



IRISH MEDICINES BOARD
GUIDE TO COSMETICS MANUFACTURE

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

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1. SCOPE

This document is designed to offer guidance to aid start-up cosmetic manufacturers understand their obligations as described in Cosmetics Directive 76/768/EEC (as amended) and transposed in Ireland by the European Communities (Cosmetic Products) Regulations, S.I. No. 870 of 2004 (as amended). This document also serves to prepare the intended user for the upcoming changes in legislation, due to Regulation (EC) 1223/2009 which comes into effect in July 2013.

For the purpose of this guide the term 'cottage industry' refers to the home-based creation of products, rather than factory-based.

2. INTRODUCTION

Details of the legislative framework for cosmetic products are found in the IMB's '[Guide to Cosmetics](#)', published on the IMB website. It is suggested that this guide is referred to for background information on the regulation of cosmetic products in Ireland.

3. THE RESPONSIBLE PERSON

The Responsible Person is defined in Regulation 4 of S.I. No. 870 of 2004 (as amended). The Responsible Person, as it relates to this guide, is usually the manufacturer or the importer of the product into the Community; however the manufacturer may delegate another company to act as the Responsible Person. The Responsible Person should be based within the EU and their address should appear on the cosmetic labelling.

4. THE PRODUCT INFORMATION FILE

Prior to placing a cosmetic product on the European market, the Responsible Person is required to prepare a Product Information File. This file should be maintained throughout the life of the cosmetic product. The IMB's '[Guide to Cosmetics](#)' outlines the requirements for the Product Information File. The Responsible Person must maintain this Product Information File at the address which appears on the label.

4.1 Qualitative and quantitative composition

Each ingredient must be identified. The Chemical Abstracts Service (CAS) Registration Number of the chemical, the International Nomenclature of Cosmetic Ingredients (INCI) name and the EC number should be given. Further information on chemical identity is available in the [SCCS safety testing guidelines](#).

For cosmetic ingredients the concentration, function and mode of action in marketed cosmetic products should be reported. In the case of perfume and aromatic compositions, the description of the name, code number of the composition and identity of the supplier should be included.

4.2 Safety assessment

The safety assessment is a summary of the scientific reasoning to support the safety of the cosmetic product. A safety assessment should be conducted by a suitably qualified person. This person, known as the safety assessor, must be clearly described in the safety evaluation report of the finished product. The name, address and qualifications of the safety assessor must be maintained in the Product Information File. The IMB's [Guide to Cosmetics](#) outlines the requirements for the safety assessor.

All toxicological data available on the individual ingredients and the end product (favourable and unfavourable), all chemical and/or biological interactions and human exposure via intended and likely routes must be taken into account. Any data generated to support the scientific reasoning should be obtained from a Good Laboratory Practices accredited laboratory.

The [SCCS safety testing guidelines](#) offers guidance on the safety evaluation of cosmetic products. In addition the [Colipa Guidelines for the Safety Assessment of a Cosmetic product](#) gives further guidance.

4.3 Label claims

Label claims should not be misleading and should be supported by sufficient, sound, and relevant evidence. The benefits delivered by the product should be consistent with reasonable consumer expectations created by the claims, and scientific, technical or consumer perception studies performed. The [Colipa Guidelines for the Evaluation of the Efficacy of Cosmetic products](#) offers guidance on supporting label claims. There are a number of methods of substantiating label claims, as outlined below.

4.3.1 Methods of substantiating label claims

Literature review

Evidence of claims that are widely accepted may be substantiated using independently peer-reviewed supporting data. Additional product specific data may be required to accompany this literature review. Where claims are based on ingredient efficacy, stability data should ensure that the ingredient is stable in the finished product and that its activity is maintained in the product. For ingredient efficacy, the concentration of ingredient in the final product should reflect the levels at which the claims have been substantiated. For example, vitamin C is widely acknowledged as an anti-oxidant. However, the effect of applying the product topically and the stability of vitamin C in the specific product should be investigated.

Sensorial approach

These are user tests taking into account the perception of product efficacy based on factors the volunteers can observe or feel. Tests are based on an appreciation of product performance made through the senses of either panellists or of experts. They give information mainly on observed or perceived parameters. An example of such a claim is '8 out of 10 women felt their skin was smoother after just one week'.

Instrumental approach

These tests are performed with instruments that can precisely measure given parameters, according to a defined protocol, following the application of a product on human subjects. For example, skin hydration tests conducted in a laboratory or colorimetric tests for the measurement of colour.

Studies conducted on volunteers should naturally respect ethical guidelines and products tested should have previously undergone a safety assessment (see section 4.2). For further information, refer to the [WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects](#).

