

BIS | Department for Business
Innovation & Skills

COSMETIC SAFETY

A Guide to the Cosmetic
Products (Safety) Regulations
2008

MARCH 2010

A Guide to the Cosmetic Products (Safety) Regulations 2008

This guide has been produced by BIS to offer guidance on certain aspects of the Cosmetic Products (Safety) Regulations 2008. However it does not carry any legal authority and does not replace the provision of the Regulations.

Quick Start

Regulation

The safety of cosmetics is covered by the EC Cosmetics Directive (76/768/EEC) as amended. This is implemented in the UK by the Cosmetic Products (Safety) Regulations 2008, http://www.opsi.gov.uk/si/si2008/uksi_20081284_en_1 as amended. There have been several amendments to the Annexes which restrict substances since the coming into force of the 2008 Regulations. However a consolidated version of the European Directive, which includes up-to date amendments, plus new directives not yet assimilated is available at

http://ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm

What is a cosmetic product?

Any substance or preparation intended to be placed in contact with the various external parts of the human body with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, correcting body odours, protecting them, or keeping them in good condition

If there is any possibility of the product being a biocide you will need to consult the Health & Safety Executive <http://www.hse.gov.uk>

If there is any possibility of a cross-over with a medical device you should first consult the Medicines and Healthcare products Regulatory Agency <http://www.mhra.gov.uk>

Safety Assessment and Product Information Pack

Every cosmetic product placed on the market requires a safety assessment carried out by a suitably European qualified professional. The website for the Cosmetic Toiletry and Perfumery Association at www.ctpa.org.uk has a link to the Regulations and can provide a list of safety assessors.

The assessment will form part of the product information pack which should also include details of the qualitative and quantitative composition of the product, specifications of raw materials and finished products and the purity and microbiological controls, details of

methods of manufacture in accordance with good manufacturing practice, data on undesirable effects on human health, and where appropriate, proof of any claimed effect.

Restrictions on Ingredients

All ingredients, natural or not, need to be in line with the Regulations (which are the same as EU Council Directive 76/768 EEC). Any restrictions on ingredients will also show up on the EU Cosmetics database at <http://ec.europa.eu/enterprise/cosmetics/cosing/> There are lists of banned substance which may not be used in any cosmetic product, lists of products which are restricted by percentage use in a particular product, and also positive lists for colours, uv-filters and preservatives – meaning only those on the list may be used.

Labelling

There are very specific requirements for labelling, which must include an address within the European Union from where the product information is available, and a full ingredients listing amongst other items. A product manufactured outside of the EU must also include country of origin.

Notification

Once the safety assessment has been carried out and before you place the product on the UK market, if the UK is the first market in the EU, please notify by email cosmeticnotification@bis.gsi.gov.uk of the type of product you are supplying, together with your name, company and address details, or if importing from outside of the EU, the details of the importing company in the UK. You are also advised to contact your local Trading Standards Office <http://www.tradingstandards.gov.uk>

Future Regulation

Regulation (ec) no 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products will come into force in full on 11 July 2013. It is available at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>

Guidance - Background

- 1 The main objective of cosmetic products safety legislation is to safeguard public health. However, in the early 1970s, it was recognised that differing requirements of the Member States of the European Community were causing difficulties for manufacturers thereby hindering free trade and preventing the establishment of a fully competitive market.
- 2 In 1976, Council Directive 76/768/EEC¹ (a copy of the Directive is available at: <http://europa.eu.int/eur-lex/en/consleg/main/1976/en1976L0768index.html>) 'on the approximation of the laws of the Member States relating to cosmetic products' introduced harmonised cosmetic safety legislation into the European Community for the first time. Council Directive 2003/15/EC² of the 27th February 2003, the Seventh Council amendment to Directive 76/768/EEC, introduced a number of changes to the control of cosmetic products. These include: the promotion of alternative methods of cosmetic safety testing; a timetable to phase out the marketing of cosmetic products, or products containing ingredients, that have been tested using animals; a ban on testing using animals within the European Community; guidelines on the use of claims regarding animal testing; and additional consumer information that includes, in certain circumstances, the labelling of a "Period After Opening". The Cosmetic Products (Safety) Regulations 2004 implemented these requirements.
- 3 The Cosmetic Products (Safety) Regulations 2008³, as amended, implement the latest version of the Cosmetic Directive, and revoke and re-enact the Cosmetic Products (Safety) Regulations 2004⁴.
- 4 This Guide seeks to provide practical advice with respect to the Regulations as they implement the Directive in the United Kingdom. The advice may vary in other Member States of the EU. The Guide does not carry any legal authority and does not replace the provisions of the Regulations. If you require further advice or information, you should contact your Local Authority or Unitary Authority.

¹ O.J. No. L262, 27.9.76,p.169

² O.J. No. L66, 11.3.03, p.26

³ SI 2008/1284

⁴ SI 2004/2152

The Regulations

Interpretation

- 5 There is no change to the definition of a cosmetic product in the 2008 Regulations. The definition comprises two parts: a function and a field of application. Both parts of the definition must be satisfied.
- 6 The Regulations specify 6 functions for substances or preparations which may be cosmetic products, namely:
 - to clean;
 - to perfume;
 - to change the appearance;
 - to protect;
 - to keep in good condition; or
 - to correct body odours.
- 7 The field of application of cosmetics is to one or more of the following:
 - the epidermis;
 - the hair system;
 - the nails;
 - the lips;
 - the external genital organs;
 - the teeth; or
 - the mucous membranes of the oral cavity.
- 8 Products intended to come into contact with the mucous membranes include those used:
 - in the vicinity of the eyes;

- on the lips;
- in the oral cavity; or
- on the external genital organs.

A cosmetic product intended to come into contact with the mucous membranes does not include any cosmetic product that is only intended to come into brief contact with the skin. For example, products that may come into brief, unintentional contact with the mucous membranes include products such as shampoos and shower gel.

9 An illustrative list of cosmetics is given in Appendix 4 of this Guide.

Borderline products

- 10 The status of many products on the borderline between medicines and cosmetics can be difficult to determine. Medicinal products may not be placed on the UK market without a marketing authorisation or product licence. The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicinal products for human use in the UK and has issued "A Guide to what is a Medicinal Product"⁵. In case of doubt as to the status of a product, advice may be sought directly from the Borderline Section of the MHRA⁶.
- 11 Aromatherapy products supplied to consumers fall within the scope of the General Product Safety Regulations 2005⁷ unless they are intended to perform a medical or cosmetic function or are presented as performing such a function. The latter are only cosmetic products if they are intended to be placed in contact with the external surfaces of the human body, as in paragraph 7, and are intended for any of the purposes listed in paragraph 6. Both Local Authorities and The Aromatherapy Trade Council will offer advice.

Cosmetic ingredient

- 12 A cosmetic ingredient is any substance or preparation of synthetic or natural origin used in the composition of a cosmetic product. Note, however, that for ingredient labelling purposes perfume and aromatic compositions, i.e. flavours, are subject to special rules and these are explained in the paragraphs dealing with ingredients listings.

⁵ "A Guide to What is a Medicinal Product" may be ordered from the MHRA or downloaded from its website.

