
STATUTORY INSTRUMENTS

1996 No. 2925

CONSUMER PROTECTION

The Cosmetic Products (Safety) Regulations 1996

Made - - - - 21st November 1996
Laid before Parliament 25th November 1996
Coming into force in accordance with regulation 1(1)–(8)

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 him to be representative of interests substantially affected by these Regulations, such other persons as he 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 powers conferred on him by sections 11, 28 and 30 of the said Act of 1987 and by section 2 of the said Act of 1972 and of all other powers enabling him in that behalf hereby makes the following Regulations:—

Citation, commencement and revocation

1.—(1) These Regulations may be cited as the Cosmetic Products (Safety) Regulations 1996 and except as provided by paragraphs (2) to (8) below shall come into force on 16th December 1996.

(2) Regulations 3(1)(b), 3(3), 4(4), 4(5), 6(1), 6(2)(h), 6(5)(a) (in so far as it relates only to regulation 6(2)(h)), 6(5)(b), 6(6), 6(7) and 6(9) to (12) shall come into force—

- (a) on 1st January 1997 in relation to the supply of cosmetic products 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, except where the cosmetic products are supplied by retail in which case they shall come into force on 1st January 1998; and
- (b) in all other cases on 1st January 1998.

(1) 1987 c. 43.

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

(3) 1972 c. 68.

- (3) The following provisions shall come into force in accordance with paragraph (4) below—
- (a) regulation 4(2)(a) and Schedule 1, in so far as they relate only to entry numbers 81, 92, 98, 113, 132, 154, 356, 462, 489, 557, 620 and 743 in that Schedule;
 - (b) regulations 4(2)(e)(ii), 4(2)(f) and 4(2)(g) and Part II of Schedule 4, in so far as they relate only to the deletion of entry number 15 in that Part; and
 - (c) regulations 4(2)(h)(i) and 4(2)(i) and Part I of Schedule 5, in so far as they relate only to entry number 10 in that Part.
- (4) The provisions referred to in paragraph (3) above shall come into force—
- (a) on 16th December 1996 in relation to the supply of cosmetic products 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, except where the cosmetic products are supplied by retail in which case they shall come into force on 1st July 1997; and
 - (b) in all other cases on 1st July 1997.
- (5) The following provisions shall come into force in accordance with paragraph (6) below—
- (a) regulation 4(2)(a) and Schedule 1, in so far as they relate only to entry numbers 342, 405 and 751 in that Schedule;
 - (b) regulation 4(2)(b) and Part I of Schedule 2, in so far as they relate only to entry numbers 15a, 15b and 15c in that Part;
 - (c) regulations 4(2)(e)(i) and 4(2)(f) and Part I of Schedule 4, in so far as they relate only to entry numbers 50, 51 and 52 in that Part;
 - (d) regulations 4(2)(e)(ii) and 4(2)(g) and Part II of Schedule 4, in so far as they relate only to the deletion of entry numbers 2 and 30 in that Part;
 - (e) regulations 4(2)(h)(i) and 4(2)(i) and Part I of Schedule 5, in so far as they relate only to entry number 11 in that Part; and
 - (f) regulations 4(2)(h)(ii) and 4(2)(i) and Part II of Schedule 5, in so far as they relate only to the deletion of entry numbers 33 and 34 in that Part.
- (6) The provisions referred to in paragraph (5) above shall come into force—
- (a) on 1st July 1997 in relation to the supply of cosmetic products 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, except where the cosmetic products are supplied by retail in which case they shall come into force on 1st July 1998; and
 - (b) in all other cases on 1st July 1998.
- (7) Paragraph 6(41) of Schedule 8 shall come into force on 30th September 1997.
- (8) Regulation 4(3) shall come into force on 1st January 1998.
- (9) Subject to paragraph (10) below, the Regulations specified in Schedule 9 hereto are revoked with effect from 16th December 1996 provided that the Cosmetic Products (Safety) Regulations 1989(4) shall continue to apply to cosmetic products which are supplied before 16th December 1996.
- (10) The notes in Part I of Schedule 2, Part II of Schedule 4 and Part II of Schedule 5 shall apply.

Interpretation

- 2.—(1) In these Regulations—

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

“common ingredients nomenclature” means the labelling nomenclature designated in the inventory of ingredients employed in cosmetic products, drawn up in accordance with the provisions of the Directive and contained in Commission Decision [96/335/EC\(5\)](#), as amended or substituted from time to time;

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

“the Confidentiality Directive” means Commission Directive [95/17/EC\(6\)](#);

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

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

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

“the Directive” means Council Directive [76/768/EEC\(7\)](#), as amended by Council Directive [82/368/EEC\(8\)](#), Commission Directive [82/147/EEC\(9\)](#), Commission Directive [83/191/EEC\(10\)](#), Commission Directive [83/341/EEC\(11\)](#), Council Directive [83/574/EEC\(12\)](#), Commission Directive [83/496/EEC\(13\)](#), Commission Directive [84/415/EEC\(14\)](#), Commission Directive [85/391/EEC\(15\)](#), Commission Directive [86/179/EEC\(16\)](#), Commission Directive [86/199/EEC\(17\)](#), Commission Directive [87/137/EEC\(18\)](#), Commission Directive [88/233/EEC\(19\)](#), Council Directive [88/667/EEC\(20\)](#), Commission Directive [89/174/EEC\(21\)](#), Council Directive [89/679/EEC\(22\)](#), Commission Directive [90/121/EEC\(23\)](#), Commission Directive [91/184/EEC\(24\)](#), Commission Directive [92/8/EEC\(25\)](#), Commission Directive [92/86/EEC\(26\)](#), Commission Directive [93/47/EEC\(27\)](#),

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- (5) O.J. No. L132, 1.6.1996, p.1.
 - (6) O.J. No. L140, 23.6.1995, p.26.
 - (7) O.J. No. L262, 27.9.1976, p.169.
 - (8) O.J. No. L167, 15.6.1982, p.1.
 - (9) O.J. No. L63, 6.3.1982, p.26.
 - (10) O.J. No. L109, 26.4.1983, p.25.
 - (11) O.J. No. L188, 13.7.1983, p.15.
 - (12) O.J. No. L332, 28.11.1983, p.38.
 - (13) O.J. No. L275, 8.10.1983, p.20.
 - (14) O.J. No. L228, 25.8.1984, p.31.
 - (15) O.J. No. L224, 22.8.1985, p.40.
 - (16) O.J. No. L138, 24.5.1986, p.40.
 - (17) O.J. No. L149, 3.6.1986, p.38.
 - (18) O.J. No. L56, 26.2.1987, p.20.
 - (19) O.J. No. L105, 26.4.1988, p.11.
 - (20) O.J. No. L382, 31.12.1988, p.46.
 - (21) O.J. No. L64, 8.3.1989, p.10.
 - (22) O.J. No. L398, 30.12.1989, p.25.
 - (23) O.J. No. L71, 17.3.1990, p.40.
 - (24) O.J. No. L91, 12.4.1991, p.59.
 - (25) O.J. No. L70, 17.3.1992, p.23.
 - (26) O.J. No. L325, 11.11.1992, p.18.

Council Directive [93/35/EEC\(28\)](#), Commission Directive [94/32/EC\(29\)](#), Commission Directive [95/34/EC\(30\)](#), and Commission Directive [96/41/EC\(31\)](#);

“EEA Agreement” means the Agreement on the European Economic Area signed at Oporto on 2 May 1992 as adjusted by the Protocol signed at Brussels on 17 March 1993(32);

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

- (a) any cosmetic product; or
- (b) anything in, on or with which the cosmetic product is supplied; or
- (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—

- (a) 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
- (b) no consideration in money or money’s worth is given by such a person for the cosmetic product or any other cosmetic product supplied to him for comparison;

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

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

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

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

(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

3.—(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.

(27) O.J. No. L203, 13.8.1993, p.24.

(28) O.J. No. L151, 23.6.1993, p.32.

(29) O.J. No. L181, 15.7.1994, p.31.

(30) O.J. No. L167, 18.7.1995, p.19.

(31) O.J. No. L198, 8.8.1996, p.36..

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

(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

4.—(1) The following provisions of this regulation are without prejudice to regulation 3 and are subject to regulation 5.

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

- (a) any substance listed in column 2 of Schedule 1, 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 Schedule 2, unless the requirements in columns 3, 4, 5 and (in the case of Part II) 7 of that Schedule in relation to that substance are satisfied;
- (c) any colouring agent listed in columns 1 and 2 of Schedule 3 with the exception of cosmetic products containing colouring agents 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;
- (d) any colouring agent which is not listed in Schedule 3 with the exception of cosmetic products containing colouring agents intended solely to colour hair;
- (e) any preservative listed in column 2 of Schedule 4 unless—
 - (i) the requirements in columns 3, 4 and 5 of Part I of that Schedule in relation to that preservative are satisfied; or
 - (ii) the requirements in columns 3, 4 and 5 of Part II of that Schedule in relation to that preservative are satisfied and the preservative in question is supplied on or before the date specified in column 7 of that Part;
- (f) any preservative which is not listed in Schedule 4;
- (g) any preservative listed in column 2 of Part II of Schedule 4 after the date specified in column 7 of that Part;
- (h) any UV filter listed in column 2 of Schedule 5 unless—
 - (i) the requirements in columns 3 and 4 of Part I of that Schedule in relation to that UV filter are satisfied; or
 - (ii) the requirements in columns 3 and 4 of Part II of that Schedule in relation to that UV filter are satisfied and the UV filter in question is supplied on or before the date specified in column 6 of that Part;
- (i) any UV filter which is not listed in Schedule 5.

(3) No person shall supply a cosmetic product which contains any ingredients or combinations of ingredients which are tested on animals where such testing takes place after 1st January 1998 and is undertaken in order that the cosmetic product may satisfy any requirements of these Regulations.

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

(5) No person shall supply any cosmetic product in respect of which the requirements of paragraph (4) above are not satisfied.

Authorisation by the Secretary of State

5.—(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 listed in Schedule 1 or 2.

(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 he considers appropriate for bringing it to the attention of persons who, in his opinion, would be likely to have an interest in it.

(5) No person shall be convicted of an offence under section 12 of the Consumer Protection Act 1987 by reason of a cosmetic product's 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

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

(2) Subject to paragraphs (3), (4), (5)(a), (6) to (8) and (13) to (16) below, no person shall supply a cosmetic product unless the container and packaging in which it is supplied bear the following particulars in lettering which is visible, indelible and easily legible—

- (a) the name or trade name and the address or registered office of the manufacturer of the product or of the supplier thereof, being a manufacturer or supplier established within a member State of the Community;
- (b) in the case of a cosmetic product likely within 30 months from the manufacture thereof to cease either to comply with the requirements of regulation 3 or to fulfil the purpose for which it was intended, the words “Best before . . .” immediately followed by
 - (i) the earliest date on which it is likely to so cease; or
 - (ii) an indication of where that date appears on the labellingand any particular precautions to be observed to ensure that the product does not so cease before that date;
- (c) in the case of a cosmetic product containing a substance listed in column 2 of Schedule 2, the information specified in column 6 of that Schedule in relation to that substance;
- (d) in the case of a cosmetic product containing a preservative listed in column 2 of Schedule 4, the information specified in column 6 of that Schedule in relation to that preservative;

- (e) in the case of a cosmetic product containing a UV filter listed in column 2 of Schedule 5, the information specified in column 5 of that Schedule in relation to that UV filter;
- (f) any particular precautions to be observed in use and any special precautionary information on a cosmetic product for professional use, in particular in hairdressing (not being precautions included in the information referred to in sub-paragraphs (b), (c), (d) and (e) above);
- (g) a means of identifying the batch in which the product was manufactured (or, if the product was not manufactured in a batch, a reference from which the date and place of manufacture can be identified); and
- (h) the function of the product unless this is clear from its presentation:

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

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

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

(5) The particulars referred to—

- (a) in sub-paragraphs (b) to (f) and (h) of paragraph (2) 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 sub-paragraphs (c) to (f) of paragraph (2) above to appear on the container and packaging, they shall appear on a leaflet, label, tag, tape or card enclosed with the cosmetic product, to which the consumer is referred either by abbreviated information or by the symbol given in Schedule 6, 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 sub-paragraph (g) of paragraph (2) above to appear on the container and packaging, the said particulars shall appear on the packaging.

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

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

- (a) the following shall not be regarded as cosmetic ingredients—
 - (i) impurities in the raw materials used;
 - (ii) subsidiary technical materials used in the preparation of the cosmetic product but not present in the final product;
 - (iii) materials used in strictly necessary quantities as solvents or as carriers for perfumes and aromatic compositions;
- (b) perfume and aromatic compositions and their raw materials shall be referred to by the words “perfume” or “flavour”;

- (c) ingredients in concentrations of less than 1% may be listed in any order after those in concentrations of 1% or more;
- (d) colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination found in Schedule 3;
- (e) for decorative cosmetic products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the words “may contain” are added; and
- (f) an ingredient shall be identified by its common name as provided for in the common ingredients nomenclature or, in the absence of the nomenclature or of a common name, by its chemical name, its CTFA name, its European Pharmacopoeia name, its International Non-proprietary Name as recommended by the World Health Organisation, its EINECS, IUPAC or CAS identification reference or its colour index number⁽³³⁾.

(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 displayed in immediate proximity to that container.

(11) Subject to paragraph (12) below, where it is impossible for practical reasons for the list of ingredients referred to in paragraph (1) above to appear on the packaging or container of a cosmetic product, it shall appear on a leaflet, label, tag, tape or card enclosed with the product, to which the consumer is referred either by abbreviated information or by the symbol given in Schedule 6, which must appear on the packaging; and where it is impracticable for reasons of size or shape for the list so to appear, it shall appear on a label, tag, tape or card attached to the cosmetic product.

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

(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 sub-paragraphs (c) to (f) of paragraph (2) above shall appear on an enclosed leaflet and an indication shall appear on both the containers and on the packaging referring the consumer to the information in the leaflet.

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

(15) In the case of a cosmetic product supplied before paragraph (6) above has come into force, where it is impracticable by reason of the size or shape of the container or packaging (if any) for the particulars referred to in sub-paragraphs (c) to (f) of paragraph (2) above to appear on the container and packaging, or on one of them, the said particulars shall appear on an enclosed leaflet and an indication shall appear on both the container and the packaging (if any) referring the consumer to the information in that leaflet.