4.3.2 Nature of claims

Care should be taken to ensure that product claims are consistent with that which is considered reasonable and consistent with the definition of a cosmetic. In particular, borderlines with other products must be considered carefully. Medicinal products and biocide products are examples of areas which can commonly fall into the borderline category with cosmetics. Further guidance on claims which would be considered consistent with these product types is provided below.

Medicinal claims

Promoting a product with claims that it treats or prevents disease or otherwise affects the structure or any function of the body may cause the product to be considered a medicinal product. For more information on medicinal claims, refer to the '[Guide to the definition of a human medicine](#)'.

Biocidal claims

For further information on consumer products which potentially may fall at the borderline between biocide and cosmetic legislation, consult the [Borderline between Directive 98/8/EC concerning the placing on the market of Biocidal product and Directive 76/768/EEC concerning Cosmetic products](#).

4.4 Stability

Stability data provides evidence that the cosmetic product is stable for the duration indicated by the date of minimum durability (best before date). Stability studies are carried out to ensure that the cosmetic product maintains physical, chemical and microbiological stability throughout its shelf-life. The study should examine the integrity of the cosmetic product under appropriate conditions of storage, transport and use. The compatibility between the contents and the container should also be investigated. Studies can be conducted in real time or under accelerated conditions; further guidance on stability testing can be found in the [Colipa Guideline on stability testing of Cosmetics products](#).

The efficacy of the preservation of the cosmetic product should be assessed experimentally in order to ensure microbial stability and preservation during storage and use. This is done by challenge testing.

Reasons for microbial preservation of cosmetics are:

- to ensure the microbial safety of cosmetics for the consumer,
- to maintain the quality and specifications intended of the product,
- to confirm hygienic and high-quality handling.

Guidelines on microbiological quality of the finished cosmetic product are available in the [SCCS safety testing guidelines](#).

In addition to the information contained within the Product Information File, provision should be made to monitor the on-going stability of the product.

4.5 Specifications

In setting specifications for a cosmetic product, the safety assessment, legislative limits, function of the product and raw material specifications should be taken into account. Physico-chemical specifications are generally set depending on the legislative limits and function of the ingredient. For example, where the label claim is based on an ingredient's function or where the preservation of the product depends on a preservative, the level of that preservative should be monitored in the physico-chemical specification. A decrease in the level of that preservative within the cosmetic product could lead to an increase in microbial growth.

In order to ensure the quality of the product and the safety for the consumer, it is recommended that routine microbiological analysis is carried out on each batch of the finished product coming on the market. The parameters examined, the criteria and methods used, and the results obtained per batch should be specified in properly filed reports, known as batch records.

A raw material manufacturer generally assigns specifications to ensure consistency of the material from batch to batch. Adopting the manufacturer's specification is only acceptable if it is adequate for the safe use of the material. For example, some raw materials contain heavy metals which are prohibited for use in cosmetics products, use of such ingredients should not be used in cosmetics manufacture.

4.6 Data on undesirable effects

An undesirable effect is an adverse effect on human health that occurs from the normal or reasonably foreseeable use of a cosmetic product. Undesirable effects do not include, for example, those resulting from abuse or misuse of the product. Examples of undesirable effects include: irritant and allergic effects, phototoxic effects, photosensitivity, anaphylactic shock and itching.

Council Directive 2001/95/EC concerning general product safety and the related European Communities (General Product Safety) Regulations 2004, S.I. No. 199 of 2004, which became mandatory on 4 May 2004, make certain provisions for post-market obligations for producers and establish powers for competent authorities to require information where this is not covered by specific sector legislation. The General Product Safety Directive obliges producers and distributors of consumer products, which includes cosmetics, to inform designated national authorities in the member states if a product placed on the market poses a risk to consumers.

The safety of the product should be reviewed on a regular basis. To that end, while the cosmetic product is available on the market, undesirable effects on human health should be monitored. An investigation into consumer complaints should include, but is not limited to:

- complaints during normal and improper use;
- examination of the documentation for the implicated batch;
- examination of the effect on other batches currently on the market;
- possible allergies;
- unclear instructions for use or warnings;
- carrying out of sample testing of marketed products;
- keeping distributors informed of such monitoring.

A manufacturer should take appropriate action where a cosmetic product poses a risk to consumers. This includes necessary measures to avoid risks, such as adequate and effective warning of consumers, recall of the product from consumers or withdrawal of the product in question from the market. Market action including recall and withdrawal should take place where other measures do not suffice to prevent the risks involved.

Any investigations, complaints or market actions should be taken into account in the next safety assessment of the product. This information should be made easily accessible to the public. For further information refer to the [Colipa Guidelines on the Management of Undesirable Event Reports](#) Composition and undesirable effects of cosmetic products to be made easily accessible to the public – practical implementation of article 7a(1)(h).