⁶ Addresses are given in Appendix 5

⁷ Statutory Instrument 2005 No 1803

Common ingredient nomenclature

- 13 The labelling nomenclature referred to in Regulation 12(2)(a) is published by the European Commission as part of the inventory of cosmetic ingredients. This nomenclature shall be used for products supplied in European Union. There are over 7000 ingredients on the current list published in 1996, amended in 2006, and it must be used for ingredient labelling purposes. This nomenclature, developed by a Colipa (European Cosmetics Association) working group, has been approved by Member States and will be updated from time to time. It is now known as the INCI nomenclature (International Nomenclature of Cosmetic Ingredients) with the objective of satisfying the need for a truly international system of labelling. For example:

water is known as *aqua*

beeswax is known as *cera alba*

cocoa butter is known as *theobroma cacao*

- 14 In developing the INCI system, the Colipa group worked closely with the equivalent organisation in the USA, the Personal Care Product Council (PCPC), and there now exists a joint Colipa/PCPC Ingredient Nomenclature Committee responsible for allocating labelling names and recommending labelling rules for all ingredients used in cosmetics for the EU and US markets. In the interests of consumer safety, the UK fully supports the use of the INCI system, which has been adopted both in Europe and the USA and is widely accepted elsewhere.
- 15 A copy of the INCI nomenclature has been published in the Official Journal of the European Communities as Commission Decision 96/335/EC (Official Journal No L132, published on 1.6.96) may be obtained from The Stationery Office⁸. An on-line version may be found at the following website:
http://ec.europa.eu/enterprise/cosmetics/html/cosm_inci_index.htm.
 Section 1 of this decision has been updated by Commission Decision 2006/257/EC of 09.02.2006, amending Decision 96/335/EC, establishing an inventory and a common nomenclature of ingredients employed in cosmetic products. The decision can be found at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:097:0001:0528:EN:PDF>.
 PCPC publishes the International Cosmetic Ingredient Dictionary and Handbook, which is updated on a regular basis⁹.
- 16 Despite these efforts at harmonisation, there are still some differences between the INCI system in Europe and the USA in the nomenclature of colours, botanicals and the so-called 'trivial' ingredients. This causes difficulties for importers and exporters.

⁸ Addresses are given in Appendix 5

⁹ Addresses and other contact details are given in Appendix 5

Where there are differences, the additional use of the alternative name, in brackets, is perfectly acceptable.

17 For example:

water (aqua) or aqua (water)

santalum album (sandalwood oil) or sandalwood (santalum album) oil

CI 14700 (Red 4) or Red 4 (CI 14700)

General Safety Requirement

Regulation 4

- 18 A product must be safe not only under normal but also under reasonably foreseeable conditions of use. Regulation 4 also stipulates that, in determining which conditions of use are “reasonably foreseeable”, all the circumstances, including the presentation of the product, which includes warnings, instructions for use and disposal, and any other information, is to be taken into account. The safety requirement does not cover misuse of a cosmetic product (except where it is a reasonably foreseeable misapplication of the product). For example:
- 19 A hair dye product for general use (i.e. not professional use), contains comprehensive and clear instructions together with warnings regarding the safe use of the product. The warnings include the statement *Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them.* The manufacturer has recognised that the product may irritate the eyes and has warned against applying the product in the vicinity of the eyes. If a consumer chooses to ignore the warnings, the manufacturer cannot be held responsible.
- 20 However, if the product was so strong that it would invariably cause severe damage to the eye, it is likely that the manufacturer would be at fault. It is reasonably foreseeable that the product may come into contact with the eyes in normal use, and the warnings are not adequate.

Prohibitions & Restrictions on Ingredients

Regulations 5 & 6

- 21 These refer to the various groups of ingredients contained in Schedules 3 to 7 of the Regulations that list prohibitions and restrictions.
- 22 Schedule 3, Part I lists ingredients prohibited in all cosmetics unless otherwise specified.
- 23 Schedule 4, Part I lists ingredients that may only be used subject to the restrictions specified. It includes certain ingredients commonly but not exclusively used in fragrances and which must be labelled individually if they exceed a certain threshold level regardless of the function they perform in the product. This labelling requirement is in addition to normal perfume labelling requirements (see paragraph 38) and does not replace them.
- 24 A number of these ingredients are also found in natural essential oils. In order to check the levels of these ingredients in their products, companies need to obtain information from their suppliers of essential oils and perfume compounds.
- 25 Schedule 4, Part II contains provisionally allowed ingredients, subject to the listed restrictions, but cosmetic products containing any of these ingredients may only be placed on the market up until the dates specified.
- 26 Only those colouring agents, preservatives and UV filters listed in the corresponding Schedule 5, 6 or 7 can be used and subject to any conditions specified.
- 27 However, Regulation 5, which bans the use of substances listed in Schedule 3, allows cosmetic products to contain traces of those banned substances if they could not reasonably be removed during or after manufacture.

Animal Testing Ban

Regulation 10

Ban on animal testing

- 28 The Cosmetics Directive banned the testing of finished cosmetic products on animals in any territory of the EU from 11th September 2004 and the testing of ingredients, or combinations of ingredients, from 11th March 2009, where the testing is undertaken in order to satisfy the requirements of the Directive. The UK Government already had a ban in place for a number of years that has a similar effect.

- 29 The Directive also aims to eliminate all safety testing of cosmetic ingredients involving the use of animals, except in extenuating circumstances that are subject to pre-approval. Where alternative test methods exist, and have been validated and accepted by the European Community, these methods must be used in place of testing on animals.

The Regulations contain a ban on the testing of finished cosmetic products on animals where the testing is undertaken to ensure compliance with Directive 76/768/EEC or with the Regulations. This prohibition had effect from 11th September 2004. The Regulations also maintain a 2-stage ban on the testing of cosmetic ingredients on animals. This applies to any test undertaken to ensure compliance with the Cosmetics Directive or with the Regulations and operates as follows:

- Until 11th March 2009 it was illegal to test any cosmetic ingredient on animals (using a method other than an alternative method) in order to satisfy any requirement of the Regulations if an alternative test method exists and has been validated at Community level. Where such an alternative test method exists, it will be listed in the Commission Regulation on test methods as specified in article 13(2) of Regulation (EC) No. 1907/2006 and in Annex IX of the Cosmetic Directive.
- After 11th March 2009 it is illegal to test any cosmetic ingredient on animals using a method other than an alternative test method *irrespective* of whether an appropriate alternative test method exists.

These alternative methods will be added to the Commission Regulation on test methods as specified in article 13 (2) of Regulation (EC) No. 1907/2006 and in Annex IX of the Cosmetic Directive once they are developed and approved.

Ban on Supply of Cosmetic Products which have been Tested on Animals

- 30 The Regulations ban the supply of cosmetic products, and cosmetic products containing ingredients, that have been tested on animals in order to ensure compliance with the Cosmetics Directive or the Regulations, where a validated alternative method exists.
- Until 11th March 2009 (or 2013 in the case of tests concerning repeated dose toxicity, reproductive toxicity or toxicokinetics) it is illegal to supply any cosmetic product which contains any ingredient or combination of ingredients which have been tested on animals (using a method other than an alternative method) in order to satisfy any requirement of the Regulations **where** an alternative test method existed and had been validated at Community level at the **time of testing**. Where such an alternative test method exists, it will be listed in the Commission Regulation on test methods as specified in article 13 (2) of Regulation (EC) No. 1907/2006 and in Annex IX of the Cosmetic Directive.

- After 11th March 2009 (or 2013 in the case of tests concerning repeated dose toxicity, reproductive toxicity or toxicokinetics) it is illegal to supply any cosmetic product which contains any ingredient or combination of ingredients which have been tested on animals using a method other than an alternative test method *irrespective* of whether an appropriate alternative test method exists.

31 The European Commission has to present an annual report to the European Parliament and the Council of Ministers on the technical difficulties in complying with the ban in relation to development, validation and legal acceptance of alternative methods to animal testing and, in particular, tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics.

