

Guide to Cosmetic Products for Responsible Persons



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1 SCOPE

This document is designed to offer guidance to cosmetic product manufacturers, importers and any other designated parties in understanding their obligations when acting as the responsible person (RP) as described in Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

A 'cosmetic product' means 'any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours'. This definition is quite specific and does not encompass products presented as having properties for treating or preventing disease in human beings. Such activities are more in keeping with medicinal product intent.

2 INTRODUCTION

The role of the HPRA, as the competent authority for cosmetic products, is to ensure that all cosmetic products on the Irish market meet the requirements of the cosmetic product legislation and in doing so, do not compromise the health and safety of the consumer and any other person using or coming into contact with such products. For example, products for professional use expose both the professional and the client to the cosmetic product.

Regulation (EC) No. 1223/2009 is the primary legislation governing the area of cosmetics in Europe. It was published in the Official Journal of the European Union, Volume 52, on 22 December 2009 and applies in full from 11 July 2013.

The aim of the cosmetics Regulation is to safeguard public health, with due regard to the welfare of animals, and to harmonise the rules in the European Economic Area (EEA) to achieve a single market for cosmetic products.

3 THE RESPONSIBLE PERSON

There must be a designated RP nominated for each cosmetic product placed on the market within the EEA. Regulation (EC) No. 1223/2009 details the responsibilities of the RP in Article 4. In general, the RP for a cosmetic product is one of the following:

- If the product is manufactured within the EEA, the manufacturer established within the EEA is considered the RP.

- If the manufacturer is established outside the EEA, the importer established within the EEA acts in the capacity of RP.
- If the manufacturer or importer within the EEA designates another party within the EEA to act as the RP, this designation and the acceptance of the role by the RP must be formally set out in writing.
- If a distributor of a cosmetic product (any natural or legal person in the supply chain, other than the manufacturer or the importer that makes the product available for sale in the EEA) modifies a cosmetic product in a way which compromises its compliance with the legislation and/or markets a cosmetic product under its name or trademark, the distributor takes on the role of RP.

The RP must always be based within the EEA and their address should appear on the cosmetic labelling. Importers are advised to contact their suppliers to establish if there is an existing RP for the product in question. If there is no such existing RP then that importer must become the RP or designate an RP in order to place the product on the market in the EEA.

4 THE PRODUCT INFORMATION FILE

Prior to placing a cosmetic product on the EEA market, one of the responsibilities of the RP is to prepare a product information file (PIF). This file should be maintained throughout the life cycle of the cosmetic product. The RP must maintain this PIF at its address which appears on the label of the cosmetic product. In the event a cosmetic product is no longer to be placed on the EEA market, the PIF must be kept for a period of 10 years following the date on which the last batch of cosmetic product was placed on the market.

The information that must be contained within the PIF is outlined in this section and in section 5 below.

4.1 Product description

Each product must be described in a way that clearly attributes the PIF to the cosmetic product; it is recommended that a product or formulation code is assigned. During the notification process (see section 13) a CPNP (Cosmetic Product Notification Portal) number is automatically assigned; this number may be used to identify the cosmetic product to which the PIF applies.

4.2 Cosmetic Product Safety Report

The cosmetic product safety report consists of detailed product safety information and an assessment conducted by a suitably qualified person. See section 5 for further information.

4.3 Method of manufacture

A brief overview of the method of manufacture and a declaration of compliance with good manufacturing practices (GMP) should be included in the PIF. See section 6 for further information.

4.4 Label claims and proof of effect

[Commission Regulation \(EU\) No. 655/2013](#) lays down common criteria for the justification of claims used in relation to cosmetic products. Guidelines on this Regulation are available on the [European Commission's website](#).

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 European Commission plans to publish a Regulation on label claims in the near future. There are a number of methods that can be used to substantiate label claims, as outlined below.

4.4.1 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, data should ensure that the ingredient is effective at the concentration present in the finished product and that its activity is maintained in the product.

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 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 which can accurately 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 adhere to ethical guidelines and products tested should have previously undergone a safety assessment (see section 5). For further information, refer to the World Health Organisation's [Handbook for good clinical research practice \(GCP\)](#) and/or the World Medical Association's [Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects](#).

4.4.2 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, borderline claims with other classes of products must be considered carefully. The European Commission has published a number of guidance documents which are available on their [website](#). Medicinal products and biocidal products are examples of classes which can commonly have a border with cosmetics.

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 render the product a medicinal product. For more information on medicinal claims, refer to the 'Guide to the definition of a human medicine'. Please see the 'Publications and Forms' section of www.hpra.ie.

Biocidal claims

For further information on consumer products which potentially may be considered within the borderline category 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](#).

