyrimidinediamine 3-oxide, its salts and derivatives	485	372
600	Pipradrol (INN) and its salts	304	285
601	Piprocuarium idodide (INN)	256	137
602	Poldine metilsulfate (INN) (Poldine methylsulphate)	84	239
603	Polyacetaldehyde	444	223
604	Potassium cyanide	(388, 390, 409)	111
605	Potassium nitroferri cyanide	(15), 606	255
606	Potassium nitroprusside	(15), 605	255
607	Pramocaine (INN)	608	405
608	Pramoxine	607	405
609	Probenecid (INN)	308	161
610	Procaïnamide (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

<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
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-(N-2-Pyridyl-N-2- thienylamino)ethyl- dimethylamine and its salts	448	144
628	Pyrithione disulphide + magnesium sulphate	310	396
629	Pyrithione sodium	—	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
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	—	293

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(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
	the general public against the dangers arising from ionising radiation)		
635	<i>Rauwolfia serpentine</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	α -Santonin	380	214
640	<i>Schoenocaulon</i> <i>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 alkyl- and alkanolamines and their salts	108, 255, 274	411
644	Selenium and its compounds (except when permitted under the restrictions laid	—	297

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
	down in Part I of Schedule 4)		
645	Sodium cyanide	(388, 390, 409)	111
646	Sodium hexacyclonate (INN)	396	114
647	Sodium nitroferri cyanide	(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	Spironolactone (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

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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
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 ₂ 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	44	21

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
	list of medicaments which are subject to medical prescription and are referred to in resolution AP (69) 2 of the Council of Europe		
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		367
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-	682	237

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	naphthylmethylmethyl)-2- imidazoline and its salts		
699	4-(Tetrahydro-2H-1,2- thiazin-2-yl)- benzenesulphonamide S,S-dioxide	679, 680	308
700	Tetrahydrozoline and its salts		394
701	N,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 nerifolia</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 Part I of Schedule 4)		321
713	Thiram (ISO)	702	162
714	Thiuram disulphides		354
715	Thiuram monosulphides		353
716	Thyropropic acid (INN) and its salts	394	9

<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
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> -Tolyboric acid ester of 2-methyl-2- propylpropane-1,3-diol	717	177
721	3- <i>o</i> - Tolyoxypropane-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-Tribromeoethanol	(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

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737	N-(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	Trifluoperidol (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 1-4-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	Tripeleminamine (INN)	95, 626	347
749	Tris(2-chloroethyl)amine	732	327
750	Tritolyl phosphate	739	277
751	Tauminohexane (INN), its isomers and salts	30	27
752	<i>Urginea scilla</i> Stern. and its galenical preparations	653	330
753	Urocanic acid	(406)	418
754	Vaccines, toxins and serums listed in the		323

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
	Annex to Council Directive No. 75/319/ EEC(a)		
755	Valnoctamide (INN)	339	184
756	Veratrine, its salts and galenical preparations		331
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 ₂ and D ₃	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 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 Part I of Schedule 5 by		391

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<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) Cross-reference to Annex II of the Directive</i>
	“*” immediately after the name or colour index number)		
769	Zoxazolamine (INN)	28	24

Regulation 5(2)

PART 2

SUBSTANCES PROHIBITED WHEN USED AS A FRAGRANCE INGREDIENT

<i>(1) Number in this Schedule</i>	<i>(2) Name of substance</i>	<i>(3) Cross-reference to this Schedule</i>	<i>(4) 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

(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
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
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- butenoate		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		451

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(1) Number in this Schedule	(2) Name of substance	(3) Cross-reference to this Schedule	(4) Cross-reference to Annex II of the Directive
	oral hygiene products)		
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), 7(9)

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](#)(16).

Regulation 1(3) provides that until 24th March 2005 entries 14, 60, 61 and 62 shall be inserted into Part 1 of this Schedule as they appear in Part 1 of Schedule 4 to the Cosmetic (Products) (Safety) Regulations 2003(17). From 24th March 2005 the above entries shall have effect as they appear in Part 1 of this Schedule.

Regulation 1(4) provides that entries 93,94 and 95 in Part 1 of this Schedule shall not form part of this Schedule until 24th March 2005.

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

(17) [SI 2003/835](#)

PART 1

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

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

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(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
				1.5 per cent calculated as boric acid	calculated as boric acid)
			The above- mentioned percentages are calculated as boric acid		
1b	Tetraborates	Bath products	18 per cent	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	(a) 8 per cent	pH 7 to 9.5	Contains thioglycolate. Follow the instructions. Keep out of reach of children.
		(b) Hair waving or straightening products for professional use	(b) 11 per cent ready for use	pH 7 to 9.5	Contains thioglycolate. Follow the instructions. Keep out of reach of children. For professional use only
		(c) Depilatories ready for use	(c) 5 per cent	pH 7 to 12.7	Contains thioglycolate. Follow the instructions. Keep out of reach of children
		(d) Other hair- care products which are removed	(d) 2 per cent ready for use	pH 7 to 9.5	Contains thioglycolate. Follow the instructions. Keep out of reach of children

(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
		after application	The above- mentioned percentages are calculated as thioglycolic acid	(a), (b), (c) and (d): The directions for use must incorporate the following: <ul style="list-style-type: none"> — 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) 	
2b	Thioglycolic acid esters	(a) Hair waving or straightening products for general use	(a) 8 per cent wavy ready for use	pH 6 to 9.5	Contains thioglycolate. Follow the instructions. Keep out of reach of children
		(b) Hair waving or straightening products for	(b) 11 per cent wavy ready for use	pH 7 to 9.5	Contains thioglycolate. Follow the instructions. Keep out of reach of children. For