References to Animal Testing

Regulation 14

32 The Directive recognises that companies should be able to make claims that no animal testing was undertaken in the development of its cosmetic products. However, the Directive is also clear that consumers must not be misled by these claims. It requires the European Commission to develop guidelines to ensure that common criteria are applied by EU Member States in the use of such claims.

33 For any cosmetic product placed on the market Regulation 14 states:

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

(a) the manufacturers and his suppliers have not carried out any tests on the finished product, its prototype or on any of the ingredients contained in the finished product or its prototype;

(b) the manufacturers and his suppliers have not commissioned any tests on the finished product, its prototype or on any of the ingredients contained in the finished product or its prototype;

(c) the cosmetic product contains no ingredients which have been tested by others for the purpose of developing new cosmetic products.

Regulation 14 implements the requirements of the Directive. The requirements under the Directive are intended to be cumulative.

- 34 In consultation with the Member States, the cosmetics industry and consumer and animal welfare groups, the European Commission published in June 2006 recommendations on claims relating to animal testing, as required by the Directive. The key points are:

The manufacturer or the person responsible for placing the product on the Community market may take advantage of the fact that no animal tests have been carried out only if the manufacturer and his suppliers have not carried out or commissioned any animal tests on the finished product, or its prototype, or any of the ingredients contained in it, or used any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products.

- “no animal tests have been carried out” means that no animal tests whatsoever were carried out in relation to the development of a cosmetic product. Only the full replacement of the animal tests by an alternative method allows the claim to be made. The claim only refers to the replacement, and not the reduction or refinement, of animal tests. Furthermore, it does not matter where the test, including retesting, is performed, whether in the European Union or in third countries, or when the test was performed.
- “the manufacturer and his suppliers have not carried out or commissioned any animal tests...” means that the manufacturer and his suppliers:
 - should not have directly carried out animal tests;
 - should not have commissioned animal tests. They should not have requested, or paid for, animal tests by means, for instance, of sponsorship of research by academic institutions.

The term ‘supplier’ refers only to the legal entity that supplies the cosmetic ingredient to the cosmetic manufacturer. This will not necessarily be the manufacturer of the ingredient.

- “manufacturer and his suppliers should not have...used any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products” means that:
 - the manufacturer and his suppliers should not have used ingredients for which data resulting from animal tests made by others for the purpose of developing a new cosmetic product are available, for instance, in scientific literature.

It should be noted in this context that “the development of new cosmetic product” means either the reformulation of product already on the market or the development *of a totally new product*.

- 35 Data relating to the safety assessment of the product, and details of any animal testing, must be kept in the product information file that is open to inspection by the enforcement authority (see Regulation 16(1)(d) and (i)).

Labelling requirements

Regulation 12

- 36 The Regulations require all cosmetic products to be marked with:

- list of ingredients paragraphs 38 - 41
- name and address of manufacturer or supplier paragraphs 42 – 44
- country of origin paragraph 45
- date of minimum durability (best before date) paragraphs 46 - 48
or a "Period After Opening" (PAO) paragraphs 49 - 53
- warning statements and precautionary information paragraphs 54 - 56
- batch number or lot code paragraphs 57 - 59
- product function, when appropriate paragraph 60

- 37 Additionally:

- the declared quantity of contents is required under the Weights and Measures Act 1985 and related legislation – see paragraphs 61 & 62.
Note: advice on Weights and Measures can be obtained from local authorities;
- all lettering must be visible, indelible and easily legible; and
- the following must be in English for products supplied in the UK but the additional use of other languages is allowed:
 - warning statements;
 - precautionary information;
 - "Best before" when used to indicate the date of minimum durability;
 - "months" and "years" when used to indicate "Period After Opening";

- product function.

List of ingredients - Regulation 12(2)

38 A full list of ingredients must be given on the outer packaging headed or preceded by the word *INGREDIENTS*. Where there is no outer packaging, the list must appear on the container (see also paragraphs 64 to 80 on Labelling Difficulties). This listing must:

- show all ingredients added to the product;
- use the name given in the Common Ingredients Nomenclature known as the INCI name (International Nomenclature for Cosmetic Ingredients). See paragraph 13. There is no requirement to use either upper or lower case text;
- in the absence of an INCI name¹⁰, use an alternative as listed in Appendix 1 of this guidance note;
- for colouring agents, use the INCI names as detailed above;
- perfume compositions and their raw materials do not need to be declared and can be simply described by the use of the word *perfume*. However, in order to achieve a harmonised European label, European industry, with the support of the European Commission and Member States, has agreed a convention to use the harmonised term *parfum*. See also paragraph 23 concerning certain ingredients that must be labelled individually even if they form part of a perfume composition or essential oil;
- aromatic compositions and their raw materials do not need to be declared and can be simply described by the use of the word *aroma*. See also paragraph 23 concerning certain ingredients that must be labelled individually even if they form part of a flavour composition or essential oil;
- show ingredients in descending order of weight, the weight determined at the time the ingredients are added to the product.

39 Additionally:

- ingredients in concentrations of less than 1% may be listed in any order after those in concentrations of 1% or more;

¹⁰ It is important that all ingredients used in the European Community have a European INCI name. If their ingredients do not have one, manufacturers of ingredients should apply to the International Nomenclature Committee, on the standard forms, to have an INCI name allocated. Further information can be obtained from the CTPA.

- colouring agents may be listed in any order after the other ingredients using the Colour Index Number or denomination shown in Schedule 5 of the Regulations;
 - for decorative cosmetics¹¹ marketed in several colour shades, all colouring agents used in the range may be listed preceded by the words “may contain” or the symbol “+/-”;
 - mixtures must be broken down into their individual components.
- 40 For the purposes of labelling, the following are not regarded as cosmetic ingredients and do not need to be shown:
- impurities in the raw materials;
 - subsidiary technical materials used in the preparation of the cosmetic product but not present in the final product. For example, alkalis used to adjust the pH at any stage of preparation would not be declared. Similarly, solvents used for extraction purposes but subsequently “driven off” would not be listed;
 - materials used in strictly necessary quantities as solvents or as carriers for perfumes and aromatic compositions.
- 41 An example of an ingredient listing as it might appear on a cosmetic product is given in Appendix 2.

Name and address - Regulation 12(1)(a)

- 42 The name and address required are those of the manufacturer or supplier established within a Member State of the Community or European Economic Area.
- 43 The name and address must be sufficient to identify the undertaking. The address may be abbreviated to a well-known city or town such that the normal postal service will deliver a letter to that address. A full postcode is also sufficient for an address within the Community. For example, London, being a major city, is sufficient for a product sold within the Community but Ipswich will require a postcode such as IP65 3TS UK. If space allows and a full address will not detract from the product, it is better to give as full an address as possible. The information must be given on both the primary container and the outer packaging.
- 44 The address shown on the label will be the address through which the Product Information (PI) is readily accessible unless an alternative location of the PI is clearly

¹¹ Decorative cosmetics are taken to be cosmetic products intended to modify the appearance of the area to which they are applied, usually by the use of colour. Examples are: lipstick, eye shadow, blusher, eye pencil, liquid foundation, powder, mascara, nail polish, etc.

stated. The European Commission has recognised that, where two or more European Community addresses are given, one may be underlined to indicate that the PI is accessible through that address (see 101 to 118).

Country of origin – Regulation 12(1)(a)

45 The 2008 Regulations introduced a requirement to label the country of origin if the product came from a non-EEA country; that is from outside the European Economic Area, comprising the European Union, Iceland, Norway and Liechtenstein. This indication should not be misleading. According to Section 36 of the Trade Description Act 1968 (TDA) goods are deemed to have been manufactured or produced in the country in which they last underwent a treatment or process resulting in a substantial change. The definition of 'substantial change' is not given but trading standards officers have interpreted this as meaning the mixing of ingredients and not just filling into containers.