4.5 Data on animal testing

A ban on testing finished cosmetic products on animals has been applied since 2004. A similar testing ban on ingredients or combinations of ingredients has been applied since 2009 where alternative validated methods to animal testing have been available. A marketing ban on finished products or ingredients tested on animals, where alternative methods are available, was imposed in 2009.

As of 11 March 2013, a ban on all animal testing of finished products and ingredients applies, even if there are no alternative non-animal tests. The Scientific Committee on Consumer Safety outlines available alternative validated methods to animal testing ([SCCS safety testing guidelines](#)).

Data on any animal testing performed by the manufacturer, agents or suppliers and any animal testing performed to meet the regulatory requirements of third countries should be

included in the PIF. Where no animal testing has been conducted a statement indicating this should be included in the PIF. Therefore, where an animal test has been performed, the following information should be contained within the PIF:

- identification of the animal test carried out
- identification of the ingredient tested
- date of the animal test
- location of the animal test
- information on the entity (or entities) that carried out the test and the entity that commissioned it
- legislative purpose of the animal test and substantiation of the stated purpose

In the case of the last point, a clear reference to the legislation in question, a short description of the scope and of the need for the testing under that legislation should be included. Substantiation of the stated legislated purpose can also take the form of the listing of the respective ingredient under other legislation (e.g. in a positive list) and it can be demonstrated by labels of products including the respective ingredient.

5 THE COSMETIC PRODUCT SAFETY REPORT

The safety assessment is an account of the scientific reasoning to support the safety of the cosmetic product. A safety assessment should be conducted by a suitably qualified natural person who may be a consultant or an employee. The name, address and qualifications of the safety assessor must be maintained in the safety report.

The SCCS notes of guidance for testing of cosmetic substances and their safety evaluation offers guidance on the safety evaluation of cosmetic products. In addition the European Commission has published guidance on how to comply with the requirements of Annex I (the Cosmetic Product Safety Report) of Regulation (EC) No. 1223/2009. These guidelines are available on the [European Commission's website](#).

The RP and safety assessor should work closely together to ensure that the safety of the product is properly assessed, documented and kept up-to-date. The RP should ensure that the safety assessment is conducted to an appropriate level to demonstrate that the product is safe.

It is recommended that the RP put in place a technical agreement or contract with its safety assessor outlining the roles and responsibilities of the safety assessor in relation to the following (this list is not exhaustive):

- access to all the technical and scientific skills necessary
- access to safety information
- ongoing review and updates to the cosmetic product safety report
- information on serious undesirable effects (SUEs)

It may be necessary to involve the suppliers of raw materials, and other technical experts to fully evaluate the safety of the cosmetic product. It is not considered sufficient to evaluate each of the ingredients in isolation; the product formulation should also be evaluated taking into consideration possible interaction between ingredients.

A specific safety assessment should be carried out for cosmetic products intended for use on children under the age of three. The physiological, metabolic and behavioural characteristics of infants should be taken into account, such as the fact that the skin surface of infants and children relative to their body weight is larger than in adults. When assessing the safety of cosmetic products intended for infants, attention should be paid to possible toxicological effects on the nervous, immune, respiratory and endocrine systems. Further information is available in '[Safe Cosmetics for Young Children – A Guide for Manufacturers and Safety Assessors](#)'.

6 GOOD MANUFACTURING PRACTICES

Regulation (EC) No. 1223/2009 Article 8 establishes [ISO 22716](#) or equivalent as the requirements for good manufacturing practice (GMP).

ISO 22716 is the GMP standard and provides organisational and technical guidance on the management of the human, technical and administrative factors affecting cosmetic product manufacture and product quality.

The documentation system implemented should incorporate the following (this list is not exhaustive):

- 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 PIF. This document should include the formulation for the product and detailed manufacturing operations for each stage, such as details of equipment used, addition of raw materials, mixing speed and time requirements, details of any critical parameters and in-process controls, details of any specific temperature/humidity requirements, packaging instructions, labelling requirements etc.

Appropriate GMP training should be provided to all relevant personnel during induction training and periodically thereafter. A personal hygiene programme should be established for all personnel to avoid contamination.

The manufacturing premises and equipment utilised should ensure protection of the product, efficient cleaning and minimise the risk of mix-ups, or cross-contamination.

When purchasing ingredients 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 and temperatures should be monitored as required.

Packaging activities should be documented and sufficient checks performed to minimise the risk of mix-ups.

Finished products should meet the defined acceptance criteria. Specifications should be established outlining the requirements to be met for raw materials, packaging materials, bulk and finished products (see section 4).

7 CONSUMER INFORMATION

The following information should be made available to the public on request but does not have to be published:

- qualitative and quantitative list of ingredients
- data on undesirable effects

Further information on the communication of consumer information is available on the [European Commission website](#).