(33) An ingredient's CTFA name is the name given to it by the Cosmetics Toiletries and Fragrances Association and listed in the sixth edition of the International Cosmetic Ingredient Dictionary published in 1995. Its EINECS identification reference is the reference given in the European Inventory of Existing Commercial Chemical Substances. Its IUPAC identification reference is the reference given by the International Union of Pure and Applied Chemistry. Its CAS identification reference is the reference assigned by the Chemical Abstracts Service. An ingredient's colour index number is the number specified in the third edition of The Colour Index published in 1971 by the Society of Dyers and Colourists. European Pharmacopoeia names, International Non-proprietary Names and EINECS, IUPAC and CAS identification references are listed in Commission Decision 96/335/EC (O.J. No. L132, 1.6.1996, p.1).

(16) Where, before paragraph (7) above has come into force, a cosmetic product is supplied or delivered pursuant to any supply in a container and packaging and it is impracticable, for reasons of size, for the particulars referred to in sub-paragraph (g) of paragraph (2) above to appear on the container, the said particulars shall appear on the packaging.

Responsible Persons and Competent Authorities

7.—(1) For the purposes of regulations 8, 9, 10 and 11—

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

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

Product Information

8.—(1) Subject to paragraph (5) below, where a cosmetic product is manufactured or supplied in the United Kingdom a responsible person shall for control purposes keep readily accessible to a United Kingdom competent authority at the address or registered office specified on the container or packaging of the cosmetic product in accordance with regulation 6(2)(a) the following information—

- (a) the qualitative and quantitative composition of the product, except to the extent that the product is composed of any perfume or perfume composition, in which case the responsible person shall only be required to keep the name and code number of the perfume or perfume composition and the identity of the supplier;
- (b) the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product;
- (c) the method of manufacture which shall be in accordance with good manufacturing practice, that is to say that the cosmetic product shall be manufactured in such a way that under normal and reasonably foreseeable conditions of use it shall not endanger human health or safety;

- (d) assessment of the safety for human health of the finished product taking into consideration the general toxicological profile of each ingredient used, its chemical structure and its level of exposure;
- (e) the name and address of the person or persons, qualified in accordance with paragraph (3) below, responsible for the assessment referred to in sub-paragraph (d) above;
- (f) existing data on undesirable effects on human health resulting from use of the cosmetic product; and
- (g) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product.

(2) The assessment referred to in sub-paragraph (d) of paragraph (1) above shall be carried out in accordance with the principles of good laboratory practice referred to in Article 1 of Council Directive 87/18/EEC⁽³⁴⁾ on the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.

(3) The person referred to in sub-paragraph (e) of paragraph (1) above must be a registered pharmacist within the meaning of the Pharmacy Act 1954⁽³⁵⁾ or a registered medical practitioner within the meaning of the Medical Act 1983⁽³⁶⁾.

(4) 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.

(5) 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.

(6) 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.

9. 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.

10.—(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.

11.—(1) Without prejudice to the provisions of regulations 3, 4, 8 and 10, a responsible person who for reasons of trade secrecy wishes not to include one or more cosmetic ingredients in the list

⁽³⁴⁾ O.J. No. L15, 17.1.87, p.29.

⁽³⁵⁾ 1954 c. 61.

⁽³⁶⁾ 1983 c. 54.

of cosmetic ingredients referred to in regulation 6(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 7; and

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

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

(5) If the competent authority decides to grant its approval to the applicant’s request it shall, in notifying the applicant of its decision, in accordance with paragraph (4) above, also notify him of the registration number which will replace the cosmetic ingredient in question in the list referred to in regulation 6(1), the said number to be allocated to the product in accordance with the procedure provided for in Part II of Schedule 7.

(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 regulations 8, 9 and 10

12.—(1) Subject to paragraph (2) below, any contravention of a requirement of regulation 8, 9 or 10 shall be treated for all purposes as though it were a contravention of a requirement of safety regulations made under section 11 of the Consumer Protection Act 1987⁽³⁷⁾.

(2) The term of imprisonment to which a person guilty of an offence of contravening any requirement of regulation 8, 9 or 10 shall be liable on summary conviction shall not exceed three months.

Enforcement

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

- (a) any failure to comply with regulations 3, 4, 6, 7, 8, 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 6(5)(a) in any case in which the enforcement authority is satisfied that the person supplying the cosmetic product reasonably believes that it will not be used in the United Kingdom.

(2) No proceedings shall be brought and no enforcement action taken in respect of any failure to comply with regulations 4(4), 4(5), 6(1), 6(2)(h), 6(5)(a) (in so far as it relates only to regulation 6(2)(h)), 6(5)(b), 6(6), 6(7) or 6(9) to (12) in the case of—

- (a) any supply of a cosmetic product before 31st December 1997 by the manufacturer in or importer into the United Kingdom or, in relation to a cosmetic product manufactured or imported into the United Kingdom on behalf of another person, by that other person, except for a supply by retail in which case no proceedings shall be brought and no enforcement action taken in respect of a supply before 31st December 1998; or
- (b) any other supply of a cosmetic product before 31st December 1998, provided that, in the case of a failure to comply with regulation 6(6), the cosmetic product complies with the requirements of regulation 6(15) and, in the case of a failure to comply with regulation 6(7), the product complies with the requirements of regulation 6(16).

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

14. Any test of goods purchased under section 28 or seized under section 29 of the Consumer Protection Act 1987 (which relate to enforcement) by or on behalf of an enforcement authority for the purpose of ascertaining whether the provisions of these Regulations have been contravened shall in all cases be carried out in accordance with the provisions of paragraphs 2 to 5 of Schedule 8 and any test for which a method is specified in paragraph 6 of Schedule 8 shall be carried out in accordance with that method.

John M Taylor

Parliamentary Under-Secretary of State for
Corporate and Consumer Affairs,
Department of Trade and Industry

21st November 1996

SCHEDULE 1

Regulations 4(2) and 5(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 4(2); in certain cases a name is given of a group of substances, the names of particular examples of which are also given, and in such a case all substances comprised in the group are included, whether or not more specifically named.

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

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
1	Acenocoumarol (INN)	396	254
2	Acetonitrile	—	393
3	3-(α -Acetonylbenzyl)-4-hydroxycoumarin and its salts	398, 760	203
4	2-Acetoxyethyltrimethylammonium hydroxide and its salts	6	2
5	2-Acetylamino-5-chlorobenzoxazole	164	1
6	Acetylcholine and its salts	4	2
7	Acetylene chlorides	249, 757	126
8	Acetylenic alcohols, their esters, ethers and salts	17	16
9	Acetylethyltetramethyltetralin (AETT)	411	362
10	7 α -Acetylthio-3-oxopregn-4-ene-17 α ,17 β -propionolactone	649	4
11	Aconitine and its salts	—	12
12	<i>Aconitum napellus</i> L. (leaves, roots and galenical preparations)	—	11

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(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
13	<i>Adonis vernalis L.</i> and its preparations	—	13
14	Adrenaline	269, 314	14
15	Alkali pentacyanonitrosylferrate(2-)	602–3, 644–5	255
16	<i>O</i> -Alkyldithiocarbonic acids, salts of	761	336
17	Alkyne alcohols, their esters, ethers and salts	8	16
18	Alloclamide (INN) and its salts	22	19
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	492	20
22	2-Allyloxy-4-chloro- <i>N</i> -[2-(diethylamino)-ethyl]benzamide and its salts	18	19
23	Alypine and its salts	45, 109	143
24	Ambenonium chloride (INN)	(527)	132
25	4-(or <i>p</i> -)Aminobenzoic acid esters	—	167
26	2-Amino-1,2-bis(4-methoxyphenyl)ethanol and its salts	—	29
27	Aminocaproic acid (INN) and its salts	31	7
28	2-Amino-5-chlorobenzoxazole	768	24
29	4-Amino- <i>N</i> -(2-diethylaminoethyl)benzamide, its salts and derivatives	607	25
30	Aminoheptane, its isomers and salts	748	25

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31	6-Aminohexanoic acid and its salts	27	7
32	α -(Aminomethyl)-3,4-dihydroxybenzyl alcohol and its salts	517–8	257
33	4-Amino- N^{10} -methylfolic acid	452	6
34	2-Amino-6-methylheptane and its salts	287, 523	28
35	2-Amino-4-methylhexane and its salts	288, 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	716	32
41	Aminoxylenes, their isomers, salts and halogenated and sulphonated derivatives	763	33
42	Amitriptyline (INN) and its salts	283	146
43	<i>Ammi majus</i> and its galencial preparations	—	35
44	Amphetamine (INN), its salts and derivatives and salts of those derivatives	(678)	21

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45	Amydricaine and its salts	23, 109	143
46	Amylene chloride	250	36
47	Amyl 4-dimethylaminobenzoate, mixed isomers	532	381
48	Amyl nitrites	—	247
49	Amylobarbitone and its salts	(69)	220
50	Amylocaine and its salts	281	50
51	<i>Anamirta cocculus L.</i> (fruit)	—	106
52	Substances with androgenic effect	—	37
53	Aniline, its salts and halogenated and sulphonated derivatives	—	22
54	Anthracene oil	—	38
55	Anti-androgens with steroid structure	—	390
56	Antibiotics	—	39
57	Antimony and its compounds	—	40
58	<i>Apocynum cannabinum L.</i> and its preparations	—	41
59	Apomorphine and its salts	694	42
60	Apronalide	419	216
61	Arecoline	482	238
62	Aristolochic acid and its salts	—	365
63	Arsenic and its preparations	—	43
64	<i>Atropa belladonna L.</i> and its preparations	—	44

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65	Atropine, its salts and derivatives	—	45
66	Azacyclonol (INN) and its salts	304	286
67	Azamethonium bromide (INN)	(473)	121
68	Barbitone and its salts	(69)	220
69	Barbiturates	various	220
70	Barium salts (except barium sulphate, barium sulphide under the condition laid down in Part I of Schedule 2 for alkaline earth sulphides, and lakes, salts and pigments prepared from those colouring agents identified in column 1 of Schedule 3 by “*” immediately after the name or colour index number)	—	46
71	Bemegride (INN) and its salts	336, 337	183
72	Benactyzine (INN)	257	157
73	Bendrofluazide and its derivatives	74, 90	53
74	Bendroflumethiazide (INN) and its derivatives	73, 90	53
75	Benzamine and its salts	741	51
76	Benzatropine (INN) and its salts	300	158
77	Benzazepines, their salts and derivatives	89	49
78	Benzene	—	47
79	Benzene-1,2-diol	153, 627	408
80	Benzene-1,2,3-triol	628	409

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81	Benzethonium chloride (INN)	92	415
82	2-Benzhydroxyethyl dimethylamine and its salts	295	339
83	Benzidine	242	26
84	Benzilium bromide (INN)	95	60
85	2-Benziloxymethyl-1,1-dimethylpyrrolidinium methyl sulphate	599	239
86	Benzimidazolone	87, 266	48
87	Benzimidazol-2(3H)-one	86, 266	48
88	Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol (except natural content of essences)	211	357
89	Benzodiazepines, their salts and derivatives	77	49
90	Benzothiadiazine and its derivatives	73, 74	53
91	Benzoyl peroxide	—	382
92	Benzyl(dimethyl) (2-{2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy}-ethyl)ammonium chloride	81	415
93	3-(N-Benzylhydrazinocarbonyl)-5-methylisoxazole	414	52
94	Benzylideneacetone	564	356
95	3-Benzyl-1,1-diethylpyrrolidine hydrobromide	84	60
96	4-Benzylphenol	(390), 487	178

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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
97	2-[Benzyl- <i>N</i> -(2-pyridyl)amino]-ethyl dimethylamine	623, 745	347
98	Bergapten(e) (except natural content of essences). In sun protection and in bronzing products, furocoumarins content shall be below 1 mg/kg	(356)	358
99	Beryllium and its compounds	—	54
100	Betamethasone (INN)	(360)	300
101	Betoxycaine (INN) and its salts	256	23
102	BHC (ISO) (<i>gamma</i> -BHC)	369, 371, 428	195
103	Bietamiverine (INN)	260	287
104	1,6-Bis(2-chloroethylamino)-1,6-dideoxymannitol and its salts	436	89
105	2-[Bis(2-chloroethyl)amino]-1-oxa-3-aza-2-phosphacyclohexane 2-oxide and its salts	108, 230	88
106	<i>N,N</i> -Bis(2-chloroethyl)methylamine and its salts	160, 490	87
107	<i>N,N</i> -Bis(2-chloroethyl)methylamine <i>N</i> -oxide and its salts	491	86
108	<i>N,N</i> -Bis(2-chloroethyl)-1,3,2-oxazaphosphinan-2-ylamine <i>p</i> -oxide and its salts	105, 230	88
109	1,1-Bis(dimethylaminomethyl)propyl benzoate and its salts	23, 45	143

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110	Bis(hydroxyalkyl)amine not further <i>N</i> -substituted	254, 273, 640	411
111	2,2-Bis(hydroxymethyl)butan-1-ol trinitrate	613	206
112	2,6-Bis(β -hydroxyphenethyl)-1-methylpiperidine and its salts	430	219
113	3,3-Bis(4-hydroxyphenyl)phthalide	557	417
114	Bis(8-hydroxyquinolinium) sulphate, except for the uses provided for in entry number 51 in Part 1 of Schedule 2	(400, 531)	395
115	Bithionol (INN)	705	352
116	Bretylum tosilate (INN) (Bretylum tosylate)	119	56
117	Bromine, elemental	—	55
118	Bromisoval (INN)	121	58
119	<i>p</i> -Bromobenzylethyldimethylammonium <i>p</i> -toluenesulphonate	116	56
120	2-Bromo-2-ethylbutyrylurea	149	57
121	2-Bromo-3-methylbutyrylurea	118	58
122	1- <i>p</i> -Bromophenyl-1-(2-pyridyl)-3-dimethylaminopropane and its salts	123	59
123	Brompheniramine (INN) and its salts	122	59
124	Brucine	—	62
125	Butanilcaine (INN) and its salts	466	90