Best before date - Regulation 12(1)(b)

46 A product which is likely to deteriorate up to and including 30 months from the date of manufacture so that it:

- ceases to satisfy the general safety requirement in Regulation 4; or
- ceases to fulfil its intended function;

must have a date of minimum durability using the words "Best before" immediately followed by either:

- the earliest date, in the form *month, year*, in which one of these may occur; or
- an indication of where that date appears on the labelling.

47 The minimum durability date must appear on both the primary container and outer packaging in English. *Best before November 2010*, *Best before Nov 10* and *Best before 11/10* are all acceptable forms. It is generally accepted practice to be able to abbreviate the words *Best before* to *Exp* and *Best Before End* to *BBE*.

48 Any special precautions to be observed, such as storage conditions, in order to maintain the product in a condition that satisfies the Regulations within the minimum durability date must also be marked in English on both the primary container and outer packaging.

“Period After Opening” (PAO) – Regulation 12(1)(b)

- 49 Any cosmetic product, subject to certain exceptions detailed below, that does not require a date of minimum durability must be marked with a “Period After Opening” (PAO). It must appear on both the primary container and outer packaging.
- 50 The “Period After Opening” is the time after which the cosmetic product may cease to comply with the general safety requirement in Regulation 4.
- 51 It shall be indicated by the symbol representing an open cream jar, given in Schedule 9, Part II of the Regulations and reproduced in Appendix 3 of this guidance, together with an indication of the period of time in months or years shown as a number, which can be located inside or outside the symbol. The European Commission and Member States have agreed on the use of **M** to represent months but no shortened version of years has been agreed.
- 52 The Member States and the European Commission have agreed the contents of a guidance document. Its key points are:
- By requiring labelling of a “Period After Opening”, the Cosmetics Directive aims to provide useful information to consumers.
 - The PAO symbol must be used when, **after opening, the deterioration of the product may lead to harm to the consumer.**
 - **Opening of the product** may be considered as occurring when the consumer opens the product for use for the first time.
 - According to the Commission Guidance, the PAO symbol will not be necessary where:
 - **no physical opening** of the product as is the case for products presented in containers where there is no possibility of contact between the product in the container and the external environment (e.g. aerosols);
 - **no period after opening** as is the case for single-use products, which are designed to be used only once;
 - **no risk of harm to the consumer**, as there is no risk of deterioration that could lead to, in accordance with Article 2 of the Cosmetics Directive, damage to human health.
- 53 The Commission guidance has no legal force but is intended to help ensure a harmonised approach throughout the EU.

Warning statements and precautionary information

Regulation 12(1)(c)

- 54 Information must be provided on both the primary container and outer packaging in English if the product is supplied in the UK. Conditions of use and warnings for a range of ingredients are specified in the Schedules to the Regulations as follows:
- Chemical substances - Schedule 4, column 6;
 - Preservatives - Schedule 6, column 6; and
 - UV filters - Schedule 7, column 5.
- 55 If the ingredients are contained in these Schedules, any associated mandatory warnings must be provided in English. Additionally any information deemed necessary for the safe use or disposal of the product must also be provided in English.
- 56 These requirements also apply to products intended for professional use, in hairdressing in particular, and careful consideration should be given as to how the product is used and whether there is increased risk due to prolonged exposure or more unusual conditions of use. If judged to be necessary, special precautionary information must be provided in English.

Batch number or lot codes - Regulation 12(1)(d)

- 57 A code which enables the manufacturer or supplier to identify the batch in which the product was manufactured must be marked on both the primary container and outer packaging. If the product is not made in a batch, then the code should enable the date and place of manufacture to be identified.
- 58 Where it is impossible for reasons of size for the lot code to appear on both the primary container and outer packaging, it may appear on the outer packaging alone.
- 59 It is good practice to identify a batch or lot in as precise a way as possible. If a problem should arise, this will limit the quantities of product which have to be recalled or "held" in stock pending further investigations.

Product function - Regulation 12(1)(e)

60 Unless this is clear from the presentation, the function of the product must be clearly stated on both the primary container and outer packaging in English. For example, the function of lipstick is obvious. However, a depilatory cream could not just be labelled as a cream. Internationally accepted generic names, such as *eau de toilette*, are acceptable.

Statement of contents

61 Article 6 (1) (b) of the Cosmetic Directive requires the labelling of the nominal content at the time of packaging, given by weight or by volume. However the following products are exempted:

- free product (the weights and measures legislation only covers products for sale);
- less than 5g or 5 ml;
- single application, for example, sachets; and
- packs normally sold as a number of items, for which the details of weight or volume are not relevant, for example, bath balls.

62 This requirement is implemented in the UK through the Weights and Measures (Packaged Goods) Regulations and related legislation.

Language - Regulations 12(3)(a) & (b)

63 The following must be in English for products supplied in the UK, but the additional use of other languages is allowed:

- any warnings or information required in Schedules 4, 6 or 7;
- precautionary information;
- "Best before" when used to indicate the date of minimum durability;
- "months" and "years" when used to indicate "Period After Opening";
- product function.,

Labelling Difficulties

- 64 It is recognised that the variety and nature of cosmetic products and their packaging will pose difficulties when trying to include all of the information specified in the Regulations. Certain provisions have, therefore, been made to take into account the practical difficulties.

Warning statements and precautionary information

- 65 Information relating to substances, preservatives and UV filters, and any particular precautions to be observed in use will normally appear on both the primary container and outer packaging. Where this is impossible for practical reasons, the information may be given on a leaflet, label, tag, tape or card enclosed with the cosmetic product or attached to it.
- 66 When the information is given in an enclosed leaflet, label, tag, tape or card, the consumer must be referred to it, either by abbreviated information or by a special symbol, given in Part 1 of Schedule 8 of the Regulations (the hand and book symbol), which must be on both the container and outer packaging. This symbol is reproduced in Appendix 3 of these Guidelines.

Batch code

- 67 Where it is impossible, for reasons of size, for details of the batch code to appear on both the primary container and outer packaging, the details may be given on the outer packaging.

Ingredient listing

- 68 An ingredient listing, as detailed in paragraphs 38 to 41, is required on the outer packaging only or, in its absence, on the primary container. Where it is impossible for practical reasons for the list to appear on the packaging (or container), it must be given on a leaflet, label, tag, tape or card enclosed with the product or attached to it. The consumer must be referred to the text either by abbreviated information or by the hand and book symbol, which must appear on the outer packaging. This symbol is reproduced in Appendix 3 of these Guidelines.

Ingredient listing for difficult shapes and small products

- 69 Where it is impracticable for reasons of size or shape for a list of ingredients to be given, the list of ingredients must be displayed on a notice in the immediate

proximity to the container in which the product is being sold, so as to be visible to the intending purchaser. The hand and book symbol is not required.

Interpretation of small, impossible and impracticable

- 70 Definitions of *small*, *impossible for practical reasons*, *impossible for reasons of size*, and *impracticable for reasons of size or shape* have not been given in the Regulations. The huge variety of cosmetic packaging defies any all-encompassing definitions of these terms in the context of marking and labelling.
- 71 The concept of *impracticable by reason of size or shape* was introduced into UK law in 1978 and interpretation has not caused any particular difficulties. If in doubt, advice can be sought from your local authority.