4.7 Data on animal testing

Data on any animal testing performed by the manufacturer, agents or suppliers including any animal testing performed to meet the regulatory requirements of third countries should be included in the Product Information File.

An animal testing ban on finished cosmetic products has been applied since 2004. A testing ban on ingredients or combinations of ingredients has been applied since 2009 where alternative validated methods to animal testing have been adopted. A marketing ban on finished products or ingredients tested on animals, where alternative methods are available, has been imposed since 2009, except for repeated-dose toxicity, reproductive toxicity and toxicokinetics where the implementation date has been extended to 2013. The Scientific Committee on Consumer Safety ([SCCS safety testing guidelines](#)) outlines available alternative validated methods to animal testing.

Where no animal testing has been conducted a statement indicating this should be included in the Product Information File.

5. GOOD MANUFACTURING PRACTICES

[ISO 22716](#) is the Cosmetics Good Manufacturing Practices (GMP) Standard and provides organisational and technical advice on the management of the human, technical and administrative factors affecting cosmetic product manufacture and product quality.

The documentation system used should be composed of the following:

- procedures,
- instructions,
- specifications,
- protocols,
- reports (such as complaint reports, deviation reports, investigation reports or recall reports),
- methods,
- records.

The manufacturing process should be documented and maintained within the Product Information File. This document should include the formulation for the product and detailed manufacturing operations for each stage, such as addition of raw materials, temperature monitoring, mixing speed and time requirements, and cleaning procedures.

Appropriate GMP training should be provided to all personnel. Personnel hygiene programmes should be established to avoid contamination. The manufacturing premises and equipment utilised should ensure protection of the product, efficient cleaning and minimize the risk of mix-ups, as well as cross contamination. When purchasing ingredients and/or packaging materials, it is necessary to take into account the technical requirements to be examined in order to ensure that the cosmetic product is manufactured consistently. Such requirements may include but are not limited to supplier approval criteria, material acceptance criteria and actions required in the case of a quality defect or complaint. A batch number should be assigned to each batch of manufactured product. Records permitting the traceability of each raw material should be maintained and it should be possible to trace which batch of raw material went into each batch of finished product.

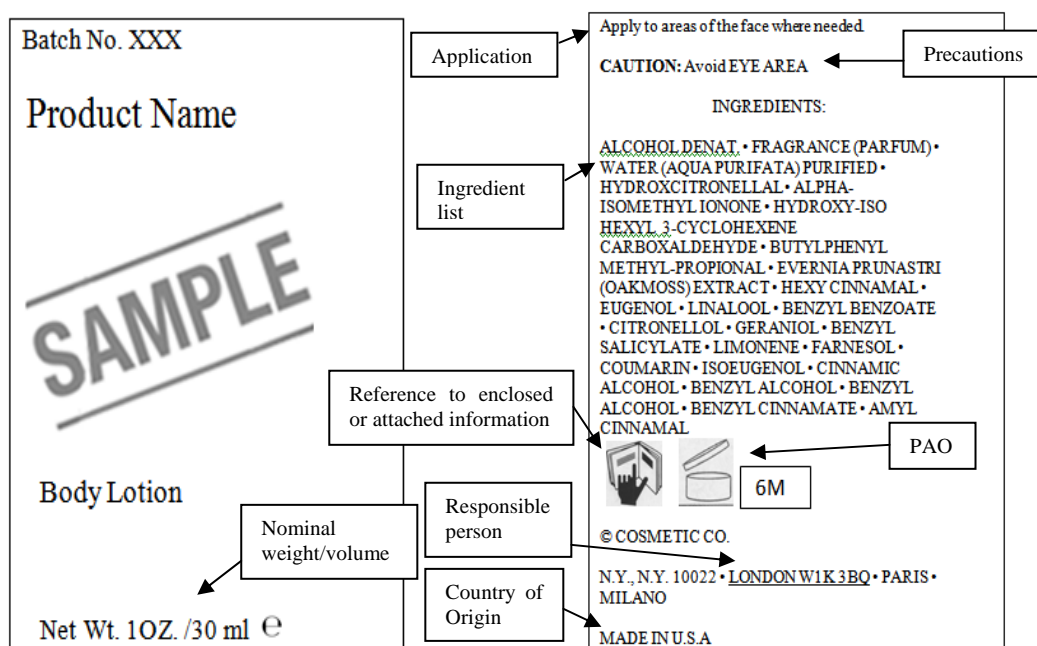
Storage conditions should be appropriate for each ingredient and for the finished product. Packaging activities should be documented and sufficient checks performed to minimize the risk of mix-ups.

Finished products should meet the defined acceptance criteria. Acceptance criteria should be established to specify the requirements to be met for raw materials, packaging materials, bulk and finished products see section 4.5.