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(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
		professional use			professional use only
			The above-mentioned percentages are calculated as thioglycolic acid	(a) and (b): The directions for use must incorporate the following: <ul style="list-style-type: none"> — May cause sensitization in the event of skin contact — Avoid contact with eyes — In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice — Wear suitable gloves 	
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 ₃		Contains ammonia (not required when concentration is not more than 2 per cent)
5	Tosylchloramide sodium (INN)	All purposes and products	0.2 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
	[Chloramine-T]				
6	Chlorates of alkali metals	Toothpaste	5 per cent		
		Other uses	3 per cent		
7	Dichloromethane	All purposes and products	35 per cent (and when mixed with 1,1,1-trichloroethane, per cent total concentration must not exceed 35 per cent)	Purity of the dichloromethane must be not less than 99.8 per cent	
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
		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. For professional use only. Can cause an allergic reaction. Wear suitable gloves

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(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
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) (see Note 1)	Oxidizing colouring agents for hair dyeing for general 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 phenylenediamines. For professional use only. Can cause an allergic reaction. Wear suitable gloves
10	Diaminophenols (see Note 1)	Oxidizing colouring agents for hair dyeing for general use	10 per cent calculated as 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

(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 preparation (b) Skin care preparation (c) Nail hardening preparation	(a) 12 per cent of H ₂ O ₂ present on release (b) 4 per cent of H ₂ O ₂ present on release (c) 2 per cent of H ₂ O ₂ present on release		(a) Wear suitable gloves Contains hydrogen peroxide. Avoid contact with eyes. Rinse eyes immediately if product comes into contact with them Contains hydrogen peroxide. Avoid contact with eyes. Rinse eyes immediately if product comes into contact with them Contains hydrogen peroxide. Avoid contact with eyes. Rinse eyes immediately if product comes into contact with them

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(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
		(d) Oral	(d) 0.1 per cent of H ₂ O ₂ present or released		
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
		Oxidizing colouring agent for hair dyeing for professional use	0.3 per cent subject to the provisions of “Combination Rule B” set out below		For professional use only. Contains hydroquinone. Rinse eyes immediately if product comes into contact with them
		Artificial nail systems for professional use	0.02 per cent (after mixing for use) subject to the provisions of “Combination Rule B” set out below		For professional use only Avoid skin contact Read directions for use carefully
15a	Potassium hydroxide	Nail cuticle solvent	5 per cent calculated		Contains alkali. Avoid

(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
	and sodium hydroxide		as sodium hydroxide (see Note 2)		contact with eyes. Can cause blindness. Keep out of reach of children
		Hair straightener for general use	2 per cent calculated as sodium hydroxide (see Note 2)		Contain alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children
		Hair straightener for professional use	4.5 per cent calculated as sodium hydroxide (see Note 2)(18)		For professional use only. Avoid contact with eyes. Can cause blindness
		pH adjuster for depilatories		PH value not to exceed 12.7	Keep out of reach of children Avoid contact with the eyes
		Other uses as pH adjuster		PH value not to exceed 11	
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
		Hair straightener for	4.5 per cent calculated as sodium		For professional use only. Avoid contact

(18) 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.

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(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
		professional use	hydroxide (see Note 2)		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	
15c	Calcium hydroxide	Hair straighteners containing two components; calcium hydroxide and a guanidine 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. Keep out of reach of children.
		Other uses e.g. pH adjuster processing aid		pH value not to exceed 11	
16	α -Naphthol [1- Naphthol] 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
17	Sodium nitrite	Rust inhibitor	0.2 per cent	Do not use with secondary and/or tertiary amines	

(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 or other substances forming nitrosamines	(6) Required information
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
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		Contain 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		Contains resorcinol

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(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
			Rule B” set out below		
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- hydroxybenzene- sulphonate	All purposes and products	1 per cent calculated as zinc		
25	Zinc 4- hydroxybenzene sulphonate [Zinc phenolsulfonate]	Deodorants, antiperspirants and astringent lotions	6 per cent calculated as percentage of anhydrous substance		Avoid contact with eyes
26	Ammonium monofluoro- phosphate	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 monofluoro- phosphate	Oral hygiene products	As for ammonium monofluorophosphate		Contains sodium monofluoro- phosphate
28	Potassium monofluoro- phosphate	Oral hygiene products	As for ammonium monofluorophosphate		Contains potassium 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
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> -hexadecylpropylenediamine dihydrofluoride [Palmityltrihydroxyethyl	Oral hygiene products	As for ammonium monofluorophosphate		Contains <i>N,N,N'</i> -tris (polyoxyethylene)- <i>N</i> -hexadecylpropylenediamine dihydrofluoride

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(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
	propylenediamine dihydrofluoride]				
39	Octadecenylammonium fluoride	Oral hygiene products	As for ammonium monofluorophosphate		Contains octadecenylammonium fluoride
40	Sodium fluorosilicate	Oral hygiene products	As for ammonium monofluorophosphate		Contains sodium fluorosilicate
41	Potassium fluorosilicate	Oral hygiene products	As for ammonium monofluorophosphate		Contain potassium fluorosilicate
42	Ammonium fluorosilicate	Oral hygiene products	As for ammonium monofluorophosphate		Contains ammonium fluorosilicate
43	Magnesium fluorosilicate	Oral hygiene products	As for ammonium monofluorophosphate		Contains magnesium fluorosilicate
44	1,3-Bis(hydroxymethyl) imidazolidine-2- thione [Dimethylol ethylene thiourea]	Hair care preparations	2 per cent	Not to be used in aerosol dispensers	Contains 1,3- bis(hydroxymethyl) imidazolidine-2- thione
45	Benzyl alcohol (See also Part I of Schedule 6)	Solvent, perfumes and flavourings			
46	6-Methylcoumarin	0.003 per cent	0.003 per cent		
47	Nicomethanol hydrofluoride	Oral hygiene products	As for ammonium monofluorophosphate		Contains nicomethanol hydrofluoride
48	Silver nitrate	Products to dye eyelashes or eyebrows	4 per cent		Contains silver nitrate. Rinse eyes immediately if product comes into contact with them
49	Selenium disulphide	Anti-dandruff shampoos	1 per cent		Contains selenium