Ingredient listing - Variable Ingredients

- 72 The Regulations make provision for the listing of all colouring agents used in a decorative range of cosmetics (see paragraph 39) although each product would only contain a selection of those colours. The intention is to simplify manufacture by allowing all of the colouring agents to be listed on one label in a market where fashions and colours change frequently. However, there is no specific provision made for other ingredients which are subject to change.
- 73 For example, minor formulation changes of non-colour ingredients are usually necessary to accommodate the different characteristics of colour pigments used within a range of colour cosmetics.
- 74 The Regulations do not make specific provision for this case and a strict interpretation would require separate labelling for each formulation. However, in this type of situation, it is the accepted industry practice to include the variable ingredients in the main body of the ingredients listing. The +/- (*may contain*) section of the ingredients listing is reserved for colouring agents.

Ingredient labelling - colours and associated ingredients

- 75 Colour ingredients which do not have a CI number, as listed in Schedule 5 to the Regulations, but are closely associated with colour might only be present in some products within the decorative range. The industry interpretation is to list these items under the +/- (*may contain*) section of the ingredient listing. Examples are *mica* and *tin oxide*, both used as opacifiers.

Multi – packs

- 76 Multi-packs come in a variety of forms, for example: two or more packs of the same product packaged together; or, two or more packs of different cosmetic products packaged together. Ingredient labelling can be dealt with as follows:
- Where the ingredient labelling is on the outer packaging, the ingredients for each product may be separately listed or combined into one list.
 - Where labelling on the outer packaging is impossible for practical reasons or impracticable for reasons of size or shape, the provisions detailed in paragraphs 68 and 69 apply.
 - If the products within the multi-pack have containers which are individually labelled or printed with an ingredient list, there is no requirement for a separate leaflet, label, tape, tag or card.
 - In the case of transparent packaging where the ingredient labelling of the individual products is clearly visible, separate labelling is not required.

Hotels

- 77 Cosmetic products made available to customers in their hotel rooms are subject to all of the requirements of the Cosmetic Products (Safety) Regulations 2008. However, full use can be made of the exemptions to ingredient labelling given for difficult shapes and small packs. For example, it is acceptable for the ingredient information to be given on a leaflet or card which can be placed close to the product where the Regulations allow this.

Public conveniences and toilet facilities open to the public

- 78 Cosmetic products made available in public conveniences are subject to all of the requirements of the Cosmetic Products (Safety) Regulations 2008. Please refer to paragraphs 81 to 84 which detail the responsibilities of manufacturers and suppliers.

Vending machines

- 79 The labelling requirements in the Regulations apply equally to products dispensed from vending machines.

Free samples

- 80 Free samples, whether they are provided in-store, by direct mail or in magazines e.g. shampoo samples, are considered to be within the definition of supply contained in the Regulations. Compliance with all of the requirements of the Regulations is, therefore, required.

Off-Pack Labelling - Responsibilities of Manufacturers, Retailers & Suppliers

- 81 There are occasions when ingredients information will need to be displayed near to the products. The respective responsibilities of manufacturers, retailers and suppliers are as follows.
- 82 Manufacturers must provide a list of ingredients relating to the products in question. It is advisable to include information which refers to the retailer's responsibility, for example *'To comply with the Cosmetic Products (Safety) Regulations 2008, a list of ingredients as given above must be displayed in immediate proximity to the container in which the product is exposed for sale'*.
- 83 Retailers or suppliers must not supply the cosmetic product unless the ingredient labelling information for that product is displayed in accordance with the Regulations.
- 84 The provision of such off-pack labels is subject to normal commercial agreements between manufacturers and suppliers etc.

Toilet Soap

Toilet soap supplied in a container or wrapper

- 85 The normal requirements apply.

Toilet soap not supplied in a container or wrapper

- 86 The name and address of the manufacturer or supplier and the batch code are required to be given on either:
- the soap itself (but only required to be indelible until it has been put into use); or
 - the packaging in which it is exposed for supply; or
 - the container in which it was packed before being exposed for supply.
- 87 The remaining information, that is:
- minimum durability date;

- warning statements and precautionary information; and
- product function

when applicable, must be provided on a leaflet supplied with the toilet soap (see paragraph 89 for ingredient listing).

Labelling conventions for toilet soap

88 INCI names must be used in the list of ingredients.

Toilet soap - labelling difficulties

89 In the case of the impracticability of enclosing a leaflet with the product or attaching a label, tag, tape or card to the product, the ingredient listing may be displayed in close proximity to the product when offered for sale.

90 'Coconut oil' and 'Palm kernel oil' are both obtained from the kernels of palm trees. When saponified in the production of soap they become a form of 'sodium palm kernelate'. The UK Cleaning Products Industry Association (UKCPI)¹² recommends the use of this term, listed in the INCI nomenclature, to cover the use of either of these raw materials in the ingredients listing.

Responsible Persons and Competent Authorities

Regulation 15

91 Defines the terms 'responsible persons' and 'competent authorities'.

Responsible person - Regulation 15(1)

92 Defines 'a responsible person' in relation to the provision of the Product Information under Regulation 16, the notification of places of manufacture or initial importation of cosmetic products under Regulation 17, and the application for confidential treatment in the listing of an ingredient under Regulation 21.

93 A list of alternatives is offered for 'responsible persons'. These are:

¹² Addresses are given in Appendix 5

- the manufacturer of a product; or
- the manufacturer's agent; or
- the person to whose order a cosmetic product is manufactured.

94 The list is not in order of precedence and the choice of responsible person will depend on company structure and organisation. Different people can be responsible for different functions.

95 Where the manufacturer, or the person to whose order the cosmetic product is manufactured, is not established in the Community and the manufacturer either:

- has not appointed an agent; or
- his agent is not the supplier of that cosmetic product;

the 'responsible person' is the person who first supplies the cosmetic product in the Community.

Competent authority - Regulations 15(2) & (3)

96 Defines a 'competent authority' which is responsible for requesting and receiving the information relating to the Product Information, notification of places of manufacture or first importation, information to Poison Centres and trade secrecy relating to ingredient labelling.

97 For the purposes of the Product Information (PI), the competent authority will be the local weights and measures authority. Within this authority the responsibility will usually be exercised by Local Authorities. In Northern Ireland the position is different. The competent authority for the Product Information will be the District Council.

98 For the purposes of notification of places of manufacture and first importation, the competent authority will be the Consumer and Competition Policy Directorate (CCP) of the Department for Business, Innovation & Skills (BIS).

99 For the purposes of notification to Poison Centres, the competent authority will be LGC.¹³

100 For the purposes of trade secrecy relating to ingredient labelling, the competent authority will be CCP at BIS.

¹³ Addresses are given in Appendix 6

Product Information

Regulation 16

- 101 This sets out the requirements relating to the Product Information (PI). The PI must be readily **accessible through** the EU address specified on the label. Where two EU addresses are given, the industry convention is that the PI will be available at the address which is underlined. All of the information present in the PI must be in the English language when the PI is to be made accessible through a UK address.
- 102 The Regulations state that the PI must be kept readily accessible. European industry and Member States interpret this as meaning that the PI itself need not be held physically at the specified address but it should be accessible there within a reasonable amount of time; in most cases, 2-3 working days is a period, which is considered acceptable.
- 103 Enforcement practice will be based around the Home Authority Principle developed by the Local Authorities Coordinators of Regulatory Services (LACORS). This means that any guidance given to business by a 'home authority' (usually the one covering the area where the headquarters of the business is based) will be recognised by all Trading Standards Departments. The Principle is designed to promote good practice and thereby protect the consumer and encourage fair trading, consistency and common sense. The four express aims of the Home Authority Principle are to:
- encourage authorities to place special emphasis on goods and services originating within their area;
 - provide businesses with a home authority source of guidance and advice;
 - support efficient liaison between local authorities; and
 - provide a system for the resolution of problems and disputes.
- 104 The Home Authority for any business is likely to be the authority where the relevant decision making base of that company is located. This authority will take on a special responsibility for giving advice on regulation, good practice and remedial action. The Principle means that where a local authority wishes to obtain information held in the PI, it will usually make contact with the Home Authority for the company concerned. There will however, be circumstances when direct contact occurs, for example to discuss problems identified with the local implementation of centrally agreed policies and procedures.
- 105 In some cases the PI may be accessible via the specified address but actually held at a different address, for example the place of manufacture. In discussion with the Home Authority it may be possible to put in place arrangements so that authorities

requiring PI can liaise directly with the 'Originating Authority', that is the authority in whose area the manufacturing operation is located.