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126	Butobarbitone and its salts	(69)	220
127	Butopirine (INN) and its salts	129	288
128	2-Butoxy- <i>N</i> -(2-diethylaminoethyl)-cinchoninamide and its salts	191	129
129	2-Butoxyethyl phenyl(piperidino)acetate and its salts	127	288
130	1-Butyl-3-(<i>N</i> -crotonoylsulphanilyl)urea	—	108
131	4-Butyl-1,2-diphenylpyrazolidine-3,5-dione	563	67
132	4- <i>tert</i> -Butyl-3-methoxy-2,6-dinitrotoluene	489	414
133	4-Butyl-1-phenylpyrazolidine-3,5-dione	486	64
134	1-Butyl-3-(<i>p</i> -methylbenzenesulphonyl)urea	715	65
135	1-Butyl-3-sulphanilylurea	150	66
136	4-Butylthiobenzhydryl 2-(dimethylamino)ethyl sulphide	143	140
137	Cadmium and its compounds	—	68
138	Calabar bean	585	281
139	Calciferol	316, (759)	335
140	Cantharides, <i>Cantharis vesicatoria</i>	647	69
141	Cantharidin	378	70
142	Captan (ISO)	734	370
143	Captodiame (INN)	136	140

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144	Caramiphen (INN) and its salts	567	169
145	<i>N</i> -(3-Carbamoyl-3,3-diphenylpropyl)- <i>N,N</i> -diisopropylmethylammonium salts	418	156
146	Carbazole, nitroderivatives of	508	72
147	Carbon disulphide	—	73
148	Carbon tetrachloride	690	315
149	Carbromal (INN)	120	57
150	Carbutamide (INN)	135	66
151	Carisoprodol (INN)	480	235
152	Catalase	—	74
153	Catechol	79, 627	408
154	Cells, tissues or products of human origin	—	416
155	Cephaeline and its salts	—	75
156	<i>Chenopodium ambrosioides</i> (essential oil)	—	76
157	Cherry laurel water	618	291
158	Chloral hydrate	732	77
159	Chlorine	—	78
160	Chlormethine (INN) and its salts	106, 490	87
161	Chlormezanone (INN)	175	91
162	4-Chlorobenzene-1,3-disulfonamide	194	85
163	5-Chloro-1,3-benzoxazol-2(3 <i>H</i>)-one	186	82
164	<i>N</i> -5-Chlorobenzoxazol-2-ylacetamide	5	1

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165	2-Chloro-4-dimethylamino-6-methylpyrimidine	169, 216	83
166	2-Chloro-9-[3-(dimethylamino)-propylidene]thioxanthene (<i>cis</i> -form) and its salts	183	84
167	Chloroethane	327	96
168	Chloroform	733	366
169	2-Chloro-6-methylpyrimidin-4-yl-dimethylamine	165, 216	83
170	Chlorophacinone (ISO)	176	93
171	1-(<i>p</i> -Chloro- α -phenylbenzyl)-4-(2-hydroxyethoxyethyl)piperazine	401	240
172	2-(4-Chlorophenyl)-1-[4-(2-diethylaminoethoxy)phenyl]-1- <i>p</i> -tolylethanol	744	92
173	4-[4-(4-Chlorophenyl)-4-hydroxypiperidin-1-yl]-1-(4-fluorophenyl)butan-1-one	368	185
174	2-(4-Chlorophenyl)-3-methylbutane-2,3-diol	551	95
175	2-(4-Chlorophenyl)-3-methyl-1,3-thiazinan-4-one 1,1-dioxide	161	91
176	2-[2-(4-Chlorophenyl)-2-phenylacetyl]indane-1,3-dione	170	93
177	2-[1-(4-Chlorophenyl)-1-phenylethoxy]ethyl-(dimethyl)amine	180	94
178	Chloropicrin	735	325

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179	3-(4-Chloro-3-sulphamoylphenyl)-3-hydroxyisoindolin-1-one	184, 185	262
180	Chlorphenoxamine (INN)	177	94
181	Chlorpromazine (INN)	(558)	320
182	Chlorpropamide (INN)	614	79
183	Chlorprothixene (INN) and its salts	166	84
184	Chlortalidone (INN)	179, 185	262
185	Chlorthalidone	179, 184	262
186	Chlorzoxazone (INN)	163	82
187	Cholecalciferol	(759)	335
188	Choline salts and their esters	—	168
189	Chromium, chromic acid and salts of the acid	—	97
190	Chrysoidine citrate hydrochloride	562	81
191	Cinchocaine (INN) and its salts	128	129
192	Cincophen (INN), its salts and derivatives and salts of those derivatives	577	8
193	<i>Claviceps purpurea Tul.</i> , its alkaloids and galenical preparations	317	98
194	Clofenamide (INN)	162	85
195	Clofenotane (INN)	232, 731	123
196	Cobalt benzenesulphonate	—	101
197	Cocculin	589	282
198	Colchicine, its salts and derivatives	—	102

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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
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 61554	—	389
210	Colouring agent CI 45170 and CI 45170:1	—	398
211	Coniferyl benzoate (except natural content of essences)	88	357
212	Coniine	615	290
213	<i>Conium maculatum</i> L. (fruit, powder, galenical preparations)	—	99
214	Convallatoxin	—	105
215	Coumetarol (INN)	454	225
216	Crimidine (ISO)	165, 169	83
217	<i>Croton tiglium</i> (oil)	—	107
218	Curare and curarine	—	109

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219	Curarizants, synthetic	—	110
220	1-(3-Cyano-3,3-diphenylpropyl)-4-ethoxycarbonyl-4-phenylpiperidinium chloride	296	80
221	Cyclarbamate (INN)	229	122
222	Cyclizine (INN) and its salts	301	159
223	Cyclobarbitone and its salts	(69)	220
224	Cyclocoumarol	267	234
225	2- α -Cyclohexylbenzyl(<i>N,N',N'</i> -tetraethyl)trimethylenediamine	552	112
226	2-Cyclohexyl-3,5-dimethylphenol and its salts	228	113
227	1-Cyclohexyl-3-(<i>p</i> -methylbenzenesulphonyl)urea	363	100
228	Cyclomenol (INN) and its salts	226	113
229	Cyclopentane-1,1-dimethanol dicarbanilate	221	122
230	Cyclophosphamide (INN) and its salts	105, 108	88
231	<i>Datura stramonium</i> L. and its galenical preparations	651	301
232	DDT (ISO) (<i>pp'</i> -DDT)	195, 731	123
233	Deanol aceglumate (INN)	278	3
234	Decamethonium bromide (INN)	(235)	214
235	Decamethylenebis(trimethylammonium) salts	234	214
236	Dextromethorphan (INN) and its salts	457	226

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237	Dextropropoxyphene (INN)	280	116
238	<i>O,O'</i> -Diacetyl- <i>N</i> - allyl- <i>N</i> -normorphine	—	117
239	2,4-Diaminoanisole and its salts	455, 461	376
240	2,5-Diaminoanisole and its salts	456, 460	377
241	1,2-Diaminobenzene and its salts	570	363
242	<i>p,p'</i> -Diaminodiphenyl	82	26
243	2-(2,4- Diaminophenyl)ethanol and its salts	—	407
244	1,4:3,6- Dianhydrosorbitol 2,5- dinitrate	421	148
245	5-(α,β - Dibromophenethyl)-5- methylhydantoin	—	119
246	Dibromosalicylanilides	247, 443	351
247	Dibromsalan (INN)	(246)	351
248	Dichloroethanes	329, 334	125
249	Dichloroethylenes	7, 757	126
250	2,3-Dichloro-2- methylbutane	46	36
251	Dichlorosalicylanilides	—	349
252	Dicoumarin	253, 469	231
253	Dicoumarol (INN)	252, 469	231
254	Diethanolamine	(110, 640)	411
255	2- (Diethylaminoethoxy)ethyl α -phenylpiperidine-1- acetate dimethiodide	598	137
256	2-Diethylaminoethyl 3-amino-4- butoxybenzoate and its salts	101	23

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257	2-Diethylaminoethyl benzilate	72	157
258	2-Diethylaminoethyl 4-ethoxybenzoate and its salts	410, 536	179
259	2-Diethylaminoethyl 3-hydroxy-4-phenylbenzoate and its salts	—	128
260	2-Diethylaminoethyl phenyl(piperidino)acetate	103	287
261	3-Diethylaminopropyl cinnamate	—	130
262	Diethyl 4-nitrophenyl phosphate	534	170
263	<i>O,O</i> -Diethyl <i>O</i> -4-nitrophenyl phosphorothioate	535	131
264	Difenclozazine (INN)	566	270
265	Digitaline and all heterosides of <i>Digitalis purpurea L.</i>	—	134
266	4,5-Dihydrobenzimidazol-4-one	86, 87	48
267	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	224	234
268	Dihydrotachysterol (INN)	—	342
269	3,4-Dihydroxy- α -(methylaminomethyl)benzyl alcohol	14, 314	14
270	4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene)dicoumarin	—	207
271	1-(3,4-Dihydroxyphenyl)-2-	293	136

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	ethylaminopropan-1-ol and its salts		
272	1-(3,4-Dihydroxyphenyl)-2-isopropylaminoethanol	417, 420	17
273	Diisopropanolamine	(110, 640)	411
274	5,5'-Di-isopropyl-2,2'-dimethylbiphenyl-4,4'-diyl dihydroiodide	412	361
275	Dimethoxane	285	368
276	4-[2-(3,4-Dimethoxyphenyl)ethyl]-1-(2-chlorophenyl)piperazine and its salts	438	141
277	Dimethylamine	—	142
278	2-Dimethylaminoethyl <i>N</i> -acetylglutamate	233	3
279	2-Dimethylaminoethyl <i>p</i> -butylaminobenzoate and its salts	687	63
280	(+)-4-Dimethylamino-3-methyl-1,2-diphenyl-2-propionyloxybutane	237	116
281	1-Dimethylaminomethyl-1-methylpropyl benzoate and its salts	50	50
282	2-Dimethylaminopropiophenone and its salts	445	145
283	3-(3-Dimethylaminopropylidene)-1,2:4,5-dibenzocyclohepta-1,4-diene and its salts	42	146
284	1,1-Dimethylbiguanide and its salts	447	147
285	2,6-Dimethyl-1,3-dioxan-4-yl acetate	275	368

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286	Dimethylformamide	—	355
287	1,5-Dimethylhexylamine and its salts	34, 523	28
288	1,3-Dimethylpentylamine and its salts	35, 471	30
289	Dimethyl sulfoxide (INN)	—	338
290	Dimevamide (INN) and its salts	297	153
291	Dinitrophenol isomers	—	151
292	Dioxane	—	343
293	Dioxethedrin (INN) and its salts	271	136
294	2,5-Dioxo-3,3-diethyl-5-methylpiperidine and its salts	483	133
295	Diphenhydramine (INN) and its salts	81	339
296	Diphenoxylate hydrochloride (INN)	220	80
297	2,2-Diphenyl-4-dimethylaminovaleramide and its salts	290	153
298	5,5-Diphenyl-4-imidazolidone	—	160
299	4-Diphenylmethoxy-1-methylpiperidine and its salts	305	154
300	3-Diphenylmethoxytropene and its salts	76	158
301	1-Diphenylmethyl-4-methylpiperazine and its salts	222	159
302	1,2-Diphenyl-4-(2-phenylsulphinylethyl)-pyrazolidine-3,5-dione	661	155

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303	α,α -Diphenyl-2-piperidinemethanol and its salts	597	285
304	α,α -Diphenyl-4-piperidinemethanol and its salts	66	286
305	Diphenylpyraline (INN) and its salts	299	154
306	2,5-Dipropoxy-3,6-bis(ethyleneimino)-1,4-benzoquinone	409	152
307	4-Dipropylsulphamoylbenzoic acid	606	161
308	Disulfiram (INN)	699, 710	162
309	Dithio-2,2'-bis(pyridine 1-oxide) 1,1' (additive with trihydrated magnesium sulphate)	625	396
310	Doxylamine (INN) and its salts	576	176
311	Emetine, its salts and derivatives	—	163
312	Endrin (ISO)	372	196
313	Ephedrine and its salts	—	164
314	Epinephrine (INN)	14, 269	14
315	1,2-Epoxybutane	—	400
316	Ergocalciferol (INN)	139, (759)	335
317	Ergot and its alkaloids	193	98
318	Eserine and its salts	586	166
319	Ethionamide (INN)	335	319
320	Ethoheptazine (INN) and its salts	476	173
321	Ethopropazine and its salts	(558)	320
322	4-Ethoxyphenol	(390)	178

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323	4-Ethoxy- <i>m</i> -phenylenediamine and its salts	—	406
324	2-Ethylamino-5-phenyloxazolin-4-one	344	180
325	Ethyl bis(4-hydroxycoumarinyl)acetate and salts of the acid	326	204
326	Ethyl bis(4-hydroxy-2-oxo-1-benzopyran-3-yl)acetate and salts of the acid	325	204
327	Ethyl chloride	167	96
328	Ethyl 1,3-dimethyl-4-phenylazepane-4-carboxylate and its salts	446	171
329	Ethylene dichloride	(248)	125
330	Ethylene oxide	—	182
331	2-Ethyl-2,3-epoxyhexamide and its derivatives	528	165
332	Ethyl <i>p</i> -fluorophenyl sulphone	347	189
333	Ethyl 1-(2-hydroxy-2-phenylethyl)-4-phenylpiperidine-4-carboxylate and its salts	530	172
334	Ethylidene dichloride	(248)	125
335	3-Ethylisothionicotinamide	319	319
336	3-Ethyl-3-methylglutarimide and its salts	71, 337	183
337	4-Ethyl-4-methylpiperidine-2,6-dione and its salts	71, 336	183
338	2-Ethyl-3-methylvaleramide	753	184

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339	Ethylphenacemide	553, 565	272
340	2-Ethyl-2-phenylglutarimide and its salts	361	181
341	3'-Ethyl-5',6',7',8'-tetrahydro-5',5',8',8'-tetramethyl-2'-acetonaphthone	9	362
342	Ethyl urocanate	(405)	418
343	Fenadiazole (INN)	526	208
344	Fenozolone (INN)	324	180
345	Fenylramidol (INN)	575, 579	274
346	Fluanisone (INN)	350	187
347	Fluoresone (INN)	332	189
348	4'-Fluoro-4-[4-hydroxy-4-(α,α,α -trifluoro- <i>m</i> -tolyl)piperino]butyrophenone	738	188
349	6-Fluoro-16-methyl-11 β ,17 α ,21-trihydroxypregna-1,4-diene-3,20-dione	533	186
350	1-(4-Fluorophenyl)-4-[4-(2-methoxyphenyl)-1-piperazinyl]butan-1-one	346	187
351	5-Fluoropyrimidine-2,4-dione	352	190
352	Fluorouracil (INN)	351	190
353	Fluphenazine (INN)	(558)	320
354	Furazolidone (INN)	511	252
355	Furfuryltrimethylammonium salts	357	192
356	Furocoumarins (except natural content of essences). In sun protection and in bronzing products,	98, 462, 620, 743	358