(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
	[Selenium sulphide]				disulphide. Avoid contact with eyes or damaged skin
50	Aluminium zirconium chloride hydroxide complexes $\text{Al}_x\text{Zr}(\text{OH})_y$ Cl_z and aluminium hydroxide glycine complexes	Anti- perspirants	20 per cent 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 to 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- hydroxyquinolin- sulphate) (See also Part I of Schedule 3) [Oxyquinoline and Oxyquinoline sulphate]	Stabilizer for hydrogen peroxide in rinse-off hair care preparations	0.3 per cent calculated as base		
		Stabilizer for hydrogen peroxide in non rinse- off hair car preparations	0.3 per cent calculated as base		
52	Methanol	Denaturant for ethanol and isopropyl alcohol	5 per cent calculated as a percentage of ethanol		

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(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
			and isopropyl alcohol		
53	Etidronic 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) [Phenoxyisopropanol]	Products rinsed off after use	2 per cent	Prohibited in oral hygiene products	
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 fluoride. 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)	(a) 1.6 per cent calculated as strontium.		Contains strontium chloride

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(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
			When mixed with other permitted strontium compounds the total strontium content must not exceed 3.5 per cent		Frequent use by children is not advisable
		Shampoo (b) 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		
58	Strontium acetate hemihydrate	Toothpaste	3.5 per cent calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3.5 per cent		Contains strontium acetate. Use by children is not advisable
59	Talc: hydrated magnesium	(a) Powder (b) products intended to be used for children under three years			(a) Keep (b) powder away from children's and mouth

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(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
		of age (b) other products			
60	Fatty acid dialkylamides and dialkanolamides	All purposes and products	Maximum secondary amine content: 0.5 per cent	Do not use with nitrosating systems. Maximum secondary amine content: 5 per cent (applies to raw materials. Maximum nitrosamine content: 50 µg/kg (applies to raw materials). Keep in nitrite-free containers	
61	Monoalkylamines Monoalkanolamines and their salts	All purposes and products	Maximum secondary amine content: 0.5 per cent	Do not use with nitrosating systems. Minimum purity: 99 per cent. Maximum secondary amine content: 0.5 per cent (applies to raw materials). Maximum nitrosamine content: 50 µg/kg (applies to raw materials). Keep in nitrite-free containers.	

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(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
62	Trialkylamines, trialkanolamines and their salts	(a) no (a) rinse- off products (b) othe (b) products	(a) 2 (a) per cent	Do not use with nitrosating systems. Minimum purity: 99 per cent. Maximum secondary amine content: 0.5 per cent (applies to raw materials) Maximum nitrosamine content: 50 µg/kg (applies to raw materials). Keep in nitrite free containers Do not use with nitrosating systems. Minimum purity: 99 per cent. Maximum secondary amine content: 0.5 per cent (applies to raw materials) Maximum nitrosamine 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.

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(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
					Avoid contact with the eyes
64	Sodium 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 ₁₄ or less must not exceed 0.1 per cent calculated as benzalkonium chloride	Avoid contact with the eyes
66	Polyacrylamides	Body-care leave-on products		Maximum residual acrylamide content 0.1 mg/kg Maximum residual acrylamide content 0.5 mg/kg	
67	Amyl cinnamal (CAS No 122-40-7)			The presence of the substance must be indicated in the list of ingredients	

(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
				referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
68	Benzyl alcohol (CAS No 100-51-6)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
69	Cinnamyl alcohol (CAS No 104-54-1)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds:	

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(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
				— 0.001 per cent in leave-on products — 0.01 per cent in rinse off products	
70	Citral (CAS No 5392-40-5)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse off products	
71	Eugenol (CAS No 97-53-0)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on 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
				— 0.01 per cent in rinse-off products	
72	Hydroxycitronellal (CAS No 107-75-5)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
73	Isoeugenol (CAS No 97-54-1)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	

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(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
74	Amylcinnamylalcohol (CAS No 101-85-9)				The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products
75	Benzyl salicylate (CAS No 118-58-1)				The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products
76	Cinnamal (CAS No 104-55-2)				The presence of the substance must be

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				indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
77	Coumarin (CAS No 91-64-5)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
78	Geraniol (CAS No 106-24-1)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1)	

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(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
				when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
79	Hydroxymethylpentyl- cyclohexene- carboxaldehyde (CAS No 31906-04-4)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
80	Anisyl alcohol (CAS No 105-13-5)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per	

(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
				cent in leave-on products — 0.01 per cent in rinse-off products	
81	Benzyl cinnamate (CAS No 103-41-3)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
82	Farnesol (CAS No 4602-84-0)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in	

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(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
				rinse-off products	
83	2-(4- <i>tert</i> - Butylbenzyl) propionaldehyde (CAS No 80-54-6)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
84	Linalool (CAS No 78-70-6)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
85	Benzyl benzoate			The presence of the	

<i>(1) Reference Number</i>	<i>(2) Name of substance</i>	<i>(3) Purpose of substance or type of product</i>	<i>(4) Maximum concentration of substance in product</i>	<i>(5) Other requirements</i>	<i>(6) Required information</i>
	(CAS No 120-51-4)			substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
86	Citronellol (CAS No 106-22-9)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
87	Hexyl cinnamaldehyde (CAS No 101-86-0)			The presence of the substance must be indicated in the list of ingredients	

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				referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
88	<i>d</i> -Limonene (CAS No 5989-27-5)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
89	Methyl heptin carbonate (CAS No 111-12-6)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds:	

(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
				— 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
90	3- Methyl-4(2,6,6- trimethyl-2- cyclohexen-1- yl)-3-buten-2- one (CAS No 127-51-5)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
91	Oak moss extract (CAS No 90028-68-5)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products	