- 106 It should be borne in mind that the Home Authority Principle can only operate as a partnership between businesses and authorities. Where an enterprise chooses not to enter into such an arrangement one likely consequence will be the need to directly address enquiries from any competent authority.

Contents of the Product Information

- 107 The information which must be present in the PI is detailed in the following sections. It may be the case that a competent authority would like to see supporting documentation, in which event adequate time is likely to be given to the company for this to be obtained. Supporting documentation may be in a language of the Community which is not English. However, companies should be prepared to provide an English translation, if needed.

Product composition - Regulation 16(1)(a)

- 108 This should be a statement of the complete quantitative composition of the product covering all raw materials added. This will also meet the specified requirement for qualitative composition.
- 109 It will be useful to link the names of the raw materials used to the equivalent INCI names used for ingredient labelling.
- 110 In the case of perfumes and perfume compositions used as ingredients, only the name and code number of the composition and the identity of the supplier have to be provided.

Physico-chemical and microbiological specifications of raw materials and finished product - Regulation 16(1)(b)

- 111 The specifications (and any related control criteria) of both raw materials and finished products will be determined by the type and use of the raw material concerned and the product type in which it will be used. The level of detail will obviously vary according to those criteria and the professional judgement of those involved in formulating and manufacturing the product. The standards adopted will reflect regulatory requirements and generally accepted industry practice.
- 112 Each raw material should be described with relevant information, such as chemical name, formula or description, physico-chemical and/or organoleptic properties. Details of the basic criteria for its identification should be provided. It may be appropriate for typical analytical profiles to be included for reference in the PI.

- 113 Full specifications for the finished product must be provided.
- 114 Industry standard guidelines on Microbial Quality Management (MQM) have been produced on behalf of the cosmetics industry by the Cosmetic, Toiletry and Perfumery Association (CTPA)¹⁴. The MQM guidance is not mandatory but assists companies manufacturing cosmetics to ensure the appropriate microbiological quality of their products from product development through to manufacturing, testing, processing, risk assessment and auditing. It can also be used to review existing systems against current industry standards.

Method of manufacture - Regulation 16(1)(c)

- 115 This should include a brief overview of the method of manufacture including storage and filling, and applicable to the manufacturing site(s) concerned. There should be a summary of the process and a cross-reference to the detailed manufacturing documentation within any specific manufacturing site. Manufacture – and also (it is generally recognised) packaging and storage - of cosmetic products should be carried out to cosmetic Good Manufacturing Practice (GMP) and the guidance documents published by Colipa¹⁵, the Council of Europe¹⁶ and the European Commission on GMP are recommended as a reference.

Safety assessment - Regulations 16(1)(d) & (e)

- 116 It is recommended that this should generally be in the form of a signed statement of opinion by an appropriately qualified and suitably experienced person or persons. This should give reassurance that the product is safe in its intended cosmetic use and takes account of foreseeable use. A specific safety assessment is also required for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.
- 117 The safety assessor should take into account all support information such as:
- the general toxicological profile of each ingredient used;
 - the chemical structure of each ingredient;
 - the level of exposure of each ingredient;
 - the specific exposure characteristics of the areas on which the cosmetic product will be applied; and

¹⁴ Address given in Appendix 6

¹⁵ Details of the Colipa GMP Guidelines are available from the CTPA (see Appendix 6 for address)

¹⁶ Council of Europe 'Guidelines on Good Manufacturing Practice of Cosmetic Products (GMPC) can be obtained from The Stationery Office ISBN 92-871-2849-9

- the specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

118 In the case of perfumery raw materials, the composition may not be known because of confidentiality. If so, it is necessary to obtain a relevant safety assessment from the supplier.

The safety assessor - Regulation 16(1)(f)

119 In the UK Regulations, the person responsible for the health assessment is called a qualified person. The name and address of the qualified person or the person responsible for the assessment under Regulation (16)(1)(d) and (e) must be provided.

Existing data on undesirable effects on human health resulting from the use of the cosmetic product - Regulation 16(1)(g)

120 All undesirable effects reported to the companies should be taken into account, although companies may wish to clarify whether or not these effects have been professionally substantiated, by a dermatologist, for example. Companies should maintain and update any such recorded adverse effects for each product on the EEA market.

121 Reports of adverse health effects should not include anecdotal or ambiguously reported incidents.

Proof of the effect - Regulation 16(1)(h)

122 The provision of information is required to support claimed effects, where justified by the nature of the effect or product. This is only required where a claimed effect is in addition to that which is obvious from the formula and product presentation. For example, the basic effect of a shampoo is clear and there is no need to include performance data on its ability to wash hair. A sunscreen, however, would require performance data such as information to support its Sun Protection Factor (SPF) and any UVA or UVB claims.

123 Documentation should comprise sufficient information, directly or indirectly, to demonstrate proof of the effect claimed. It may, for example, comprise a short summary of the technical support for the claimed effects which may be cross-referenced to more detailed support information not held as part of the PI.

Data on any animal testing – Regulation 16(1)(i)

124 Data are required on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety evaluation of the product or its

ingredients, including any animal testing performed to meet the legislative or regulatory requirements of countries which are outside the European Community.

Public access - Regulations 16(3) & (4)

125 Certain parts of the PI are to be made accessible to members of the public on request to the cosmetic manufacturer or importer. The public is entitled to ask for the following information:

- the qualitative ingredient listing (i.e. the ingredients list already on the pack);
- the quantitative declaration of certain ingredients (see paragraph 127); and
- information on existing data on undesirable effects on human health resulting from the use of the cosmetic product.

126 The qualitative information made accessible ought to be consistent with the ingredient list on the product's package.

127 There is no obligation to provide a full declaration of quantitative formula. However, for any cosmetic ingredients present in the product that are also covered by Directive 67/548/EEC (the Dangerous Substances Directive), the use concentration should be indicated. Colipa and CTPA provide to their members, a cross-reference between the International Cosmetic Ingredient Dictionary and Handbook database and Annex I of 67/548/EEC.

128 When necessary, in order not to compromise commercial secrecy or intellectual property rights, the value can be rounded up and indicated as a maximum or a range that encompasses the actual value, e.g.

INCI name a (<y%)

INCI name b (x-y%)

129 Information on perfume or perfume compositions is generally subject to commercial secrecy and is part of a company's intellectual property and so need not be made available to the public.

130 An "undesirable effect" is an adverse effect on human health that occurs from the normal or reasonably foreseeable use of a cosmetic product. There should be a demonstrable link between the affected person and the product; undesirable effects do not include anecdotal or ambiguously reported effects or those resulting from abuse or misuse of the product, and do not include those related to associated items, such as the packaging. Undesirable effects include but are not limited to irritant or allergic reactions that can affect the skin or eyes; if other undesirable effects occur, they should be specified.