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	furocoumarins content shall be below 1 mg/kg		
357	Furtrethonium iodide (INN)	(355)	192
358	Galantamine (INN)	—	193
359	Gallamine triethiodide (INN)	516	329
360	Glucocorticoids	100	300
361	Glutethimide (INN) and its salts	340	181
362	Glycerol trinitrate	512, 612	253
363	Glycyclamide (INN)	227	100
364	Gold salts	—	296
365	Guaifenesin (INN)	459	230
366	Guanethidine (INN) and its salts	367	259
367	<i>N</i> -(2-Guanidinoethyl)azocane and its salts	366	259
368	Haloperidol (INN)	173	185
369	HCH (ISO) (<i>gamma</i> -HCH)	102, 371, 428	195
370	HETP	377	316
371	1,2,3,4,5,6-Hexachlorocyclohexane	102, 369, 428	195
372	(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	372	196
373	Hexachloroethane	—	197
374	3,3',4,4',6,6'-Hexachloro-2,2'-methylenediphenol	375	371
375	Hexachlorophene (INN)	374	371
376	(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-	376	198

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	hexahydro-1,4:5,8-dimethanonaphthalene		
377	Hexaethyl tetraphosphate	370	316
378	(1 <i>R</i> ,2 <i>S</i>)-Hexahydro-1,2-dimethyl-3,6-epoxyphthalic anhydride	141	70
379	(3 <i>S</i> ,5 <i>aR</i> ,9 <i>bS</i>)-3,3 <i>a</i> ,4,5,5 <i>a</i> ,6- Hexahydro-3,5 <i>a</i> ,9-trimethylnaphtho[1,2- <i>b</i>]furan-2,8-dione	386	217
380	Hexamethonium bromide (INN)	(381)	124
381	<i>N,N'</i> -Hexamethylenebis(trimethylammonium) salts	380	124
382	Hexapropymate (INN)	616	115
383	Hydrastine, hydrastinine and their salts	—	199
384	Hydrazides and their salts	—	200
385	Hydrazine, its derivatives and their salts	—	201
386	2-Hydrazino-octane and its salts	521	202
387	Hydrocyanic acid and its salts	389, 408, 601, 642	111
388	Hydrofluoric acid, its normal salts, complexes and hydrofluorides (except those listed in Part I of Schedule 2)	—	191
389	Hydrogen cyanide and its salts	387, 408, 601, 642	111
390	Hydroquinone monobenzyl,	96, 322, 458, 487	178

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	monoethyl and monomethyl ethers		
391	7-[2-Hydroxy-3-(2-hydroxyethyl-N-methylamino)propyl]theophylline	762	135
392	[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid and its salts	739	5
393	3-[4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]propionic acid and its salts	713	9
394	2-Hydroxy-3-(2-methoxyphenyl)propyl carbamate	450	205
395	1-Hydroxymethyl-1-cyclohexylacetic acid, sodium salt	643	114
396	4-Hydroxy-3-[1-(4-nitrophenyl)-3-oxobutyl]coumarin	1	254
397	8-Hydroxy-5-nitroquinoline and its salts	515	209
398	4-Hydroxy-3-(3-oxo-1-phenylbutyl)coumarin and its salts	3, 760	203
399	11 α -Hydroxypregn-4-ene-3,20-dione and its esters	—	385
400	Hydroxy-8-quinoline and its sulphate, except for the uses provided for in entry number 51 in Part I of Schedule 2	114, 531, 630	395
401	Hydroxyzine (INN)	171	240
402	Hyoscine, its salts and derivatives	638	295

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403	Hyoscyamine, its salts and derivatives	—	210
404	<i>Hyoscyamus niger</i> L. (leaves, seeds, powder and galenical preparations)	—	211
405	3-Imidazol-4-ylacrylic acid and its ethyl ester	342, 751	418
406	2-Imino-5-phenyloxazolidin-4-one and its salts	538	212
407	Imperatorin	465	34
408	Inorganic cyanides	(387, 389) 601, 642	111
409	Inproquone (INN)	306	152
410	Intracaine and its salts	258, 536	179
411	Iodine	—	213
412	Iodothymol	274	361
413	Ipecacuanha (<i>Cephaelis ipecacuanha</i> Brot. and related species) (roots, powder and galenical preparations)	—	215
414	Isocarboxazid (INN)	93	52
415	Isodrin	376	198
416	Isometheptene (INN) and its salts	463	228
417	Isoprenaline (INN)	272, 420	17
418	Isopropamide iodide (INN)	(145)	156
419	(2-Isopropylpent-4-enoyl)urea	60	216
420	Isoproterenol	272, 417	17
421	Isosorbide dinitrate (INN)	244	148
422	<i>Juniperus sabina</i> L. (leaves, essential oil and galenical preparations)	—	294

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423	Laurel oil	424	359
424	<i>Laurus nobilis</i> L. (oil from seeds)	423	359
425	Lead and its compounds (except lead acetate subject to the restrictions laid down in entry number 55 in Part I of Schedule 2)	—	289
426	Levopropacetoperane and its salts	594	284
427	Lidocaine (INN) (Lignocaine)	—	399
428	Lindane	102, 369, 371	195
429	<i>Lobelia inflata</i> L. and its galenical preparations	—	218
430	Lobeline (INN) and its salts	112	219
431	LSD	(433, 434)	127
432	Lupinidine and its salts	648	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	104	89
437	Mecamylamine (INN)	698	229
438	Mefeclozazine (INN) and its salts	276	141
439	Mephesisin (INN) and its esters	718	322
440	Meprobamate (INN)	481	236
441	Mercury and its compounds (except	—	221

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	those listed in Part I of Schedule 4)		
442	Mescaline and its salts	740	222
443	Metabromsalan (INN)	(246)	351
444	Metaldehyde	600	223
445	Metamfepramone (INN) and its salts	282	145
446	Metethoheptazine (INN) and its salts	328	171
447	Metformin (INN) and its salts	284	147
448	Methapyrilene (INN) and its salts	624	144
449	Metheptazine (INN) and its salts	468	174
450	Methocarbamol (INN)	394	205
451	Methohexitone and its salts	(69)	220
452	Methotrexate (INN)	33	6
453	2-[4-Methoxybenzyl- <i>N</i> -(2-pyridyl)amino]-ethyl-dimethylamine maleate	622	346
454	1-Methoxy-2,2-bis(4-hydroxy-3-coumarinyl)ethane	215	225
455	1-Methoxy-2,4-diaminobenzene and its salts	239, 461	376
456	1-Methoxy-2,5-diaminobenzene and its salts	240, 460	377
457	(+)-3-Methoxy- <i>N</i> -methylmorphinan and its salts	236	226
458	4-Methoxyphenol	(390)	178

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459	3-(2-Methoxyphenoxy)propane-1,2-diol	365	230
460	2-Methoxy- <i>p</i> -phenylenediamine and its salts	240, 456	377
461	4-Methoxy- <i>m</i> -phenylenediamine and its salts	239, 455	376
462	Methoxypsoralens (except natural content of essences). In sun protection and in bronzing products, furocoumarins content shall be below 1 mg/kg	(356)	358
463	6-Methylamino-2-methylhept-2-ene and its salts	416	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	407	34
466	2-Methyl-6-chloroanilide of <i>n</i> -butylaminoacetic acid and its salts	125	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)	252, 253	231
470	2-Methylheptylamine and its salts	—	227

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471	4-Methyl-2-hexylamine and its salts	35, 288	30
472	1-Methylimidazole-2-thiol	474, 704	233
473	<i>N-N'</i> -[(Methylimino)diethylene]bis-(ethylmethylammonium) salts	67	121
474	1-Methyl-2-mercaptoimidazole	472, 704	233
475	Methylphenidate (INN) and its salts	572	175
476	1-Methyl-4-phenyl-4-carbethoxyhexamethyleneimine and its salts	320	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	555	232
480	2-Methyl-2-propyl-1-isopropylcarbamoyloxy-3-carbamoyloxypropane	151	235
481	2-Methyl-2-propyltrimethylene dicarbamate	440	236
482	<i>N</i> -Methyl-1,2,5,6-tetrahydro-3-nicotinic acid methyl ester	61	238
483	Methyprylon (INN) and its salts	294	133
484	Metyrapone (INN)	464	292
485	Minoxidil (INN), its salts and derivatives	596	372
486	Mofebutazone (INN)	133	64

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487	Monobenzene (INN)	96, (390)	178
488	Morpholine and its salts	—	344
489	Musk ambrette	132	414
490	Mustine and its salts	106, 160	87
491	Mustine <i>N</i> -oxide and its salts	107	86
492	Nalorphine (INN), its salts and ethers	21	20
493	Naphazoline (INN) and its salts	499	244
494	2-Naphthol	495	241
495	β -Naphthol	494	241
496	1- and 2-Naphthylamines and their salts	497	242
497	α - and β -Naphthylamines and their salts	496	242
498	3-(1-Naphthyl)-4-hydroxycoumarin	—	243
499	2-(1-Naphthylmethyl)-2-imidazoline and its salts	493	244
500	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
501	Narcotine and its salts	519	258
502	Neodymium and its salts	—	309
503	Neostigmine and its salts	—	245
504	Nicotine and its salts	—	246

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505	Nitrites, inorganic (except sodium nitrite)	—	248
506	Nitrobenzene	—	249
507	Nitrocresols and their alkali metal salts	—	250
508	Nitroderivatives of carbazole	146	72
509	Nitrofurantoin (INN)	510	251
510	<i>N</i> -(5-Nitro-2-furfurylidene)-1-aminohydantoin	509	251
511	3-(5-Nitrofurfurylideneamino)oxazolidin-2-one	354	252
512	Nitroglycerine	362, 612	253
513	Nitrosamines	—	410
514	Nitrostilbenes, their homologues and derivatives	—	256
515	Nitroxoline (INN) and its salts	397	209
516	<i>N,N,N,N',N',N', "N, "N, "N</i> 359 Nonaethyl-2,2',2"- (benzene-1,2,3-triyltrioxy)- tris(ethanaminium) triiodide		329
517	Noradrenaline and its salts	32, 518	257
518	Norepinephrine (INN) and its salts	32, 517	257
519	Noscapine (INN) and its salts	501	258
520	Nux vomica and its preparations	(658)	305
521	Octamoxin (INN) and its salts	386	202
522	Octamylamine (INN) and its salts	—	267

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(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
523	Octodrine (INN) and its salts	34, 287	28
524	Oestrogens	—	260
525	Oleandrin	—	261
526	2-(1,3,4-Oxadiazol-2-yl)phenol	343	208
527	[Oxalylbis(iminoethylenammonium)]bis[(<i>o</i> -chlorobenzyl)diethylammonium] salts	—	132
528	Oxanamide (INN) and its derivatives	331	165
529	2-Oxo-3-isobutyl-9,10-dimethoxy-1,2,3,4,6,7-hexahydro-11 <i>bH</i> -benzo[<i>a</i>]quinolizine and its salts	685	139
530	Oxpheneridine (INN) and its salts	333	172
531	Oxyquinoline and its sulphate, except for the uses provided for in entry number 51 in Part I of Schedule 2	114, 400, 630	395
532	Padimate A	47	381
533	Paramethasone (INN)	349	186
534	Paraoxon	262	170
535	Parathion (ISO)	263	131
536	Parethoxycaine (INN) and its salts	258, 410	179
537	Pelletierine and its salts	595	263
538	Pemoline (INN) and its salts	406	212
539	Pentachloroethane	—	264
540	Pentaerythritol chloral	549	266
541	Pentaerythritol tetranitrate	542, 548	265

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542	Pentaerythrityl tetranitrate (INN)	541, 548	265
543	Pentamethonium bromide (INN)	(544)	120
544	<i>N,N'</i> -Pentamethylenebis(trimethylammonium) salts	543	120
545	Pentobarbitone and its salts	(69)	220
546	Perchloroethylene	689	314
547	Perphenazine (INN) and its salts	(558)	320
548	PETN	541, 542	265
549	Petrichloral (INN)	540	266
550	Phenacemide (INN)	561	269
551	Phenaglycodol (INN)	174	95
552	Phenetamine	225	112
553	Pheneturide (INN)	339, 565	272
554	Phenindone (INN)	571	271
555	Phenmetrazine (INN), its derivatives and salts	479	232
556	Phenobarbitone and its salts	(69)	220
557	Phenolphthalein (INN)	113	417
558	Phenothiazine (INN) and its compounds	various	320
559	Phenprobamate (INN)	573	71
560	Phenprocoumon (INN)	574	273
561	<i>N</i> -Phenylacetylurea	550	269
562	4-Phenylazophenylene-1,3-diamine citrate hydrochloride	190	81
563	Phenylbutazone (INN)	131	67
564	4-Phenylbut-3-en-2-one	94	356
565	(2-Phenylbutyryl)urea	339, 553	272

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566	N-[2-(α -Phenyl- <i>p</i> -chlorobenzyl)-ethyl]morpholine	264	270
567	1-Phenylcyclopentanecarboxylic acid diethylaminoethyl ester and its salts	144	169
568	2-Phenylcyclopropylamine (<i>trans</i> -form) and its salts	719	324
569	1-Phenyl-2,3-dimethyl-4-isopropylpyrazol-5-one	617	138
570	<i>o</i> -Phenylenediamine and its salts	241	363
571	2-Phenylindan-1,3-dione	554	271
572	α -Phenyl-2-piperidineacetic acid methyl ester and its salts	475	175
573	3-Phenylpropyl carbamate	559	71
574	3-(α -Phenylpropyl)-4-hydroxycoumarin	560	273
575	1-Phenyl-2-(2-pyridylamino)ethanol	345, 579	274
576	2-[1-Phenyl-1-(2-pyridyl)ethoxy]-ethyl dimethylamine and its salts	310	176
577	2-Phenylquinoline-4-carboxylic acid, its salts and derivatives and salts of those derivatives	192	8
578	6-Phenyl-2,4,7-triaminopteridine and its salts	722	275
579	Phenyramidol	345, 575	274