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(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
				— 0.01 per cent in rinse-off products	
92	Treemoss extract (CAS No 90028-67-4)			The presence of the substance must be indicated in the list of ingredients referred to in regulation 7(1) when its concentration exceeds: — 0.001 per cent in leave-on products — 0.01 per cent in rinse-off products	
93	2,4-Diaminopyrimidin-3-oxide (CAS No 74638-76-9)	Hair care formulations	1.5 per cent		
94	Benzoyl peroxide (CAS No 94-36-0)	Artificial nail systems for professional use	0.7 per cent (after mixing for use)		For professional use only Avoid skin contact Read directions for use carefully
95	Hydroquinone methyl ether (4-methoxyphenol) (CAS No 150-76-5)	Artificial nail systems for professional use	0.02 per cent (after mixing for use)		For professional use only Avoid skin contact

(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
					Read directions for use carefully

PART 2

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 (CAS No 2390-60-5)	Non- oxidising colouring agents for hair dyeing	0.2 per cent	—	Can cause allergic reaction	30.9.2004
2	2-Amino-3- nitrophenol (CAS No 603-85-0) 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
		Non- 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

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(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
3	4-Amino-3-nitrophenol (CAS No 610-81-1) 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
		Non-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
4	Naphthalene-2,10-diol (CAS No 582-17-2) 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 (CAS No 591-27-5) and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration upon	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
6	3,4-Dimethylpyridine-2,6-diol (CAS No 84540-47-6) and its salts	Oxidising colouring agents for hair dyeing	2 per cent	application is 1 per cent In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	Can cause allergic reaction	30.9.2004
7	4-(3-Hydroxypropyl)-2-nitrophenol (CAS No 92952-81-3) and its salts	Oxidising colouring agents for hair dyeing	5.2 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 2.6 per cent	Can cause allergic reaction	30.9.2004
		Non-oxidising colouring agents for hair dyeing	2.6 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 2.6 per cent	Can cause allergic reaction	30.9.2004
8	6-Nitropyridine-2,5-diamine (CAS No 69825-83-8) and its salts	Non-oxidising colouring agent for hair dyeing	3 per cent	—	Can cause allergic reaction	30.9.2004

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(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
9	HC Blue No. 11 (CAS No 23920-15-2) 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
		Non- oxidising colouring agents for hair dyeing	2 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
10	2-(2- Nitro- <i>p</i> -toluidino)- ethanol (CAS No 100418-33-5) 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
		Non- oxidising colouring agents for hair dyeing	1 per cent	In combination with hydrogen peroxide the maximum use concentration upon	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
11	2-(2-Hydroxyethylamino)-4,6-dinitrophenol (CAS No 99610-72-7) and its salts	Oxidising colouring agents for hair dyeing	3 per cent	application is 1 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
		Non-oxidising colouring agents for hair dyeing	2 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
12	4-Methylaminophenol (CAS No 150-75-4) 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
13	2-(2,4-Diamino-5-methylphenoxy)ethanol (CAS No 141614-05-3) and its salts	Oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use	Can cause allergic reaction	30.9.2004

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(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
				concentration upon application is 1.5 per cent		
14	HC Violet No. 2 (CAS No 104226-19-9) and its salts	Non- oxidising colouring agent for hair dyeing	2 per cent	—	—	30.9.2004
15	2-(2,6- Dinitro- <i>p</i> -anisidinyl)- ethanol (CAS No 122252-11-3) 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 (CAS No 104516-93-0) and its salts	Oxidising colouring agents for hair dyeing	1.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.75 per cent	Can cause allergic reaction	30.9.2004
		Non- oxidising colouring agent for hair dyeing	1.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.75 per cent	Can cause allergic reaction	30.9.2004
17	4-Ethoxy-6- methyl- <i>m</i> - phenylenediamine (CAS No	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the	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
	113715-25-6)			maximum use concentration upon application is 1 per cent		
18	4,4'- (Trimethylenedioxy)bis- phenylenediamines (CAS No 81892-72-0) 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 (CAS No 61693-43-4) 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- l-phenyl-5- pyrazolone (CAS No 89-25-8) 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
21	5-(2- Hydroxyethyl)- o-cresol (CAS No	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the	Can cause allergic reaction	30.9.2004

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	55302-96-0) and its salts			maximum use concentration upon application is 1 per cent		
22	3,4-Dihydro-2H-1,4-benzoxazin-6-ol (CAS No 26021-57-8) 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-1,4-diol (CAS No 575-38-2) 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 (CAS No 109023-83-8) and its salts	Non- oxidising colouring agents for hair dyeing	0.2 per cent	—	—	30.9.2004
25	2,6-Dimethoxy-3,5-pyridinediamine (CAS No 85679-78-3) and its salts	Oxidising colouring agents for hair dyeing	0.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application	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
				is 0.25 per cent		
26	HC Orange No.2 (CAS No 85765-48-6) and its salts	Non-oxidising colouring agent for hair dyeing	1 per cent	—	—	30.9.2004
27	HC Violet No.1 (CAS No 82576-75-8) 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
		Non-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
28	2-(3-Methylamino-4-nitrophenoxy)ethanol (CAS No 59820-63-2) and its salts	Non-oxidising colouring agents for hair dyeing	1 per cent	—	—	30.9.2004
29	2-(2-Methoxy-4-nitroanilino)ethanol (CAS No 66095-81-6) and its salts	Non-oxidising colouring agents for hair dyeing	1 per cent	—	—	30.9.2004

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30	2-(4-Amino-2-chloro-5-nitroanilino)ethanol (CAS No 50610-28-1) 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
		Non-oxidising colouring agents for hair dyeing	1 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1 per cent	—	30.9.2004
31	HC Red No. 13 (CAS No 94158-13-1)	Oxidising colouring agents for hair dyeing	2.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 1.25 per cent	—	30.9.2004
		Non-oxidising colouring agents for hair dyeing	2.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon application	—	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
32	Naphthalene-1,6-diol (CAS No 83-56-7) and its salts	Oxidising colouring agents for hair dyeing	1 per cent	is 1.25 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)]methanol (CAS No 128729-30-6) 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 (CAS No 95-55-6) 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
35	5-Amino- <i>o</i> -cresol (CAS No 2835-95-2) and its salts	Oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use concentration	—	30.9.2004