Regulation 1223/2009 Article 8 establishes [ISO 22716](#) or equivalent as the requirements for Good Manufacturing Practices. This legislation comes into effect in July 2013.

6. LABELLING

An example of cosmetic product labelling is given below. It should be noted that not all of the items depicted are obligatory and guidance is given below.



6.1 Name and address of the Responsible Person (EU Address)

The cosmetics legislation allows for the address to be abbreviated. For example, 'Company X, London' is sufficient, once the company is easily identifiable using an internet search. The name of the company accompanied by a phone number, PO Box and/or e-mail address are considered acceptable. Where a product is being manufactured at a residential property, the full address is not required on the label but the company name should be accompanied by contact details as listed above. Reference to a web address with contact information is also considered acceptable.

6.2 Nominal weight or volume

A cosmetic product should display the nominal content at the time of packaging, given by weight or by volume. However the following products are exempt:

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

6.3 Date of minimum durability or period after opening

The date of minimum durability or period after opening (PAO) are assigned to a cosmetic product based on the outcomes of the stability study data (see section 4.4 above). A date of minimum durability (best before date) is required unless stability data indicating that the product has a shelf-life of more than 30 months can be produced. The period after opening refers to the time for which the product can be used once opened without any harm to the consumer. An open jar symbol is used to indicate 'the period' (Annex VIIIa of Directive 76/768/EEC). There are some exceptions where 'the period' is not required, and this should be justified in the Product Information File, for example, where the product is single use only, there is no physical opening or there is no risk of deterioration which could lead to a risk to the consumer.

6.4 Precautions for use

The conditions of use and warnings which must be printed on the label are generally related to the ingredient list. A search for each ingredient on the European Commission database, [CosIng](#), will give this information. The safety assessment should also address precautions which should appear on the label taking into account how the product is used and presented for use. For example, restricting a product to professional use only, see section 6.5.

6.5 Professional use only (if applicable)

The restriction to professional use ensures that certain products are used by a professional only. A professional is more familiar with the health risks of a specific substance or its concentration in the cosmetic product than a consumer and/or has more professional expertise in applying cosmetic products correctly on the consumer. For example, products intended to be applied to the nails or on the hair but which must not come into contact with the skin.

Where a restriction to professional use is required, it will be stated in Schedule 3 of S.I. No. 870 of 2004 (as amended) and should be taken into consideration in the safety assessment. A search for each ingredient on the [CosIng](#) database will give this information.

The restriction applies to cosmetic products which:

- contain certain substances or
- contain substances in a higher concentration than for general use or
- do not contain certain warnings which are obligatory when used by the consumer

6.6 Batch number for traceability

The batch number should be a unique identifier relating to the manufacture of a single batch allowing traceability of the cosmetic product. A product code or bar code does not constitute a batch number unless a new code is generated for each batch of product manufactured. It should be clear which code on the cosmetic product identifies the batch.

6.7 Product function

The function or instructions for use are required where they are not obvious from the way the product is presented. In some instances, instructions may be necessary to ensure that the cosmetic product is used correctly. For example, a mouthwash product may require instructions such as 'rinse around teeth and gums for 30 seconds, then spit out'.

6.8 List of ingredients

A full list of ingredients must be given on the outer packaging headed or preceded by the word 'INGREDIENTS'. An exception applies where it is impractical to label the product with a list of ingredients due to size or shape. In such cases, the product may refer to the ingredients being on display at retail level. The open book symbol (Annex VIII of Directive 76/768/EEC) can be used to indicate that the information is given elsewhere.

The name given in the Common Ingredients Nomenclature known as the INCI name (International Nomenclature for Cosmetic Ingredients) should be used to list ingredients. The ingredients should be listed in decreasing order of weight.

6.9 A suitable language

English and Irish are considered suitable languages for labelling of cosmetic products on the Irish market.

7. NOTIFICATION

The Cosmetic Products Directive 76/768/EEC and related S.I. No. 870 of 2004 requires the Responsible Person to notify the Competent Authority of the address of the place of manufacture, or of the place of initial importation into the Community, of that cosmetic product before its first sale or supply in the Community. For further information on the procedures for notification to the IMB please refer to the IMB's '[Guide to Notification of a Cosmetic Product](#)'.

The National Poisons Information Centre has been appointed as the body responsible for receiving emergency health response information relating to cosmetic products. The National Poisons Information Centre accepts the COLIPA/EAPCCT frame formulations for cosmetic products. Their website is: <http://www.poisons.ie/>.

8. FURTHER INFORMATION

For queries on the cosmetic product notification process, you may contact the Irish Medicines Board at the following address:

Compliance Department,
Irish Medicines Board,
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2.

Telephone: +353-1-6764971

Fax: +353-1-6764061

E-mail: cosmetics@imb.ie

Information is also available from the IMB website at www.imb.ie