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580	Phosphides, metal	—	279
581	Phosphorus	—	279
582	4-Phosphoryloxy- <i>N,N</i> - dimethyltryptamine	619	278
583	3- Phthalimidopiperidine-2,6- dione and its salts	701	280
584	Phthalylsulphathiazole (INN) and its salts	(675)	307
585	<i>Physostigma venenosum</i> Balf.	138	281
586	Physostigmine and its salts	318	166
587	<i>Phytolacca Spp</i> and their preparations	—	374
588	Picric acid	742	268
589	Picrotoxin	197	282
590	Pilocarpine and its salts	—	283
591	<i>Pilocarpus jaborandi Holmes</i> and its galenical preparations	—	311
592	Pipazetate (INN) and its salts	593	118
593	2-(2- Piperidinoethoxy)ethyl 10-thia-1,9- diazanthracene-9- carboxylate and its salts	592	118
594	α -Piperidin-2-ylbenzyl acetate, laevorotatory <i>threo</i> -form and its salts	426	284
595	1-(2- Piperidyl)propan-2- one and its salts	537	263
596	6-(Piperidiny)-2,4- pyrimidinediamine 3-oxide, its salts and derivatives	485	372

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597	Pipradrol (INN) and its salts	303	285
598	Piprocuarium iodide (INN)	255	137
599	Poldine metilsulfate (INN) (Poldine methylsulphate)	85	239
600	Polyacetaldehyde	444	223
601	Potassium cyanide	(387, 389, 408)	111
602	Potassium nitroferricyanide	(15), 603	255
603	Potassium nitroprusside	(15), 602	255
604	Pramocaine (INN)	605	405
605	Pramoxine	604	405
606	Probenecid (INN)	307	161
607	Procainamide (INN), its salts and derivatives	29	25
608	Prochlorperazine (INN) and its salts	(558)	320
609	Progestogens	—	194
610	Promazine (INN) and its salts	(558)	320
611	Promethazine (INN) and its salts	(558)	320
612	Propane-1,2,3-triyl trinitrate	362, 512	253
613	Propatylnitrate (INN)	111	206
614	1-Propyl-3-(4-chlorobenzenesulphonyl)urea	182	79
615	2-Propylpiperidine	212	290
616	1-(2-Propynyl)cyclohexyl carbamate	382	115
617	Propyphenazone (INN)	569	138
618	<i>Prunus laurocerasus</i> L.	157	291

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619	Psilocybine (INN)	582	278
620	Psoralen (except natural content of essences). In sun protection and in bronzing products, furocoumarins content shall be below 1 mg/kg	(356)	358
621	<i>Pyrethrum album</i> L. and its galenical preparations	—	345
622	Pyrianisamine maleate	453	346
623	Pyribenzamine	97, 745	347
624	2-(<i>N</i> -2-Pyridyl- <i>N</i> -2-thienylamino)ethyl-dimethylamine and its salts	448	144
625	Pyrithione disulphide +magnesium sulphate	309	396
626	Pyrithione sodium (INN)	—	369
627	Pyrocatechol	79, 153	408
628	Pyrogallol	—	409
629	Quinalbarbitone and its salts	(69)	220
630	Quinolin-8-ol except for the uses provided for in entry number 51 in Part I of Schedule 2	(400, 531)	395
631	Radioactive substances (except substances which are radioactive naturally or by reason of contamination from the environment, which have not been enriched for manufacturing purposes, and of which the concentration complies with Council	—	293

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(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
	Directive No. 76/579/ Euratom(38))		
632	<i>Rauwolfia serpentina</i> alkaloids and their salts	633	15
633	Reserpine (INN) and its salts	(632)	15
634	Retinoic acid and its salts	721, 758	375
635	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
636	α -Santonin	379	214
637	<i>Schoenocaulon officinale</i> Lind. (seeds and galenical preparations)	—	332
638	Scopolamine, its salts and derivatives	402	295
639	Secbutobarbitone and its salts	(69)	220
640	Secondary dialkanolamines	110, 254, 273	411

(38) O.J. No. L187, 12.7.76, p.1.

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641	Selenium and its compounds except when permitted under the restrictions laid down in Part I of Schedule 2	—	297
642	Sodium cyanide	(387, 389, 408)	111
643	Sodium hexacyclonate (INN)	395	114
644	Sodium nitroferricyanide	(15), 645	255
645	Sodium nitroprusside	(15), 644	255
646	<i>Solanum nigrum</i> L. and its galenical preparations	—	298
647	Spanish Fly	140	69
648	Sparteine (INN) and its salts	432	299
649	Spiroinolactone (INN)	10	4
650	Squill and its preparations	750	330
651	Stramonium and its preparations	231	301
652	Strontium lactate	—	402
653	Strontium nitrate	—	403
654	Strontium polycarboxylate	—	404
655	Strophanthines and their aglucones and their respective derivatives	—	302
656	<i>Strophanthus</i> species and their galenical preparations	—	303
657	Strychnine and its salts	—	304
658	<i>Strychnos</i> species and their galenical preparations	520	305
659	Succinonitrile	—	150

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660	Succinylsulphathiazole and its salts	(675)	307
661	Sulfinpyrazone (INN)	302	155
662	Sulphacetamide and its salts	(675)	307
663	Sulphadiazine and its salts	(675)	307
664	Sulphadimethoxine and its salts	(675)	307
665	Sulphadimidine and its salts	(675)	307
666	Sulphafurazole and its salts	(675)	307
667	Sulphaguanidine and its salts	(675)	307
668	Sulphamethizole and its salts	(675)	307
669	Sulphamethoxazole and its salts	(675)	307
670	Sulphamethoxydiazine and its salts	(675)	307
671	Sulphamethoxypyridazine and its salts	(675)	307
672	Sulphanilamide and its salts	(675)	307
673	Sulphapyridine and its salts	(675)	307
674	Sulphathiazole and its salts	(675)	307
675	Sulphonamides (sulphanilamide and its derivatives obtained by substitution of one or more H-atoms of the $-NH_2$ groups) and their salts	584, 660, 662–674	307
676	Sulthiame	677, 696	308
677	Sultiame (INN)	676, 696	308

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678	Sympathomimetic amines acting on the central nervous system: any substance contained in the first list of medicaments which are subject to medical prescription and are referred to in resolution AP (69) 2 of the Council of Europe	44	21
679	Tefazoline (INN) and its salts	695	237
680	Tellurium and its compounds	—	312
681	TEPP (ISO)	693	276
682	2-(4- <i>tert</i> -Butyl-2,6-dimethylbenzyl)-2-imidazoline and its salts	764	313
683	4- <i>tert</i> -Butylphenol	—	340
684	4- <i>tert</i> -Butylpyrocatechol	—	341
685	Tetrabenazine (INN) and its salts	529	139
686	Tetrabromosalicylanilides—		350
687	Tetracaine (INN) and its salts	279	63
688	2,3,7,8-Tetrachlorodibenzo- <i>p</i> -dioxin	—	367
689	Tetrachloroethylene	546	314
690	Tetrachloromethane	148	315
691	Tetrachlorosalicylanilides—		348
692	Tetraethylammonium bromide	700	61
693	Tetraethyl pyrophosphate	681	276
694	(<i>R</i>)-5,6,6a,7-Tetrahydro-6-	59	42

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	methyl-4 <i>H</i> -dibenzo[<i>de,g</i>]quinoline-10,11-diol and its salts		
695	2-(5,6,7,8-Tetrahydro-1-naphthylmethyl)-2-imidazoline and its salts	679	237
696	4-(Tetrahydro-2 <i>H</i> -1,2-thiazin-2-yl)-benzenesulphonamide <i>S,S</i> -dioxide	676, 677	308
697	Tetrahydrozoline and its salts	—	394
698	<i>N</i> ,2,3,3-Tetramethyl-2-norcamphanamine	437	229
699	Tetramethylthiuram disulphide	710	162
700	Tetrylammonium bromide (INN)	692	61
701	Thalidomide (INN) and its salts	583	280
702	Thallium and its compounds	—	317
703	<i>Thevetia neriifolia</i> <i>Juss.</i> , glycoside extract	—	318
704	Thiamazole (INN)	472, 474	233
705	2,2'-Thiobis(4,6-dichlorophenol)	115	352
706	Thiopentone and its salts	(69)	220
707	Thioridazine (INN) and its salts	(558)	320
708	Thiotepa (INN)	723	310
709	Thiourea and its derivatives (except those listed in Part I of Schedule 2)	—	321
710	Thiram (ISO)	699	162
711	Thiuram disulphides	—	354

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712	Thiuram monosulphides	—	353
713	Thyropropic acid (INN) and its salts	393	9
714	Tolboxane (INN)	717	177
715	Tolbutamide (INN)	134	65
716	Toluidines, their isomers, salts and halogenated and sulphonated derivatives	40	32
717	<i>p</i> -Tolylboric acid ester of 2-methyl-2-propylpropane-1,3-diol	714	177
718	3- <i>o</i> -Tolyloxypropane-1,2-diol	(439)	322
719	Tranlycypromine (INN) and its salts	568	324
720	Tretamine (INN)	724	328
721	Tretinoin (INN) and its salts	634, 758	375
722	Triamterene (INN) and its salts	578	275
723	Tri(aziridin-1-yl)phosphine sulphide	708	310
724	2,4,6-Tri(aziridin-1-yl)-1,3-triazine	720	328
725	2,2,2-Tribromoethanol	(726)	326
726	Tribromoethyl alcohol	725	326
727	Tribromsalan (INN)	728	373
728	3,4',5-Tribromosalicylanilide	727	373
729	Trichlormethine (INN) and its salts	746	327
730	Trichloroacetic acid	—	10
731	1,1,1-Trichloro-2,2-bis(4-chlorophenyl)ethane	195, 232	123

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732	2,2,2-Trichloroethane-1,1-diol	158	77
733	Trichloromethane	168	366
734	<i>N</i> -(Trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide	142	370
735	Trichloronitromethane	178	325
736	Tricresyl phosphate	747	277
737	Trifluoperazine (INN) and its salts	(558)	320
738	Trifluoperidol (INN)	348	188
739	3,3',5-Triiodothyroacetic acid and its salts	392	5
740	3,4,5-Trimethoxyphenethylamine and its salts	442	222
741	2,2,6-Trimethyl-4-piperidyl benzoate and its salts	75	51
742	2,4,6-Trinitrophenol	588	268
743	Trioxysalen (INN) (except natural content of essences). In sun protection and in bronzing products, furocoumarins content shall be below 1 mg/kg	(356)	358
744	Triparanol (INN)	172	92
745	Tripelennamine (INN)	97, 623	347
746	Tris(2-chloroethyl)amine	729	327
747	Tritolyl phosphate	736	277
748	Tuaminoheptane (INN), its isomers and salts	30	27
749	Tyrothricin (INN)	—	392

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750	<i>Urginea scilla</i> Stern. and its galenical preparations	650	330
751	Urocanic acid	(405)	418
752	Vaccines, toxins and serums listed in the Annex to Council Directive No. 75/319/EEC (39)	—	323
753	Valnoctamide (INN)	338	184
754	Veratrine, its salts and galenical preparations	—	331
755	<i>Veratrum spp</i> and their preparations	—	333
756	Vinyl chloride monomer	—	334
757	Vinylidene chloride	(7, 249)	126
758	Vitamin A acid and its salts	634, 721	375
759	Vitamins D ₂ and D ₃	139, 187, 316	335
760	Warfarin (ISO) and its salts	3, 398	203
761	Xanthates	16	336
762	Xanthinol	391	135
763	Xylidines, their isomers, salts and halogenated and sulphonated derivatives	41	33
764	Xylometazoline (INN) and its salts	682	313
765	Yohimbine and its salts	—	337
766	Zirconium and its compounds (except aluminium zirconium chloride hydroxide complexes and aluminium zirconium	—	391

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

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

(1) <i>Number in this Schedule</i>	(2) <i>Name of substance</i>	(3) <i>Cross-reference to this Schedule</i>	(4) <i>Cross-reference to Annex II of the Directive</i>
767	chloride hydroxide glycine complexes under the conditions laid down in Part I of Schedule 2 and zirconium lakes, salts and pigments prepared from those colouring agents identified in column 1 of Part I of Schedule 3 by “*” immediately after the name or colour index number) Zoxazolamine (INN)	28	24

SCHEDULE 2

Regulations 4(2), 5(1) and 6(2)

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

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

Names which appear in square brackets in column 2 are the International Nomenclature Cosmetic Ingredient names of the substances in question given in the inventory of ingredients employed in cosmetic products drawn up in accordance with the provisions of the Directive and contained in Commission Decision [96/335/EC](#)(40).

(40) O.J. No. L132, 1.6.1996, 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.

PART I

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

(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>	(5) <i>Other requirements</i>	(6) <i>Required information</i>
1	Boric acid	Talcum powder	5 per cent	Not to be used in products intended for children less than three years old	Not to be used for children under three years of age
		Oral hygiene products	0.5 per cent	—	—
		Other products	3 per cent	—	—
2a	Thioglycolic acid and its salts	(a) Hair waving or straightening products for general use	8 per cent ready for use	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	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	5 per cent ready for use	pH 7 to 12.7	Contains thioglycolate. Follow the instructions. Keep out of reach of children

Note 1: Entry 15a is substituted with effect from the dates specified in regulation 1(6). Until then, entry number 15 in Part I of Schedule 2 to S.I.1989/2233 continues in force.