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(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
				upon application is 1.5 per cent		
36	2-(2,4-Diamino-phenoxy)ethanol (CAS No 66422-95-5) 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 (CAS No 608-25-3) 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 (CAS No 2835-99-6) 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 (CAS No 83763-47-7) and its salts	Oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use	—	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
				concentration upon application is 1.5 per cent		
40	3,4-Diaminobenzoic acid (CAS No 619-05-6) 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
41	6-Amino-o-cresol (CAS No 17672-22-9) 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-4-aminophenol (CAS No 79352-72-0) 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	2-Amino-2-(2-hydroxyethyl)aminoethanol (CAS No 10101-91-8) and its salts	Oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the	—	30.9.2004

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(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
	110952-46-0 and its salts			maximum use concentration upon application is 1.5 per cent		
44	N-(2-Hydroxyethyl)-2,2,4,4-tetramethyl-1,3-dioxane-1,3-diol (CAS No 81329-90-0) 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 (CAS No 3618-58-4) 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 (CAS No 5307-14-2) and its salts	Oxidising colouring agents for hair dyeing	0.3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.15 per cent	—	30.9.2004
		Non- oxidising colouring	0.3 per cent	In combination with	—	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
		agents for hair dyeing		hydrogen peroxide the maximum use concentration upon application is 0.15 per cent		
47	HC Blue No.2 (CAS No 33229-34-4) and its salts	Non- oxidising colouring agents for hair dyeing	2.8 per cent	—	—	30.9.2004
48	4-(2- Hydroxyethyl- nitrophenol (CAS No 65235-31-6) and its salts	Oxidising colouring agents for hair dyeing	6 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 3 per cent	—	30.9.2004
		Non- oxidising colouring agents for hair dyeing	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 (CAS No 27080-42-8) and its salts	Oxidising colouring agents for hair dyeing	0.5 per cent	In combination with hydrogen peroxide the maximum use concentration upon	—	30.9.2004

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(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
				application is 0.25 per cent		
		Non- 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
50	HC Red No. 10 (CAS No 95576-89-9) + HC Red No. 11 (CAS No 95576-92-4) and their 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
		Non- oxidising colouring agents for hair dyeing	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 (CAS No 104333-00-8) and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use concentration	—	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
				upon application is 1 per cent		
		Non- oxidising colouring agents for hair dyeing	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 (CAS No 59320-13-7) 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
		Non- oxidising colouring agents for hair dyeing	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 (CAS No 102767-27-1) and its salts	Oxidising colouring agents for hair dyeing	2 per cent	In combination with hydrogen peroxide the maximum use	—	30.9.2004

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(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
				concentration upon application is 1 per cent		
54	HC Blue No. 9 (CAS No 114087-47-1) 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
		Non- oxidising colouring agents for hair dyeing	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 (CAS No 131657-78-8) 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
		Non- oxidising colouring agents for hair dyeing	3 per cent	In combination with hydrogen peroxide the maximum use	—	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
				concentration upon application is 1.5 per cent		
56	2-Amino-6-chloro-4-nitrophenol (CAS No 6358-09-4) 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
		Non-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
57	C.I. Basic Blue 26 (CAS No 2580-56-5) (C.I. No. 44045)	Oxidising colouring agents for hair dyeing	0.5%	In combination with hydrogen peroxide the maximum use concentration upon application is 0.25 per cent	—	30.9.2004
		Non-oxidising colouring agents for hair dyeing	0.5%	In combination with hydrogen peroxide the maximum	—	30.9.2004

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

(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
				use concentration upon application is 0.25 per cent		
58	C.I. Acid Red 33 (CAS No 3567-66-6) (C.I. No. 17200)	Non- oxidising colouring agents for hair dyeing	2 per cent	—	—	30.9.2004
59	C. I. Food Red 1 (CAS No 4548-53-2) (C.I. No. 14700)	Non- oxidising colouring agents for hair dyeing	2 per cent	—	—	30.9.2004
60	C.I. Basic Violet 14 (CAS No 632-99-5) (C.I. No. 42510)	Oxidising colouring agents for hair dyeing	0.3 per cent	In combination with hydrogen peroxide the maximum use concentration upon application is 0.15 per cent	—	30.9.2004
		Non- oxidising colouring agents for hair dyeing	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	(6) Required information	(7) Permitted for supply until
61	1- <i>tert</i> - Butyl-3,5- dimethyl-2,4,6- trinitrobenzene (CAS No 81-15-2) (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 (CAS No 81-14-1) (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 substances 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.

Note 1: 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.

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.

SCHEDULE 5

Regulation 5(2) and 7(9)

**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 fourth edition of The Colour Index published by the Society of Dyers and Colourists and the American Society of Textile Chemists and Colourists (available by on-line subscription at <http://www.colour-index.org/>). ;
- (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 (19), as amended (20) adapted (21) and replaced in part (22) 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) Name or colour index number	(2) Colour	(3) Type of production Field of application				(4) Other requirement
		1	2	3	4	
10006	Green				X	
10020	Green			X		

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

(20) 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).

(21) Annexes 1 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).

(22) 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).