- 131 In order to ensure consistent information to the public, companies should generally compute a value for the number of undesirable effects per million units placed on the market (including all Member States but excluding non-EU markets). However, in situations where the actual number of items placed on the market is small (such as a recent launch or sale through selective distribution), the actual number of undesirable effects may be provided.
- 132 A member of the public will expect a response in his own language (and which is an official EU language) from the company within three weeks of the company receiving the request. If a correspondent is unhappy with the manner in which their request is handled, they have the option of complaining to the national competent authority. Companies should keep records of all enquiries and responses to help in any such complaint investigation.
- 133 Companies must ensure they have the ability to respond to consumers from anywhere within the European Union. All cosmetic products placed on the European market must indicate on the packaging the manufacturer or the person responsible for placing the product on the EU market with an appropriate contact address within the European Community.
- 134 In addition, Colipa has set up a central website (www.European-Cosmetics.info) to provide easy access to cosmetic companies' contact details by the public. It is free and available for all companies to give the most appropriate contact details for each EU Member State where their product is available. This may be a postal address, telephone and/or fax number, website address and/or e-mail details.

Notification of Supply

- 135 The competent authority is CCP at BIS.

Regulation 17

- 136 The Regulation does not require the notification of every new cosmetic product put on the market but is designed to ensure that manufacturing premises within the UK are notified together with the names of the companies responsible for importing products into the Community.
- 137 Where a product is manufactured in the UK, the responsible person must notify a UK competent authority of the place of manufacture. Where a product is imported into the Community via the UK, the responsible person must notify a UK competent authority of the place of initial importation of that product.
- 138 Responsible persons must notify the type of product supplied, not the individual products, according to the following list:

- perfumes
- decorative cosmetics
- skin care
- hair care
- toiletries.

139 In all cases, notification of the product type must take place before a product is placed on the market. There is no set format for providing this information. A letter to the competent authority, giving the required information, will suffice.

The safety assessor - Regulation 18

140 The 2008 Regulations allow for safety assessments for human health to be undertaken by pharmacists, doctors (as defined by the Medical Act 1983), chartered biologists and chartered chemists. In addition, the Regulations also permit any person holding a diploma within the meaning of Regulation 7 of the European Communities (Recognition of Professional Qualifications) Regulations 2007 which shows that they are qualified to practise in an equivalent profession in any other Member State.

141 The Regulations require that the bulk of the education and training was undertaken in the European Economic Area (EEA). In addition, the assessor must have at least three years working experience in his or her profession in a Member State of the EEA and this professional experience must be certified by a competent authority.

Poison Centres

142 The competent authority is LGC¹⁷.

Regulation 19

143 The Regulations specify that a UK competent authority may require information for prompt and appropriate medical treatment.

144 To facilitate European Harmonisation, European industry worked with EAPCCT¹⁸ and Colipa to prove the operational feasibility of a completely updated frame formulation system. This resulted in the publication of Frame Formulation 2000 (available from

¹⁷ Addresses are given in Appendix 6

¹⁸ European Association of Poisons Centres and Clinical Toxicologists

Colipa¹⁹) and is supplied to UK Poison Centres by EAPCCT. The system is now in operation in several EU Member States. The UK is considering whether or not to adopt the system.

Authorisation for Use of Ingredients not Listed in Schedules

Regulation 20

145 Colouring agents (with the exception of hair dyes), antimicrobial preservatives and UV filters (unless they are intended to protect the product) can only be used if they are positively listed, that is named in Schedules 5, 6 or 7 to the Regulations. If a manufacturer wishes to use a substance which is normally subject to positive listing but which is not listed in the Schedules, authorisation must be obtained. Regulation 20 describes the requirements necessary to obtain Prior National Approval before such a substance can be used.

Trade Secrecy

146 The competent authority is the CCP at BIS.

Regulation 21

147 Regulation 21 describes the procedure by which a supplier of a cosmetic product may be exempted from the requirement to list one or more cosmetic ingredients for reasons of trade secrecy. It gives procedural details and the role played by the Secretary of State (acting through CCP at BIS) as the competent authority. BIS will not consider an application has been received until all the details described below have been provided.

148 Applicants who submit a request for confidentiality must include, at least, all the particulars set out in Schedule 9 Part 1 of the Regulations. There are very detailed and extensive requirements which must be met before BIS will consider granting any exemption.

149 In paragraph 2 (a) of the Schedule the name or trade name or registered office of the applicant is that of the responsible person who makes the application. A responsible person is defined in Regulation 15.

150 All the chemical names of the ingredient under the various nomenclatures listed must be given, where they exist (paragraph 2 (b) of the Schedule). It is the responsibility of the applicant to ensure all this information is provided. Applicants

¹⁹ Addresses are given in Appendix 6

must also ascertain whether the ingredient has been subject to a confidentiality request under Article 19 of Directive 67/548/EEC (the Dangerous Substances Directive). If it has, the result of this request must be made known to the BIS.

151 Paragraph 2 (c) in the Schedule requires considerable detail, and all this information must be supplied to BIS for consideration by government toxicologists. Note that an assessment is required for the ingredient as it is used in the finished cosmetic products or products. This means that a new application is required if the ingredient is used in a product not originally specified in an earlier application, as required by Paragraph 2(d) of the Schedule.

152 A detailed justification of why confidentiality is sought is required by Paragraph 2(e). This paragraph gives an example of such a justification, namely that:

- no one else knows about the ingredient or knows what it can do when used in the cosmetic product; **and**
- the 'information; is not in the public domain, but a patent application has been lodged, **and**
- if anyone did know, competitors could easily use the ingredient or copy the effect, thereby damaging the applicant's business.

153 This is, however, only one example of a possible justification. Confidentiality applications could certainly be entertained in relation to ingredients used in a new way or used for the first time in a cosmetic product. However, BIS would expect to see evidence of a real trade secret which deserves to be protected. Absence from the INCI list would be evidence that an ingredient has not been previously in a cosmetic product. In the case of a novel use for a cosmetic ingredient, convincing scientific evidence of showing the new use would be expected.

Enforcement

Offences - Regulation 22

154 Any contravention of the Cosmetic Products (Safety) Regulations 2008 (as amended) is treated as a contravention of the safety regulations made under the Consumer Protection Act 1987. Please refer to the Regulations themselves for full details.

Regulations 23 & 24

155 Where the product concerned is for export to a state outside the European Economic Area, that is the European Union, Iceland, Norway and Liechtenstein, enforcement action will not to be taken on regulations concerning:

- the general safety requirement (Regulation 4)
- substances prohibited in cosmetics (Regulation 5)
- restrictions on ingredients (Regulation 6)
- coloring agents, preservatives & UV filters (Regulations 7, 8 & 9)
- labelling requirements (Regulations 12 & 13)
- product information (Regulation 16)
- notification of manufacture or import (Regulation 17)
- qualified persons (Regulation 18)

156 Note, in particular, that Regulation 10 still applies. It prohibits the testing of ingredients or finished products on animals, subject to the circumstances specified, for the purposes of the Regulations or the Cosmetics Directive,

157 No action will be taken against the supply of cosmetic products which are not labelled in English, that is, the information which is required to be in English as specified in Regulation 12(3)(a), where the person supplying the product reasonably believes that it will not be used in the UK.

158 As well as their role as competent authorities for the PI, local authorities are responsible for ensuring compliance with the general safety requirements (Regulation 4), ingredient restrictions and prohibitions (Regulation 6) and marking of packaging (Regulation 12).