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

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(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>	(5) <i>Other requirements</i>	(6) <i>Required information</i>
		(d) Other hair-care products which are removed after application	2 per cent ready for use	pH 7 to 9.5	Contains thioglycolate. Follow the instructions. Keep out of reach of children
			The abovementioned 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	8 per cent ready for use	pH 6 to 9.5	Contains thioglycolate. Follow the instructions. Keep out

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		(b) Hair waving or straightening products for professional use	11 per cent ready for use	pH 6 to 9.5	of reach of children Contains thioglycolate. Follow the instructions. Keep out of reach of children. For professional use only
			The abovementioned percentages are calculated as thioglycolic acid	(a) and (b): the directions for use must incorporate the following: — 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	

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				—	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) [Chloramine-T]	All purposes and products	0.2 per cent	—	—
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, 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	Oxidizing colouring agents for hair-dyeing for general use	6 per cent calculated as a free base, subject to the provision of “Combination Rule A” set out below	—	Contains phenylenediamines. Can cause an allergic reaction. Do not use to dye eyelashes or eyebrows

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	of <i>o</i> - phenylenediamines	Oxidizing colouring agents for hair- dyeing for professional use	6 per cent calculated as a free base, subject to the provisions of “Combination Rule A” set out below	—	Contains phenylenediamines. For professional use only. Can cause an allergic reaction. Wear suitable gloves
9	Methylphenylenediamines (other than 4-methyl- <i>m</i> - phenylenediamine and its salts), their <i>N</i> - substituted derivatives and their salts (Toluenediamines (other than toluene-1,3- diamine and its salts), their <i>N</i> -substituted derivatives and their salts)	Oxidizing colouring agents for hair-dyeing for 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	Oxidizing colouring agents for	10 per cent calculated as a free base, subject to the	—	Contains diaminophenols. Can cause allergic

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		hair-dyeing for general use	provisions of “Combination Rule A” set out below		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
11	Dichlorophen (INN) [Dichlorophene]	All purposes and products	0.5 per cent	—	Contains dichlorophen
12	Hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide including hydrogen peroxide-urea (hydrogen peroxide- carbamide) and zinc peroxide	(a) Hair care preparations (b) Skin- care preparations (c) Nail hardening preparations (d) Oral hygiene products	(a) 12 per cent of H ₂ O ₂ present or released (b) 4 per cent of H ₂ O ₂ present or released (c) 2 per cent of H ₂ O ₂ present or released (d) 0.1 per cent of H ₂ O ₂ present or released	— — — —	(a): Wear suitable gloves (a)(b)(c): Contains hydrogen peroxide. Avoid contact with eyes. Rinse eyes immediately if product comes into contact with them —
13	Formaldehyde (see also Part I of Schedule 4)	Nail hardeners	5 per cent	—	Contains formaldehyde. Protect cuticles with grease or oil. (Not required when concentration is not more

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					than 0.05 per cent)
14	Hydroquinone	Oxidizing colouring agent for hair dyeing for general use	2 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	2 per cent subject to the provisions of “Combination Rule B” set out below	—	Contains hydroquinone. For professional use only. Rinse eyes immediately if product comes into contact with them
		Agents for localised skin lightener	2 per cent	—	Contains hydroquinone. Avoid contact with eyes. Apply to small areas. If irritation develops discontinue use. Do not use on children under the age of 12
15a	Potassium hydroxide and sodium hydroxide (see Note 1)	Nail cuticle solvent	5 per cent calculated as sodium hydroxide (see Note 2)	—	Contains alkali. Avoid contact with eyes. Can cause blindness.

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					Keep out of reach of children
		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 professional use	4.5 per cent calculated as sodium hydroxide (see Note 2)	—	For professional use only. Avoid contact with eyes. Can cause blindness
		pH adjuster for depilatories	—	pH value not to exceed 12.7	Keep out of reach of children. Avoid contact with 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 professional use	4.5 per cent calculated as sodium hydroxide (see Note 2)	—	For professional use only. Avoid contact with eyes.

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					Can cause blindness
15c	Calcium hydroxide	Other uses Hair straighteners containing two components: calcium hydroxide and guanidine salt	— 7 per cent	—	— Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children
16	α -Naphthol[1-Naphthol]	Other uses Colouring agent for hair dyeing	— 0.5 per cent	—	— Contains α -naphthol
17	Sodium nitrite	Rust inhibitor	0.2 per cent	Do not use with secondary and/or tertiary amines or other substances forming nitrosamines	—
18	Nitromethane	Rust inhibitor	0.3 per cent	—	—
19	Phenol and its alkali salts	Soaps and shampoos	1 per cent calculated as phenol	—	Contains phenol
20	ENTRY DELETED				
21	Quinine and its salts	Shampoos	0.5 per cent calculated as quinine base	—	—
		Hair lotions	0.2 per cent calculated as quinine base	—	—

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22	Resorcinol	Oxidizing colouring agent for hair dyeing for general use	5 per cent subject to the provisions of “Combination Rule B” set out below	—	Contains resorcinol. Rinse hair well after application. Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them
		Oxidizing colouring agent for hair dyeing for professional use	5 per cent subject to the provisions of “Combination Rule B” set out below	—	Contains resorcinol. For professional use only. Rinse eyes immediately if product comes into contact with them
		Hair lotions and shampoos	0.5 per cent subject to the provisions of “Combination Rule B” set out below	—	Contains resorcinol
23a	Alkali sulphides	Depilatories	2 per cent calculated as sulphur	pH value not to exceed 12.7	Keep out of reach of children. Avoid contact with eyes
23b	Alkaline earth sulphides	Depilatories	6 per cent calculated as sulphur	pH value not to exceed 12.7	Keep out of reach of children. Avoid contact with eyes

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24	Water-soluble zinc salts with the exception of zinc 4-hydroxybenzenesulphonate	All purposes and products	1 per cent calculated as zinc	—	—
25	Zinc 4-hydroxybenzenesulphonate [Zinc phenolsulfonate]	Deodorants, antiperspirants and astringent lotions	6 per cent calculated as percentage of anhydrous substance	—	Avoid contact with eyes
26	Ammonium monofluorophosphate	Oral hygiene products	0.15 per cent calculated as fluorine. When mixed with other fluorine compounds the total fluorine concentration must not exceed 0.15 per cent	—	Contains ammonium monofluorophosphate
27	Sodium monofluorophosphate	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains sodium monofluorophosphate
28	Potassium monofluorophosphate	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains potassium monofluorophosphate
29	Calcium monofluorophosphate	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains calcium monofluorophosphate
30	Calcium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains calcium fluoride
31	Sodium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains sodium fluoride

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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 [Palmityl trihydroxyethyl propylenediamine dihydrofluoride]	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains <i>N,N',N'</i> -tris(polyoxyethylene)- <i>N</i> -hexadecylpropylenediamine dihydrofluoride
39	Octadecenylammonium fluoride	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains octadecenylammonium fluoride

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40	Sodium fluorosilicate	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains sodium fluorosilicate
41	Potassium fluorosilicate	Oral hygiene products	As for ammonium monofluorophosphate	—	Contains 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)imidazolidene-2-thione [Dimethylol ethylene thiourea]	Hair care preparations Nail care preparations	2 per cent 2 per cent	Not to be used in aerosol dispensers pH value as applied must be less than 4	Contains 1,3-bis(hydroxymethyl)imidazolidene-2-thione Contains 1,3-bis(hydroxymethyl)imidazolidene-2-thione
45	Benzyl alcohol (See also Part I of Schedule 4)	Solvent, perfumes and flavourings	—	—	—
46	6-Methylcoumarin	Oral hygiene products	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

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49	Selenium disulphide [Selenium sulfide]	Anti-dandruff shampoos	1 per cent	—	Contains selenium disulphide. Avoid contact with eyes or damaged skin
50	Aluminium zirconium chloride hydroxide complexes $Al_xZr(OH)_yCl_z$ and aluminium zirconium chloride hydroxide glycine complexes	Anti-perspirants	20 per cent as anhydrous aluminium zirconium chloride hydroxide, 5.4 per cent as zirconium	The ratio of the number of aluminium atoms to that of zirconium atoms must be between 2 and 10 The ratio of the number of (Al+Zr) atoms to chlorine atoms must be between 0.9 and 2.1 Not to be used in aerosol dispensers (sprays)	Do not apply to irritated or damaged skin
51	Quinolin-8-ol and bis(8-hydroxyquinolin-8-yl) sulphate) (See also Part II of this Schedule) [Oxyquinoline and Oxyquinoline sulfate]	Stabilizer for hydrogen peroxide in rinse-off hair care preparations	0.3 per cent calculated as base	—	—
		Stabilizer for hydrogen peroxide in non rinse-	0.03 per cent calculated as base	—	—

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		off hair care preparations			
52	Methanol	Denaturant for ethanol and isopropyl alcohol	5 per cent calculated as a percentage of ethanol and isopropyl alcohol	—	—
53	Etidronic acid and its salts (1-hydroxyethylidene-diphosphonic acid and its salts)	Hair care Soap	1.5 per cent expressed as etidronic acid 0.2 per cent expressed as etidronic acid	— —	— —
54	1-Phenoxypropan-2-ol (See also Part I of Schedule 4) [Phenoxyisopropanol]	Products used off after use. Prohibited in oral hygiene products	2 per cent	—	—
55	Lead acetate	Only for hair dyeing	0.6 per cent calculated as lead	—	Contains lead acetate. Keep away from children. Avoid all contact with the eyes. Wash hands after use. Do not use to dye eyelashes, eyebrows or moustaches. If irritation develops discontinue use
56	Magnesium fluoride	Dental hygiene products	0.15 per cent calculated as fluorine.	—	Contains magnesium fluoride

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			When mixed with other fluorine compounds the total fluorine concentration must not exceed 0.15 per cent		
57	Strontium chloride hexahydrate	Toothpaste	3.5 per cent calculated as strontium. When mixed with other permitted strontium compounds the total strontium content must not exceed 3.5 per cent	—	Contains strontium chloride. Use by children is not advisable
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 silicate	(a) Powdery products intended to be used for children under	—	—	(a): Keep powder away from children's nose and mouth

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		three years of age			
		(b) other products	—	—	
60	Fatty acid dialkanolamides and products	All purposes	Maximum dialkanolamine content: 0.5 per cent	Do not use with nitrosating systems. Maximum dialkanolamine content: 5 per cent (applies to raw materials). Maximum <i>N</i> -nitrosodialkanolamine content: 50 µ g/kg (applies to raw materials). Keep in nitrite-free containers	—
61	Monoalkanolamines and products	All purposes and products	Maximum dialkanolamine content: 0.5 per cent	Do not use with nitrosating systems. Minimum purity: 99 per cent. Maximum dialkanolamine content: 0.5 per cent (applies to raw materials). Maximum <i>N</i> -nitrosodialkanolamine content: 50 µ g/kg (applies to raw materials).	—

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				Keep in nitrite-free containers	
62	Trialkanolamines	(a) no(rinse-off products (b) other products	(a) 2(5) per cent	(a) (b): Do not use with nitrosating systems. Minimum purity: 99 per cent. Maximum dialkanolamine content: 0.5 per cent (applies to raw materials). Maximum N-nitrosodialkanolamine content: 50 µ g/kg (applies to raw materials). Keep in nitrite-free containers	—
63	Strontium hydroxide	pH-regulator in depilatory products	3.5 per cent calculated as strontium	pH value not to exceed 12.7	Keep out of reach of children. Avoid contact with the eyes
64	Strontium peroxide	Rinse-off hair care preparations for professional use	4.5 per cent calculated as strontium in the ready-for-use preparation	All products must meet the hydrogen peroxide release requirements	Avoid contact with eyes. Rinse eyes immediately if product comes into contact with them. For professional use only. Wear suitable gloves

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PART II

SUBSTANCES LISTED IN ANNEX III, PART 2 (FORMERLY ANNEX IV, PART 1) OF THE DIRECTIVE(41)AS SUBSTANCES PROVISIONALLY ALLOWED

(1) <i>Reference Number</i>	(2) <i>Name of Substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>	(5) <i>Other requirements</i>	(6) <i>Required information</i>	(7) <i>Permitted for use until</i>
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NOTE—There are presently no entries in this Part.

Combination Rules

A. Where a cosmetic product contains two or more substances to which this Combination Rule applies, the concentration in the product of each of those substances shall be such that the sum of the relevant quotients for those substances (as defined in Rule C below) shall not exceed 1.

B. Where a cosmetic product contains the substances to which this Combination Rule applies, the concentration in the product of each of those substances shall be such that the sum of the relevant quotients for those substances (as defined in Rule C below) shall not exceed 2; but the concentration of each substance shall not in any event exceed the limit specified for the substance in respect of the product in column 4 above.

C. The relevant quotient for each substance is the actual concentration of the substance in the product divided by the maximum concentration specified for the substance in respect of the product in Column 4 of this Schedule.

SCHEDULE 3

Regulations 4(2) and 6(9)

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

In this Schedule the colouring agents referred to in regulation 4(2)(c) are—

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

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 23 October 1962 on the approximation of the rules of member States concerning foodstuffs and

(41) See Directives 86/199/EEC, 87/137/EEC, 88/233/EEC, 88/667/EEC, 89/174/EEC, 90/121/EEC, 91/184/EEC, 92/8/EEC, 92/86/EEC, 93/47/EEC, 94/32/EC, 95/34/EC.

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

colouring matter(42), as amended(43), adapted(44) and replaced in part(45) must fulfil the purity requirements laid down in those Directives.

PART I

COLOURING AGENTS LISTED IN ANNEX IV PART 1 (FORMERLY ANNEX III PART 2) OF THE DIRECTIVE(46) AS COLOURING AGENTS WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN

Field of application

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

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

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

Sub-column 3 = Colouring agents allowed exclusively in cosmetic products except cosmetic products intended to come into contact with the mucous membranes;

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

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

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

(43) 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).

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

(45) Council Directive 94/36/EC (O.J. No. L237, 10.9.1994, p.13) and Commission Directive 95/45/EC (O.J. No. L226, 22.9.1995, p.1).

(46) See Directives 86/179/EEC, 87/137/EEC, 88/233/EEC, 88/667/EEC, 89/174/EEC, 90/121/EEC, 91/184/EEC, 92/8/EEC, 92/86/EEC.