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

(1) Name or colour index number	(2) Colour	(3) Type of production Field of application				(4) Other requirement
		1	2	3	4	
10316*	Yellow	X				
11680	Yellow			X		
11710	Yellow			X		
11725	Orange				X	
11920	Orange	X				
12010	Red			X		
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

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(1) Name or colour index number	(2) Colour	(3) Type of production Field of application				(4) Other requirement
		1	2	3	4	
15800	Red			X		
15850*	Red	X				
15865*	Red	X				
15800	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
20040	Yellow				X	Maximum 3,3'- dimethyl- benzidine concentration in the colouring agent: 5 mg/kg
20170	Orange			X		
20470	Black				X	
21100	Yellow				X	Maximum 3,3'- dichloro- benzidine

(1) Name or colour index number	(2) Colour	(3) Type of production Field of application				(4) Other requirement
		1	2	3	4	
						concentration in the colouring agent: 5 mg/ kg
21108	Yellow				X	Maximum 3,3'- dichloro- benzidine concentration in the colouring agent: 5 mg/ kg
21230	Yellow			X		
24790	Red				X	
26100	Red			X		Purity criteria: aniline \leq 0.2 per cent, 2- naphthol \leq 0.2 per cent, azobenzene-4- amine \leq 0.1 per cent, 1- phenylazo-2- naphthol \leq 3 per cent, 1-[2- (phenylazo)phenylazo]-2- naphthol \leq 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

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(1) Name or colour index number	(2) Colour	(3) Type of production Field of application				(4) Other requirement
		1	2	3	4	
42045	Blue			X		
42051*	Blue	X				
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	
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> -

(1) Name or colour index number	(2) Colour	(3) Type of production Field of application	(4) Other requirement
		1 2 3 4	
			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-3H-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-3H-xanthen-9-yl)benzoic acid and 3 per cent 2-(iodo-6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid
45430*	Red	X	As immediately

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(1) Name or colour index number	(2) Colour	(3) Type of production Field of application				(4) Other requirement
		1	2	3	4	
						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
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

(1) Name or colour index number	(2) Colour	(3) Type of production Field of application				(4) Other requirement
		1	2	3	4	
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				
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

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

(1) Name or colour index number	(2) Colour	(3) Type of production Field of application				(4) Other requirement
		1	2	3	4	
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-section 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.

(1) Name or colour index number	(2) Colour	(3) Type of production	Field of application	(4) Other requirement	(5) Cosmetic product supplied until
		1	2	3	4

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 column 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 not 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 —

- (b) 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
- (c) the purpose for which any such excess is present in the product is apparent from the labelling of the product.

In this Schedule—

“salt” means salts of the cations sodium, potassium, calcium, magnesium, ammonium and ethanolamines and of the anions chloride, bromide, sulphate and acetate;

“ester” 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 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](#)(23).

Regulation 1(3) provides that until 24th March 2005 entry 36 in Part 1 of this Schedule shall be inserted into Part 1 of this Schedule as it appears in the Cosmetic Products (Safety) Regulations 2003(24). From 24th March 2004 entry 36 shall have effect as it appears in Part 1 of this schedule.

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) 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
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 in preparations for children under three years of age except for shampoos	Not to be used for children under three years of age (solely for products which might be used for children under three years of age and which remain in prolonged contact with the skin)
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)	—

(23) O. J. No. L132, 1.6..96, p.1.

(24) [SI 2003/835](#)

(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
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 ₂)	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'-	All products	0.1 per cent	—	—

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(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
	hexa- methylenedioxydibenzamidine [Dibromohexamidine] and its salts (including isethionate)				
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
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 formatation of nitrosamines	—

(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
21	Bronopol (INN) [2-Bromo-2-nitropropane-1,3-diol]	All products	0.1 per cent	A Avoid formatation of nitrosamines	—
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'-tetra- chloroazobenzene < 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- xylenol [Chloroxylenol]	All products	0.5 per cent	A —	—
27	3,3'-Bis(1- hydroxymethyl-2,5- dioxoimidazolidin-4- yl)-1,1'- methylenediurea [Imidazolidinyl urea]	All products	0.6 per cent	A —	—
28	Poly(1- hexamethylenebiguanide hydrochloride) [Polyaminopropyl biguanide]	All products	0.3 per cent	A —	—
29	2- Phenoxyethanol [Phenoxyethanol]	All products	1.0 per cent	A —	—

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(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
30	Hexamethylenetetramine (Methenamine (INN)) [Methenamine]	All products	0.15 per cent	A —	—
31	Methenamine 3-chloroallylo- chloride (INNM) [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	1.0 per cent	A —	—
36	2-Bromo-2-(bromomethyl) glutaronitrile (1,2-dibromo-2,4-dicyanobutane)	Other products Rinse-off products only	0.5 per cent 0.1 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
37	[Methyldibromo glutaronitrile] 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	—	—
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 1 of Schedule 4)	Products used off after use	1.0 per cent	—	—

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(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
44	Alkyl (C ₁₂ -C ₂₂)- trimethyl- ammonium 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-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea [Diazolidinyl urea]	All products	0.5 per cent	—	—
47	Hexamidine (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)

(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
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	—	—
51	Sodium <i>N</i> -hydroxymethylglycinate [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 benzalkonium chloride	A —	Avoid contact with eyes
55	Benzylhemiformal	Products rinsed off after use	0.15 per cent	—	—
56	3-Iodoprop-2-ynyl butylcarbamate	Not to be used in oral	0.05 per cent	—	Contains iodine (Only required

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(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
	[Iodopropynyl butylcarbamate]	hygiene and lip products			where the 3- iodoprop-2- ynyl butylcarbamate concentration in products intended to remain on the skin exceeds 0.02 per cent)

PART 2

PRESERVATIVES LISTED IN ANNEX VI, PART 2 OF THE DIRECTIVE AS PRESERVATIVES WHICH COSMETIC PRODUCTS MAY NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LIAID 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), 7(2) and 7(9)

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](#)(25)

PART 1

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) Reference Number	(2) Name of substance	(3) Maximum concentration of substance in product	(4) Other requirements	(5) Required information
1	4-Aminobenzoic acid [PABA]	5 per cent	—	—
2	N,N,N-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	8 per cent (expressed as acid)	—	—

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(1) Reference Number	(2) Name of substance	(3) Maximum concentration of substance in product	(4) Other requirements	(5) Required information
	triethanolamine salts			
7	3,3-(1,4-Phenylenedimethyl-2-oxo-bicyclo[2.2.1]hept-1-ylmethanesulfonic acid) [Terephthalylidene 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 (Avobenzone (INN))	5 per cent	—	—
	[Butyl methoxy dibenzoylmethane]			
9	α -(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 <i>N</i> -[(2 and 4)-[2-oxoborn-3-ylidene)methyl]benzyl]acrylamide	6 per cent	—	—
	Polyacrylamidomethyl benzylidene camphor]			
12	2-Ethylhexyl 4-methoxycinnamate	10 per cent	—	—