159 The enforcement powers available for all these responsibilities are contained in the Consumer Protection Act 1987. If there are reasonable grounds to suspect an offence, the officer of the competent authority (normally a Local Authority Trading Standards Officer) has the power to require companies or individuals to produce any records relating to their business and to seize and detain goods or records which the Officer has reasonable grounds for believing may be required as evidence in court proceedings.

160 Similar powers are available to Local Authority Trading Standards Officers (Department of Economic Development in Northern Ireland) in relation to false or misleading product claims. The Consumer Protection from Unfair Trading Regulations 2008 makes it an offence to either apply a false trade description to goods, or to supply goods which are falsely described. Claims about both the product composition (for example, *preservative free*) and function (for example, *wrinkle reducing*) will be covered by consumer protection law. Competent authorities can request to view the PI held to prove the claimed effect.

161 It may only be practicable for Trading Standards Officers to obtain from companies or individuals the information necessary to carry out their duties. In these circumstances, the Officer may seek information and assistance from them. They should be prepared to co-operate with Trading Standards Officers and respond to reasonable requests for information and assistance. It is an offence to obstruct a Trading Standards Officer intentionally or to fail (without good cause) to give any assistance or information the Officer may reasonably require to carry out enforcement duties.

Penalties

162 Penalties for contravention of the Regulations 16, 17 and 19 are, on summary conviction, imprisonment for not more than 6 months or a fine not exceeding £5000, or both. For Regulations 10, 11, 14 and 16 (1) (i), the maximum fine is the same, but imprisonment cannot exceed 3 months.

APPENDIX 1

Identification of Ingredients

An ingredient should be identified by its common name that is its INCI name, as listed in the common ingredients nomenclature of the European Union.

In the absence of an INCI name, any of the following means of identification may be used:

- chemical name;
- European Pharmacopoeia name;
- International non-proprietary name as recommended by the World Health Organisation;
- EINECS, IUPAC or CAS identification reference; or
- colour index number.

Note: *the Cosmetics Directive and the UK Regulations refer to the INCI, published by the European Commission. The International Cosmetic Ingredient Dictionary and Handbook published by PCPC is also referred to as INCI. In the absence of an EU INCI name the US name may be used.*

Unlisted Ingredients

Where an INCI name for an ingredient does not exist, then an application for a name should be made to the International Nomenclature Committee (INC) based in Washington, USA. Colipa is represented on the INC through members from European companies. Application forms, together with the procedure to be followed, can be obtained from the CTPA.

APPENDIX 2

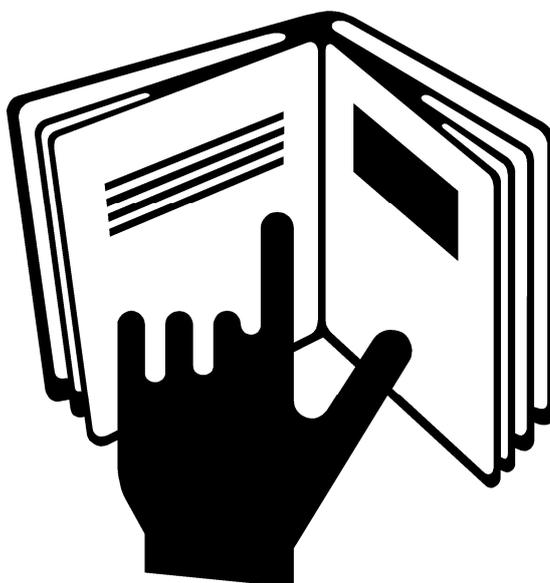
Ingredient labelling example

INGREDIENTS

Aqua, Cyclomethicone,
Mica, Polybutene, Triisostearin,
Prunus Persica Flower Extract, Betula
Alba Oil, Lavandula officinalis Oil
Paraffinum Liquidum,
Propylene Carbonate,
Methylparaben,
Phenoxyethanol, Propylparaben,
Lecithin, Alcohol Denat., BHT,
Parfum, Aroma,
Cinnamyl Alcohol, Citronellol,
[+/- CI 15580, CI 45430]

APPENDIX 3

Hand and book symbol from Annex VIII of the Cosmetics Directive



Examples of "Period After Opening" (PAO) symbol



APPENDIX 4

Illustrative list of cosmetics (Annex I of the Cosmetic Directive)

The following list is not exhaustive but is provided by way of example

Creams, emulsions, lotions, gels & oils for the skin (hands, face, feet etc.)

Face masks (with the exception of peeling products)

Tinted bases (liquids, pastes, powders)

Make-up powders, after-bath powders, hygienic powders etc.

Toilet soaps, deodorant soaps, etc.

Perfumes, toilet waters and eau de Cologne.

Bath & shower preparations (salts, foams, oils, gels etc.

Depilatories.

Deodorants and anti-perspirants.

Hair care products:

- hair tints and bleaches,

- products for waving, straightening and fixing,

- setting products,

- cleansing products (lotions, powders, shampoos),

- conditioning products (lotions, creams, oils)

- hairdressing products (lotions, lacquers, brilliantines).

Shaving products (creams, foams, lotions).

Products for making up and removing make-up from the face and eyes.

Products intended for application to the lips.

Products for care of the teeth and mouth.

Products for nail care and make-up.

Products for external intimate hygiene.

Sunbathing products.

Products for tanning without sun.

Skin-whitening products.

Anti-wrinkle products.

APPENDIX 5

Addresses

Aromatherapy Trade Council
PO Box 387,
Ipswich IP2 9AN
tel: 01473 603 630
Website: www.a-t-c.org.uk

Consumer and Competition Policy Directorate (CCP)
Department for Business Innovation & Skills
1 Victoria St
London SW1H 0ET
tel: 020 7215 5000
website: www.bis.gov.uk

Colipa (The European Cosmetics Association)
Avenue Herrmann Debroux 15A
B-1160 Auderghem - Brussels
tel: + 32 2 227 66 10
website: <http://www.colipa.eu/>

Personal Care Products Council (PCPC)
1101 17th Street, NW
Suite 300
WASHINGTON
DC 20036
USA
tel: +1 202 331 1770
website: www.personalcarecouncil.org/

In the UK, PCPC publications can be obtained from:
MICELLE PRESS
10-12 Ullswater Crescent
Weymouth
Dorset DT3 5HE
tel: 01305 781574

Cosmetic, Toiletry & Perfumery Association Ltd (CTPA)
Josaron House
5/7 John Princes Street
London W1G OJN
tel: 020 7491 8891
website: www.ctpa.org.uk

The CTPA website is a source of information for all cosmetic legislation and industry standards.

www.thefactsabout.org.uk

The CTPA's consumer-facing website

LGC
Queens Road
Teddington
Middlesex TW11 OLY
tel: 020 8943 7000
website: www.lgc.co.uk

Local Authorities Coordinators of Regulatory Services (LACORS)
10 Albert Embankment
London SE1 7SP
tel: 020 7840 7200
website: www.lacors.gov.uk

Medicines and Healthcare products Regulatory Agency (MHRA)
Market Towers,
1 Nine Elms Lane,
London SW8 5NQ
tel: 020 7084 2000 (weekdays 0900 -1700)
tel: 020 7210 3000 (other times)
website: www.mhra.gov.uk

The Stationery Office
PO Box 29
St Crispins
Duke Street
Norwich NR3 1GN
tel: 0870 600 5522
online ordering: www.tsoshop.co.uk

UK Cleaning Products Industry Association
1st Floor Suite
Century House
High Street
Tattenhall
Cheshire CH3 9RJ
tel: 01829 770055
website: www.ukcpi.org