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 product Field of application				(4) Other requirements
		1	2	3	4	
12085*	Red	X				3 per cent maximum concentration in the finished product
12120	Red				X	
12150	Red	X				
12370	Red				X	
12420	Red				X	
12480	Brown				X	
12490	Red	X				
12700	Yellow				X	
13015	Yellow	X				E 105
14270	Orange	X				E 103
14700	Red	X				
14720	Red	X				E 122
14815	Red	X				E 125
15510*	Orange		X			
15525	Red	X				
15580	Red	X				
15620	Red				X	
15630*	Red	X				3 per cent maximum concentration in the finished product
15800	Red			X		
15850*	Red	X				
15865*	Red	X				
15880	Red	X				
15980	Orange	X				E 111
15985*	Yellow	X				E 110

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 product Field of application				(4) Other requirements
		1	2	3	4	
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 concentration in the colouring agent: 5 mg/kg
21108	Yellow				X	Maximum 3,3'- dichloro- benzidine concentration

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(1) Name or colour index number	(2) Colour	(3) Type of product Field of application				(4) Other requirements
		1	2	3	4	
						in the colouring agent: 5 mg/kg
21230	Yellow			X		
24790	Red				X	
26100	Red			X		Purity criteria: aniline ≤0.2 per cent, 2- naphthol ≤0.2 per cent, azobenzene-4- amine ≤0.1 per cent, 1- phenylazo-2- naphthol ≤3 per cent, 1-[2- (phenylazo)phenylazo]-2- naphthol ≤2 per cent
27290*	Red				X	
27755	Black	X				E 152
28440	Black	X				E 151
40215	Orange				X	
40800	Orange	X				
40820	Orange	X				E 160e
40825	Orange	X				E 160f
40850	Orange	X				E 161g
42045	Blue			X		
42051*	Blue	X				E 131
42053	Green	X				
42080	Blue				X	
42090	Blue	X				
42100	Green				X	

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 product Field of application				(4) Other requirements
		1	2	3	4	
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> -xanthen-9-yl)benzoic acid
45380*	Red	X				as immediately above
45396	Orange	X				When used in

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(1) Name or colour index number	(2) Colour	(3) Type of product Field of application				(4) Other requirements
		1	2	3	4	
						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 and 2 per cent 2-(bromo-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-hydroxyl-3-oxo-3H-xanthen-9-yl)benzoic acid

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 product Field of application				(4) Other requirements
		1	2	3	4	
45430*	Red	X				as immediately above, E 127
47000	Yellow			X		
47005	Yellow	X				E 104
50325	Violet				X	
50420	Black			X		
51319	Violet				X	
58000	Red	X				
59040	Green			X		
60724	Violet				X	
60725	Violet	X				
60730	Violet			X		
61565	Green	X				
61570	Green	X				
61585	Blue				X	
62045	Blue				X	
69800	Blue	X				E 130
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				

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(1) Name or colour index number	(2) Colour	(3) Type of product Field of application				(4) Other requirements
		1	2	3	4	
75120	Orange	X				E 160b
75125	Yellow	X				E 160d
75130	Orange	X				E 160a
75135	Yellow	X				E 161d
75170	White	X				
75300	Yellow	X				E 100
75470	Red	X				E 120
75810	Green	X				E 140 and E 141
77000	White	X				E 173
77002	White	X				
77004	White	X				
77007	Blue	X				
77015	Red	X				
77120	White	X				
77163	White	X				
77220	White	X				E 170
77231	White	X				
77266	Black	X				
77267	Black	X				
77268:1	Black	X				E 153
77288	Green	X				Free from chromate ions
77289	Green	X				Free from chromate ions
77346	Green	X				
77400	Brown	X				
77480	Brown	X				E 175
77489	Orange	X				E 172
77491	Red	X				E 172
77492	Yellow	X				E 172

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 product Field of application				(4) Other requirements
		1	2	3	4	
77499	Black	X				E 172
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				
Anthocyanin	Red	X				E 163
Beetroot red	Red	X				E 162
Bromocresol green	Green				X	
Bromothymo 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 OF PART 2
OF THE DIRECTIVE(47)AS COLOURING AGENTS WHICH
COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT

(47) See Directives 86/179/EEC, 87/137/EEC, 88/233/EEC, 89/174/EEC, 90/121/EEC, 91/184/EEC, 92/8/EEC, 92/86/EEC.

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

**SUBJECT TO THE RESTRICTIONS LAID DOWN AND WHERE
COSMETIC PRODUCT SUPPLIED BEFORE A CERTAIN DATE**

Field of application

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

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

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

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

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

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

NOTE: There are presently no entries in this part.

SCHEDULE 4

Regulations 4(2) and 6(2)

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

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

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

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

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

In this Schedule—

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

“esters” means esters of methyl, ethyl, propyl, isopropyl, butyl, isobutyl and phenyl.

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

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

Names which appear in square brackets in column 2 of this Schedule are the 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(48).

PART I

PRESERVATIVES LISTED IN ANNEX VI, PART I OF THE DIRECTIVE(49)AS PRESERVATIVES WHICH COSMETIC PRODUCTS MAY NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN

(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>		(5) <i>Other requirements</i>	(6) <i>Required information</i>
1	Benzoic acid, its salts and esters	All products	0.5 per cent (acid)	A	—	—
2	Propionic acid and its salts	All products	2 per cent (acid)	A	—	—
3	Salicylic acid and its salts	All products	0.5 per cent (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

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

(49) See Directives 86/199/EEC, 87/137/EEC, 88/233/EEC, 89/174/EEC, 90/121/EEC, 91/184/EEC, 92/8/EEC, 92/86/EEC, 93/47/EEC, 94/32/EC, 95/34/EC, 96/41/EC.

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

(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>		(5) <i>Other requirements</i>	(6) <i>Required information</i>
						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 (acid)	A	—	—
5	Formaldehyde and paraformaldehyde	For oral hygiene	0.1 per cent (expressed as free formaldehyde)		Not to be used in aerosol dispensers (sprays)	—
		Except for oral hygiene (see also Part I of Schedule 2)	0.2 per cent (expressed as free formaldehyde)			
6	ENTRY DELETED					
7	Biphenyl-2-ol [<i>o</i> -phenylphenol] and its salts	All products	0.2 per cent (expressed as the phenol)	A	—	—
8	Pyrithione zinc (INN) [Zinc pyrithione]	Products rinsed off after use	0.5 per cent	A	Not to be used in oral hygiene products	—
9	Inorganic sulphites and hydrogen sulphites	All products	0.2 per cent (expressed as free SO 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	Contains chlorobutanol

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(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>		(5) <i>Other requirements</i>	(6) <i>Required information</i>
					dispensers (sprays)	
12	4-Hydroxybenzoic acid and its salts and esters [the Parabens]	All products	0.4 per cent (acid) for 1 ester, 0.8 per cent (acid) for mixtures of esters	A	—	—
13	3-Acetyl-6-methylpyran-2,4(3H)-dione [Dehydroacetic acid] and its salts	All products	0.6 per cent (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'-hexamethylene-dioxydibenzamidine [Dibromohexamidine] and its salts (including isethionate)	All products	0.1 per cent		—	—
16	Thiomersal (INN) [Thimerosal]	Eye make-up and eye make-up remover	0.007 per cent calculated as mercury. When mixed with other authorised mercury compounds total mercury concentration must not exceed 0.007 per cent		—	Contains thiomersal

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(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>		(5) <i>Other requirements</i>	(6) <i>Required information</i>
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 (acid)	A	—	—
19	Hexetidine (INN)	Products rinsed off after use	0.1 per cent	A	—	—
20	5-Bromo-5-nitro-1,3-dioxane	Products rinsed off after use	0.1 per cent		Avoid formation of nitrosamines	—
21	Bronopol (INN) [2-Bromo-2-nitropropane-1,3-diol]	All products	0.1 per cent	A	Avoid formation 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'-tetrachloro-	—

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(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>		(5) <i>Other requirements</i>	(6) <i>Required information</i>
					azobenzene<1 mg/kg	
					3,3',4,4'-tetrachloro-azoxybenzene<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-dioximidazolidin-4-yl)-1,1'-methylenediurea [Imidazolidinyl urea]	All products	0.6 per cent	A	—	—
28	Poly(1-hexamethylene-biguanide hydrochloride) [Polyaminopropyl biguanide]	All products	0.3 per cent	A	—	—
29	2-Phenoxyethanol [Phenoxyethanol]	All products	1.0 per cent	A	—	—
30	Hexamethylenetetramine (Methenamine (INN)) [Methenamine]	All products	0.15 per cent	A	—	—
31	Methenamine 3-	All products	0.2 per cent		—	—

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(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>		(5) <i>Other requirements</i>	(6) <i>Required information</i>
	chloroallylochloride (INNM) [Quaternium-15]					
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 2)	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 0.5 per cent	A A	— —	— —
36	1,2-Dibromo-2,4-dicyanobutane [Methyldibromoglutaronitrile]	All products	0.1 per cent		Not to be used in cosmetic sunscreen products at a concentration exceeding 0.025 per cent	—

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(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>	(5) <i>Other requirements</i>	(6) <i>Required information</i>	
37	6,6-Dibromo-4,4-dichloro-2,2'-methylenediphenol [Bromochlorophen]	All products	0.1 per cent	A	—	—
38	4-Isopropyl- <i>m</i> -cresol [<i>o</i> -Cymen-5-ol]	All products	0.1 per cent	—	—	—
39	Mixture of 5-chloro-2-methylisothiazol-3(2 <i>H</i>)-one and 2-methylisothiazol-3(2 <i>H</i>)-one with magnesium chloride and magnesium nitrate [Methylchloroisothiazolinone and Methylisothiazolinone]	All products	0.0015 per cent of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol-3(2 <i>H</i>)-one to 2-methylisothiazol-3(2 <i>H</i>)-one	—	—	—
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-Phenoxypropanol (see also Part I of Schedule 2)	Products intended for use after use	1.0 per cent	—	—	—

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(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>		(5) <i>Other requirements</i>	(6) <i>Required information</i>
44	Alkyl (C12-C22)-trimethylammonium bromide and chloride (Cetrimonium bromide (INN) and Cetrimonium chloride (INN))	All products	0.1 per cent	A	—	—
45	4,4-Dimethyl-1,3-oxazolidine [Dimethyl oxazolidine]	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'-(Hexamethylene-dioxy)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)

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(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Purpose of substance or type of product</i>	(4) <i>Maximum concentration of substance in product</i>	(5) <i>Other requirements</i>	(6) <i>Required information</i>
49	5-Ethyl-3,7-dioxa-1-azabicyclo[3.3.0]octane[7-Ethylbicyclooxazolidine]	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	—

PART II

PRESERVATIVES LISTED IN ANNEX VI PART 2 OF THE DIRECTIVE (50) AS PRESERVATIVES WHICH COSMETIC PRODUCTS MAY NOT

(50) See Directives 86/199/EEC, 87/137/EEC, 88/233/EEC, 89/174/EEC, 91/184/EEC, 92/86/EEC, 94/32/EC, 96/41/EC.

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CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID
DOWN AND WHERE SUPPLIED BEFORE A CERTAIN DATE

(1) Reference Number in Annex VI Part 2 of the Directive	(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) Preservative supplied until
1 to 15	ENTRIES DELETED (see Note)					
16	Benzalkonium chloride (INN), bromide and saccharinate (Alkyl(C8- C18) benzyl- dimethyl- ammonium chloride, bromide and saccharinate)	All products	0.1 per cent A	—	—	30.06.1997
17 to 20	ENTRIES DELETED					
21	Benzylhemifor- (a 1:1 mixture of benzyloxymethanol and benzyloxy- methoxymethanol)	Products rinsed off after use	0.03 per cent	—	—	30.06.1997
22 to 28	ENTRIES DELETED					
29	3- iodoprop-2- ynyl butylcarbamate	All products	0.1 per cent	—	—	30.06.1997
30	ENTRY DELETED (see Note)					

Note: Entry number 15 is deleted with effect from the dates specified in regulation 1(4) and entry numbers 2 and 30 are deleted with effect from the dates specified in regulation 1(6). Until then entry number 15 in Part II of Schedule 4 to S.I. 1989/2233 (as amended by S.I. 1995/1478 but not by S.I. 1996/1446) and entry numbers 2 and 30 in Part II of Schedule 4 to S.I. 1989/2233 (amended most recently by S.I. 1996/1446) continue in force.

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SCHEDULE 5

Regulations 4(2) and 6(2)

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

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

Names which appear in square brackets in column 2 are the International Nomenclature Cosmetic Ingredient names of the substances in question given in the inventory of ingredients employed in cosmetic products drawn up in accordance with the provisions of the Directive and contained in Commission Decision [96/335/EC](#)(51)

PART I

UV FILTERS LISTED IN ANNEX VII PART I OF THE DIRECTIVE(52)AS
UV FILTERS WHICH COSMETIC PRODUCTS MAY NOT CONTAIN
EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN

(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Maximum concentration of substance in product</i>	(4) <i>Other requirements</i>	(5) <i>Required information</i>
1	4-Aminobenzoic acid [PABA]	5 per cent	—	—
2	<i>N,N,N</i> -Trimethyl-4-(2-oxoborn-3-ylidenemethyl)anilinium methyl sulphate [Camphor benzalkonium methosulfate]	6 per cent	—	—
3	Homosalate (INN)	10 per cent	—	—
4	Oxybenzone (INN) [Benzophenone-3]	10 per cent	—	Contains oxybenzone. (Not required when concentration is not more than 0.5 per cent, and when the

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

(52) See Directives [83/574/EEC](#), [91/184/EEC](#), [92/86/EEC](#), [93/47/EEC](#), [94/32/EC](#), [95/34/EC](#), [96/41/EC](#).

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(1) Reference Number	(2) Name of substance	(3) Maximum concentration of substance in product	(4) Other requirements	(5) Required information
				substance is only intended to protect the product.)
5	ENTRY DELETED			
6	2- Phenylbenzimidazole sulphonic acid [Phenylbenzimidazole sulfonic acid] and its potassium, sodium and triethanolamine salts	8 per cent (expressed as acid)	—	—
7	3,3'-(1,4- Phenylenedimethyl- dimethyl-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)) [Butyl methoxy dibenzoylmethane]	5 per cent	—	—
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-	10 per cent (expressed as acid)	—	—

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(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Maximum concentration of substance in product</i>	(4) <i>Other requirements</i>	(5) <i>Required information</i>
11	diphenylacrylate [Octocrylene] Polymer of N- {(2 and 4)-[2- oxoborn-3- ylidene)methyl]benzyl}acrylamide [Polyacrylamidomethyl benzylidene camphor]	6 per cent	—	—

PART II

UV FILTERS LISTED IN ANNEX VII PART 2 OF THE DIRECTIVE(53)AS UV FILTERS WHICH COSMETIC PRODUCTS MAY NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN AND WHERE SUPPLIED BEFORE A CERTAIN DATE

(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Maximum concentration of substance in product</i>	(4) <i>Other requirements</i>	(5) <i>Required information</i>	(6) <i>UV filter supplied until</i>
1	ENTRY DELETED				
2	Ethoxylated ethyl 4- aminobenzoate [PEG-25 PABA]	10 per cent	—	—	30.6.1997
3-4	ENTRIES DELETED				
5	2- Ethylhexyl 4- dimethylamino- benzoate [Octyl dimethyl PABA]	8 per cent	—	—	30.6.1997

Note: Entry numbers 33 and 34 are deleted with effect from the dates specified in regulation 1(6). Until then the corresponding entries in Part II of Schedule 5 to S.I. 1989/2233 (amended most recently by S.I. 1996/1446) continue in force.

(53) See Directives 83/574/EEC, 89/174/EEC, 90/121/EEC, 92/8/EEC, 92/86/EEC, 93/47/EEC, 94/32/EC, 95/34/EC, 96/41/EC.