(1) Reference Number	(2) Name of substance	(3) Maximum concentration of substance in product	(4) Other requirements	(5) Required information
13	[Octyl methoxycinnamate] Ethoxylated ethyl-4-aminobenzoate	10 per cent	—	—
14	[PEG-25 PABA] Isopentyl 4-methoxycinnamate	10 per cent	—	—
15	[Isoamyl <i>p</i> -methoxycinnamate] Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate	5 per cent	—	—
16	[Octyl triazone] 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	15 per cent	—	—
17	[Drometrizole trisiloxane] Bis(2-ethylhexyl) 4,4'-[6- <i>tert</i> -butylcarbamoylanilino)-1,3,5-triazine-2,4-diyl-diimino]dibenzoate	10 per cent	—	—
18	3-(4-Methylbenzylidene)bornan-2-one [4-Methylbenzylidene camphor]	4 per cent	—	—

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(1) Reference Number	(2) Name of substance	(3) Maximum concentration of substance in product	(4) Other requirements	(5) Required information
19	3-Benzylodenebornan-2-one	2 per cent	—	—
	[3-Benzylidene camphor]			
20	2-Ethylhexyl salicylate	5 per cent	—	—
	[Octyl salicylate]			
21	2-Ethylhexyl 4-dimethylaminobenzoate	8 per cent	—	—
	[Octyl dimethyl PABA]			
22	2-Hydroxy-4-methoxybenzophenone (expressed as sulfonic acid)	5 per cent	—	—
	[Benzophenone-4] and its sodium salt			
	[Benzophenone-5] (Sulisobenzone (INN) and Sulisobenzone sodium (INN))			
23	2,2'-Methylenebis[6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol]	10 per cent	—	—
24	diSodium 2,2'-(1,4-phenylene)bis(1H-benzotriazole-4,6-disulfonate)	10 per cent (expressed as acid)	—	—
25	5,5'-Bis(2-ethylhexyloxy)-2,2'-(6-p-methoxyphenyl-1,3,5-triazine-2, 4-diyl)diphenol	10 per cent	—	—
26	α -(Trimethylsilyl)- ω -(trimethylsilyloxy)poly[oxy(dimethyl)silylene]-co-	10 per cent	—	—

(1) Reference Number	(2) Name of substance	(3) Maximum concentration of substance in product	(4) Other requirements	(5) Required information
	[oxymethyl] (2-[p-[2,2- bis(ethoxycarbonyl)vinyl]phenoxy]-1- methyleneethyl)silylene]-co- [oxymethyl] (2-[p-[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 (Dimethicodiethylbenzylmalonate) (CAS No. 207574-74-1)			
27	Titanium dioxide	25 per cent	—	—

PART II

UV FILTERS LISTED IN ANNEX VIII, 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) Reference Number	(2) Name of substance	(3) Maximum concentration of substance in product	(4) Other requirements	(5) Required information	(6) UV filter supplied until
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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)—

- 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);

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

SCHEDULE 9

Regulations 7(2), 7(6) and 7(11)

PART 1

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

PART 2

SYMBOL IN ANNEX VIIIa OF THE DIRECTIVE WHICH IS
REQUIRED FOR THE PURPOSES OF REGULATION 7(2)(c)

SCHEDULE 10

Regulation 12(3) and (5)

PART 1

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](#) **(26)** 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.

(26) O.J. L 196, 16.8.1967, p.1 as last amended by Directive [2004/73/EEC](#) (O.J. L152, 30.4.2004, p.1)

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 (e) and carried out in accordance with the requirements of regulations 9(2), 9(3) and 9(4).

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 identify 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.—(1) 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.

(2) 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.

(3) 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 17

SAMPLING AND TESTING

1. In this Schedule—

“Annex A” means the Annex to Commission Directive No. [80/1335/EEC](#)(27) as amended by Commission Directive No.[87/143/EEC](#)(28)

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

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

“Annex B” means the Annex to Commission Directive No. [82/434/EEC](#)(29) as amended by Commission Directive No.[90/207/EEC](#)(30)

“Annex C” means the Annex to Commission Directive No. [83/514/EEC](#)(31);

“Annex D” means the Annex to Commission Directive No. [85/490/EEC](#)(32);

“Annex E” means the Annex to Commission Directive No. [93/73/EEC](#)(33);

“Annex F” means the Annex to Commission Directive No. [95/32/EC](#)(34);

“Annex G” means the Annex to Commission Directive No. [96/45/EC](#)(35);

“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 1 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 1 of Annex A; samples shall be regarded as having the sample batch number if—

- (a) the means of identifying the batch referred to in regulation 7(2)(h) 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)(h) 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)(h) 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.

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.

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

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

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

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

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

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

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

5.—(1) Subject to sub-paragraph (2) below, the provisions of Part 1 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\(36\)](#), 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.

(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.

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

(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 (monobenzene) 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.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

SCHEDULE 12

Regulation 3(1), 5(7), (9) and (12)

List of Alternative Methods to Animal Testing

PART 1

Part 1 of this Schedule lists the alternative methods validated by the European Centre for the Validation of Alternative Methods (“ECVAM”) which are necessary to meet the requirements of these Regulations and which are listed in Annex V to Council Directive [67/548/EEC](#) of 27th June 1967 on the approximation of laws, regulations and administrative provisions relating to classification, packaging and labelling of dangerous substances **(37)**.

The reference number given in the second column of the table in Part 1 refers to the reference number under which the type of test is listed in Annex V to Directive [67/548/EEC](#).