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(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Maximum concentration of substance in product</i>	(4) <i>Other requirements</i>	(5) <i>Required information</i>	(6) <i>UV filter supplied until</i>
6	2-Ethylhexyl salicylate [Octyl salicylate]	5 per cent	—	—	30.6.1997
7–11	ENTRIES DELETED				
12	Isopentyl 4- methoxycinnamate, mixed isomers [Isoamyl <i>p</i> - methoxycinnamate]	10 per cent	—	—	30.6.1997
13	2- Ethylhexyl 4- methoxycinnamate [Octyl methoxycinnamate]	10 per cent	—	—	30.6.1997
14–16	ENTRIES DELETED				
17	2-Hydroxy-4- methoxybenzo- phenone-5- sulphonic acid [Benzophenone-4] and its sodium salt [Benzophenone-5] (Sulisobenzone (INN) and Sulisobenzone sodium (INN))	5 per cent (expressed as acid)	—	—	30.6.1997
18–24	ENTRIES DELETED				
25	3-(4- Methylbenzyl- idene)bornan-2- one [4- Methylbenzylidene camphor]	6 per cent	—	—	30.6.1997
26	3- Benzylidenebornan-2-	6 per cent	—	—	30.6.1997

Note: Entry numbers 33 and 34 are deleted with effect from the dates specified in regulation 1(6). Until then the corresponding entries in Part II of Schedule 5 to S.I. 1989/2233 (amended most recently by S.I. 1996/1446) continue in force.

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(1) <i>Reference Number</i>	(2) <i>Name of substance</i>	(3) <i>Maximum concentration of substance in product</i>	(4) <i>Other requirements</i>	(5) <i>Required information</i>	(6) <i>UV filter supplied until</i>
	one [3- Benzylidene camphor]				
27–28	ENTRIES DELETED				
29	4- Isopropylbenzyl salicylate [Isopropylbenzyl salicylate]	4 per cent	—	—	30.6.1997
30–31	ENTRIES DELETED				
32	Tris(2- ethylhexyl) 4,4',4''-(1,3,5- triazin-2,4,6- triyiltrimino)- tribenzoate [Octyl triazone]	5 per cent	—	—	30.6.1997
33–34	ENTRIES DELETED (see Note)				

Note: Entry numbers 33 and 34 are deleted with effect from the dates specified in regulation 1(6). Until then the corresponding entries in Part II of Schedule 5 to S.I. 1989/2233 (amended most recently by S.I. 1996/1446) continue in force.

SCHEDULE 6

Regulations 6(6) and (11)

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



SCHEDULE 7

Regulation 11

PART I

PARTICULARS TO BE INCLUDED WITH
A REQUEST FOR CONFIDENTIALITY

1. The name or trade name and address or registered office of the applicant.
2. Precise identification of the cosmetic ingredient for which confidentiality is requested, namely—
 - (a) where they exist, the CAS, EINECS and colour index numbers, the chemical name, the IUPAC name, the INCI name, the European Pharmacopoeia name, the International Non-proprietary Name as recommended by the World Health Organization and the common name as provided for in the common ingredients nomenclature;
 - (b) the Elincs name and the official number allocated to it if it has been notified pursuant to Council Directive [67/548/EEC](#) and an indication of the decision to approve or refuse any request for confidentiality made under Article 19 of that Directive;
 - (c) where the names or numbers referred to in sub-paragraphs (a) and (b) above do not exist, for example in the case of certain ingredients of natural origin, the name of the base material, the name of the part of the plant or animal used and the names of the cosmetic ingredient's compounds, such as solvents.
3. The evaluation of the safety for human health of the cosmetic ingredient as used in the finished cosmetic product or products taking into account the cosmetic ingredient's toxicological profile, chemical structure and the level of exposure as specified in regulation 8(1)(d) and carried out in accordance with the requirements of regulations 8(2) and (3).

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4. The envisaged use of the cosmetic ingredient and in particular the different categories of cosmetic products in which it will be used.
5. A detailed justification of why confidentiality is sought addressing for example—
 - (a) the fact that the identity of the cosmetic ingredient or its function in the cosmetic product to be supplied has not been described in the literature accompanying the cosmetic product and is unknown to other manufacturers or suppliers of cosmetic products;
 - (b) the fact that the information is not yet in the public domain even though a patent application has been lodged for the cosmetic ingredient or its use;
 - (c) the fact that if the information were known it would be easily reproducible, to the detriment of the applicant.
 - (a) (a) If known, the name of each cosmetic product which is to contain the cosmetic ingredient and if different names are to be used in other member States, precise details of each one of them.
 - (b) If the name of a cosmetic product is not yet known, it may be communicated at a later date, but at least 15 days before the cosmetic product is supplied.
 - (c) If the cosmetic ingredient is used in several products, one request shall suffice, provided that the cosmetic products are clearly indicated to the competent authority.
7. A statement setting out whether a request has been submitted to the competent authority of any other member State in respect of the cosmetic ingredient for which confidentiality is sought and particulars on the outcome of any such request.

PART II

PROCEDURE FOR GRANT OF REGISTRATION NUMBER

1. The registration number referred to in regulation 11(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 8

Regulation 14

SAMPLING AND TESTING

1. In this Schedule—

“Annex A” means the Annex to Commission Directive No. [80/1335/EEC](#)(**54**) as amended by Commission Directive No. [87/143/EEC](#)(**55**);

“Annex B” means the Annex to Commission Directive No. [82/434/EEC](#)(**56**) as amended by Commission Directive No. [90/207/EEC](#)(**57**);

“Annex C” means the Annex to Commission Directive No. [83/514/EEC](#)(**58**);

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

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

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

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

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

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“Annex D” means the Annex to Commission Directive No. [85/490/EEC](#)(59);

“Annex E” means the Annex to Commission Directive No. [93/73/EEC](#)(60);

“Annex F” means the Annex to Commission Directive No. [95/32/EC](#)(61);

“Annex G” means the Annex to Commission Directive No. [96/45/EC](#)(62);

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

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

- (a) the means of identifying the batch referred to in regulation 6(2)(g) above shows that they were manufactured in the same batch; or
- (b) in the case of a product not manufactured in a batch, the reference referred to in regulation 6(2)(g) above shows that they are derived from the same unit of production; or
- (c) in the case of a product which does not comply with the requirements of regulation 6(2)(g) above, the officer effecting the purchase has reasonable cause to believe that they were manufactured in the same batch or are derived from the same unit of production, as the case may be.

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

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

- (a) either—
 - (i) place a seal on the product’s container or outer packaging, or
 - (ii) place the product in a container and forthwith place a seal on that container, in such a way that the product’s immediate container cannot be opened or (in the case of a product which was not in a container when it was purchased) the product cannot be touched without (in either case) the seal being broken in such a manner that it would be apparent thereafter that it had been broken, and
- (b) attach to the product a label indicating—
 - (i) the name of the product,
 - (ii) the date, time and place at which the product was purchased,
 - (iii) his own name, and
 - (iv) the name of the enforcement authority making the purchase.

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

(2) Where, because of the way in which a cosmetic product is put up for sale, it is not practicable for Part II of Annex A to be complied with, it shall be prepared for testing in accordance with good

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

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

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

(62) O.J. No. L213, 2.7.1996, p.8.

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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-hydroxybenzenesulphonate 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(63), 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-hydroxybenzenesulphonic 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.

(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”.

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

(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”.

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(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 monomethylether, hydroquinone monoethylether and hydroquinone monobenzylether (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 monomethylether, hydroquinone monoethylether and hydroquinone monobenzylether 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.

SCHEDULE 9

Regulation 1(9)

REVOCATIONS

(1) <i>Regulations revoked</i>	(2) <i>References</i>
The Cosmetic Products (Safety) Regulations 1989	S.I. 1989/2233
The Cosmetic Products (Safety) (Amendment) Regulations 1990	S.I. 1990/1812
The Cosmetic Products (Safety) (Amendment) Regulations 1991	S.I. 1991/447
The Cosmetic Products (Safety) (Amendment) Regulations 1992	S.I. 1992/1525
The Cosmetic Products (Safety) (Amendment) Regulations 1993	S.I. 1993/1539
The Cosmetic Products (Safety) (Amendment) Regulations 1994	S.I. 1994/1529
The Cosmetic Products (Safety) (Amendment) Regulations 1995	S.I. 1995/1478
The Cosmetic Products (Safety) (Amendment) Regulations 1996	S.I. 1996/1446

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

These Regulations consolidate with amendments the Cosmetic Products (Safety) Regulations 1989 as amended. They implement Council Directive [76/768/EEC](#) (O.J. No. L262, 27.9.1976, p.169) on the approximation of the laws of the member States relating to cosmetic products, as amended (“the Cosmetics Directive”). They implement for the first time the amendments made to the Cosmetics Directive by Council Directive [93/35/EEC](#) (O.J. No. L151, 23.6.1993, p.32) and Commission Directive [96/41/EC](#) (O.J. No. L198, 8.8.1996, p.36). They also implement Commission Directives [95/32/EC](#) (O.J. No. L178, 28.7.1995, p.20) and [96/45/EC](#) (O.J. No. L213, 2.7.1996, p.8) relating to methods of analysis necessary for checking the composition of cosmetic products. Further, they implement Commission Directive [95/17/EC](#) (O.J. No. L140, 23.6.1995, p.26) laying down detailed rules for the application of the Cosmetics Directive as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products.

These Regulations give effect to Council Directive [93/35/EEC](#) and Commission Directive [96/41/EC](#) as follows—

- (1) they contain an amended definition of “cosmetic product”(regulation 2(1));
- (2) they contain an expanded general safety requirement for cosmetic products (regulation 3(1));

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(3) they prohibit the use of urocanic acid and its ethyl ester in cosmetic products (regulation 4(2)(a) and Schedule 1, entry numbers 342, 405 and 751);

(4) they permit the use in certain cosmetic products of potassium hydroxide, sodium hydroxide, lithium hydroxide and calcium hydroxide, subject to restrictions (regulation 4(2)(b) and Schedule 2, Part I, entry numbers 15a, 15b and 15c);

(5) they permit the use as preservatives in cosmetic products of chlorphenesin, sodium hydroxymethylglycinate and silver chloride deposited on titanium dioxide, subject to restrictions (regulations 4(2)(e)(i) and 4(2)(f) and Schedule 4, Part I, entry numbers 50, 51 and 52);

(6) they permit, subject to restrictions, the use in cosmetic products until 30 June 1997 of three preservatives listed as entry numbers 16, 21 and 29 in Schedule 4, Part II (regulation 4(2)(e)(ii) and Schedule 4, Part II);

(7) they permit the use as a UV filter in cosmetic products of polymer N-[(2 and 4)-(2-oxoborn-3-ylidene)methyl]benzyl]acrylamide, subject to a restriction (regulation 4(2)(h)(i) and 4(2)(i) and Schedule 5, Part I, entry number 11);

(8) they permit the use in cosmetic products until 30 June 1997 of 10 UV filters listed as entry numbers 2, 5, 6, 12, 13, 17, 25, 26, 29 and 32 in Schedule 5, Part II, subject to restrictions (regulation 4(2)(h)(ii) and Schedule 5, Part II);

(9) they prohibit the use in cosmetic products of any ingredients which have been tested on animals after 1st January 1998 (regulation 4(3));

(10) they provide that any reference to testing on animals in the labelling, putting up for sale or advertising of a cosmetic product must state clearly whether the tests carried out involved the cosmetic product itself or its ingredients (regulation 4(4) and (5));

(11) they require cosmetic products to be labelled with information about their function, unless this is clear from their presentation (regulation 6(2)(h));

(12) they require cosmetic products to be labelled with details of their ingredients, identified by their common names as provided for in the common ingredients nomenclature (an inventory of ingredients compiled by the Commission and contained in Commission Decision [96/335/EC](#) (O.J. No. L132, 1.6.1996, p.1), and they make provision for the manner of labelling required and for cases where ingredients are not listed in the common ingredients nomenclature (regulation 6(1), (5)(b) and (9) to (12));

(13) they require manufacturers, their agents, persons to whose order cosmetic products are manufactured and (in certain circumstances) persons responsible for supplying cosmetic products for the first time in the Community to keep for control purposes detailed information (which must be readily accessible to a United Kingdom competent authority) bearing on the composition, ingredients, method of manufacture, safety and effect of the cosmetic products in question (regulation 8);

(14) they require manufacturers, their agents, persons to whose order cosmetic products are manufactured and (in certain circumstances) persons responsible for supplying cosmetic products for the first time in the Community to notify a United Kingdom competent authority of the address of the place of manufacture or initial importation into the Community of a type of cosmetic product before that type of product is first supplied in the Community, where the place of manufacture or initial importation is within the United Kingdom (regulation 9); and

(15) they enable United Kingdom competent authorities to require that any holder of information on substances used in cosmetic products must make that information available where this may overcome or ease any difficulties encountered in providing prompt and appropriate medical treatment (regulation 10).

These Regulations give effect to the requirements of Commission Directives [95/32/EC](#) and [96/45/EC](#) by introducing procedures for the identification and determination of benzoic acid,

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4-hydroxybenzoic acid, sorbic acid, salicylic acid, propionic acid, hydroquinone, hydroquinone monomethylether, hydroquinone monoethylether, hydroquinone monobenzylether (monobenzone), 2-phenoxyethanol, 1-phenoxypropan-2-ol, and methyl, ethyl, propyl, butyl and benzyl 4-hydroxybenzoate in cosmetic products (regulation 14 and Schedule 8, paragraph 6(39), (40) and (41)).

Finally, these Regulations give effect to the requirements of Commission Directive [95/17/EEC](#) by providing that manufacturers, their agents, persons to whose order cosmetic products are manufactured and (in certain circumstances) persons responsible for supplying cosmetic products for the first time in the Community may, if for reasons of trade secrecy they do not wish to include a particular cosmetic ingredient in the list of cosmetic ingredients required for labelling purposes, apply to a competent authority for approval to use a reference number in that list rather than the ingredient's name. Provision is made for the particulars which must accompany such an application and for the procedures which apply to applications and to the withdrawal of any approval (regulation 11 and Schedule 7).

The Colour Index referred to in these Regulations may be obtained from the Society of Dyers and Colourists, PO Box No. 244, 82 Grattan Road, Bradford BD1 2JB.

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

A Compliance Cost Assessment is available, copies of which have been placed in the libraries of both Houses of Parliament. Copies are also available from the Consumer Affairs and Competition Policy Directorate of the Department of Trade and Industry, Room 4.D.2, 1 Victoria Street, London SW1H 0ET.