<i>Entry Number</i>	<i>Reference Number</i>	<i>Type of Test (toxicological endpoint)</i>	<i>Alternative Test Method</i>	<i>Date after which this method is required to be used</i>
1	B40	Skin corrosion	Rat skin TER assay	11.9.04
2	B40	Skin corrosion	Human skin model assay	11.9.04
3	B41	Phototoxicity	In vitro 3T3 NRU phototoxicity test	11.9.04

PART 2

Part 2 of this Schedule lists the alternative methods validated by ECVAM which are necessary to meet the requirements of these Regulations and which are listed in Annex IX to the Directive. As an alternative method may not replace completely the experimentation on animals, column 3 of the table below specifies whether the alternative method fully or partially replaces the animal test.

<i>Entry Number</i>	<i>Reference Number</i>	<i>Nature of replacement</i>	<i>Alternative Test Method</i>	<i>Date after which this method is required to be used</i>
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Note: There are no entries in this Part at the date that these Regulations are made.

(37) O.J. L 196, 16.8.1967, p.1 as last amended by Directive [2004/73/EC](#) (O.J. L152, 30.4.2004, p.1)

SCHEDULE 13

Regulation 5(15)

LIST OF SUBSTANCES CLASSIFIED AS CARCINOGENIC, MUTAGENIC
OR TOXIC FOR REPRODUCTION OF CATEGORY 3 UNDER DIRECTIVE
[67/548/EEC](#) WHICH APPEAR IN THE APPROVED SUPPLY LIST

The substances listed in this table are classified as carcinogenic, mutagenic or toxic for reproduction under directive [67/548/EEC](#)(**38**) and in the approved supply list. These substances have been evaluated as safe by the Scientific Committee on Cosmetic Products(**39**) in accordance with article 4b of the Directive and are permitted for use in cosmetic products.

<i>Substance</i>	<i>Index Number</i>	<i>EC Number</i>	<i>CAS Number</i>
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Note: There are no entries in this Part at the date that these Regulations are made.

EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations revoke and re-enact the Cosmetic Products (Safety) Regulations 2003 ([S.I. 2003/835](#)) (“the 2003 Regulations”). The 2003 Regulations give effect to Council Directive [76/768/EEC](#) (O.J. No. L262, 27.9.76, p.169) (“the Directive”) 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 Council Directive [2003/15/EC](#) (O.J. L66, 11.3.2003, p.26) which amends Directive [67/548/EEC](#) for the 7th time, as follows:

- (a) Prohibit the supply of cosmetic products where the final formulation or ingredients have been tested on animals using a method other than an “alternative method”. The Regulations also introduce an outright prohibition in respect of the supply of cosmetic products after specified dates (2009 and 2013);
- (b) Prohibit the testing of “finished cosmetic products” on animals with immediate effect;
- (c) Prohibit the testing of ingredients for use in cosmetic products after specified dates;
- (d) Introduce provisions governing the use by cosmetic product manufacturers of claims in respect of animal testing;
- (e) Prohibit the use in cosmetic products of substances which are classified under directive [67/548/EEC](#) as carcinogenic, mutagenic or toxic to reproduction (and listed in the approved supply list) subject to an exemption in respect of substances which have been evaluated as safe by the Scientific Committee on Cosmetic Products(**40**);

(**38**) Council Directive [1967/548/EEC](#) (OJ 196, 16.8.67, p.1) as last amended by [2004/73/EC](#) (O.J. L152, 30.4.2004, p.1)

(**39**) the Scientific Committee on Cosmetic Products was previously called the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (“SCCNFP”)

(**40**) the Scientific Committee on Cosmetic Products was previously called the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (“SCCNFP”)

- (f) Requires manufacturers to label products with a symbol (contained in Schedule 9, Part 2) indicating the time after opening after which the product may harm the consumer (this only applies to products with a minimum durability of more than 30 months);
- (g) Requires certain perfumes and aromatic compositions to be specifically listed on product packaging;
- (h) Requires a specific safety assessment to be undertaken in respect of cosmetic products intended for children or for intimate hygiene;
- (i) Inserts further entries into Schedule 4 to these Regulations;

These Regulations also give effect to Council Directive [2003/80/EC](#) (O.J. No. 224, 6.9.2003, p.27) which amends the Directive for the 30th time. Directive [2003/80/EC](#) amends the Directive by inserting a new Annex VIIIa containing a symbol to be used by manufacturers to indicate the time after opening after which the product may harm the consumer (as required by Directive [2003/15/EC](#)).

These Regulations also give effect to Council Directive 2003/83 (O.J. No. L238, 25.9.2003, p.23) which amends the Directive by inserting, deleting or amending entries in Annexes II, III and VI. These Regulations make appropriate amendments to Schedules 3,4 and 6, which implement those Annexes. Directive [2003/83/EC](#) requires Member States to ensure that cosmetic products, which fail to comply with that directive, shall not be placed on the market from 24th March 2005 and that they shall not be supplied to the final consumer from 24th September 2005. Accordingly, regulations 1(3) and 1(4) provide that newly inserted or amended entries in the schedules to the regulations shall not have effect until 24th March 2005. Equally, these regulations provide that certain entries, which are amended or deleted by 2003/83, shall continue to operate in their existing form (i.e. as they appear in the Cosmetic Products (Safety) Regulations 2003) until 24th March 2005. Regulation 16(3) provides that no proceedings or enforcement action shall be taken in respect of the new or amended entries where the cosmetic product in question is placed on the market before 24th March 2005 and is supplied before 24th September 2005.

The Colour Index referred to in these Regulations may be obtained from the Society of Dyers and Colourists and the American Society of Textile Chemists and Colourists by on-line subscription at <http://www.colour-index.org/>.

A full regulatory impact assessment of the effect that this instrument will have on costs to business is available from the Consumer and Competition Policy Directorate of the Department of Trade and Industry, 1 Victoria Street, London SW1H 0ET. Copies of a transposition note relating to these Regulations have been placed in the libraries of both Houses of Parliament. Copies are also available to the public from the Consumer and Competition Policy Directorate of the Department of Trade and Industry, 1 Victoria Street, London SW1H 0ET.