8 COMMUNICATION OF SERIOUS UNDESIRABLE EFFECTS

Regulation (EC) No. 1223/2009 is the basis for a uniform approach to the communication of serious undesirable effects (SUEs) attributable to the use of cosmetics. It provides for notification of SUEs to the Competent Authorities of the Member State where the undesirable

effect occurred, without delay, as well as the notification of any corrective measures taken by the RP or distributor.

In order to facilitate the implementation of a harmonised communication and management system on SUEs throughout the EU, [SUE Reporting Guidelines](#) were developed.

9 TRACEABILITY WITHIN THE SUPPLY CHAIN

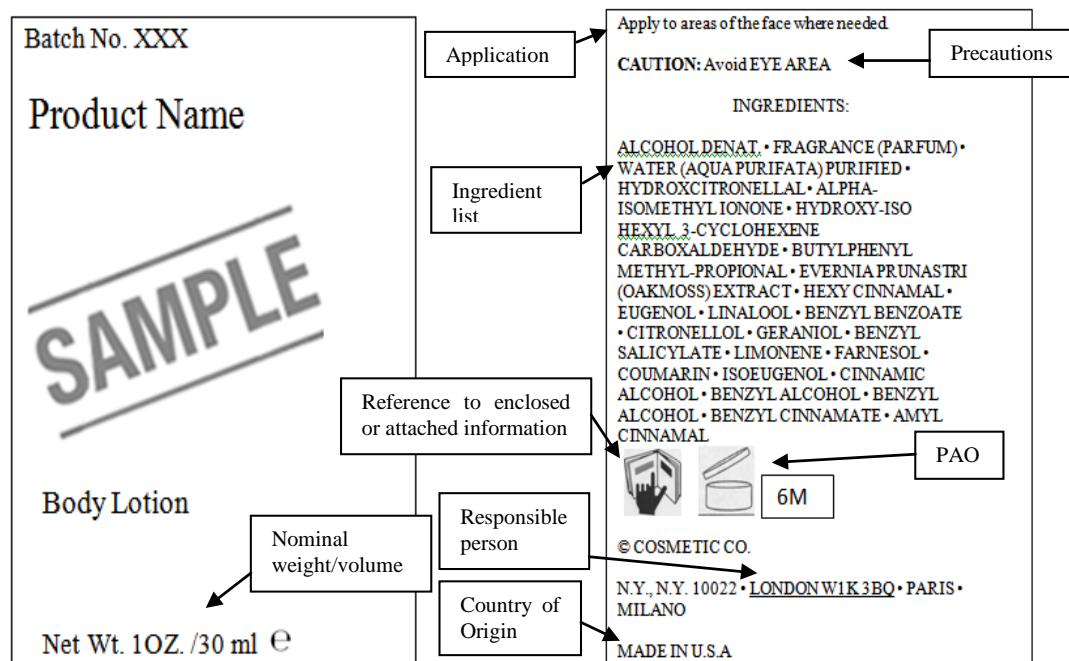
Traceability of a cosmetic product throughout the entire supply chain is necessary, owing to the free movement of goods within the EEA. Accordingly, the RP should keep records of the distributors (including retailers) they supply, including contact details and dates of supply. In turn, distributors should document who they receive a cosmetic product from i.e. their suppliers, and details of all operators to whom they supply.

Good systems of traceability will make market surveillance more efficient and this has benefits to the free movement of goods. For example, a consignment of cosmetic product may be detained by market surveillance authorities whilst they identify the economic operators involved. An efficient traceability system facilitates the task of tracing economic operators and thereby speeds up the entire process resulting in the prompt release of the consignment to the market.

This obligation with respect to identification within the supply chain must be met for three years after each batch of product was made available to the distributor. Further information is available in the HPRA's 'Guide to Distribution of Cosmetic Products in Ireland'.

10 LABELLING

All cosmetic products are required to be appropriately labelled. An example of cosmetic product labelling is given below. It should be noted that not all of the items depicted are obligatory; further guidance is provided below.



10.1 Name and address of the RP (EEA Address)

Article 19 of Regulation (EC) No 1223/2009 stipulates that the name and address of the responsible person must be on the container and packaging of the cosmetic product. The cosmetics legislation allows for the address to be abbreviated. 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. Where there is more than one address on the product label, the address at which the PIF is located should be indicated (usually by underlining the address).

10.2 Nominal weight or volume

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

- 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.

10.3 Date of minimum durability or period after opening

The date of minimum durability or period after opening (PAO) is assigned to a cosmetic product and must be supported by stability study data. A date of minimum durability (best before date) is required unless stability data indicate that the product is stable for more than 30 months. The PAO refers to the time within which the product may be used, once opened by 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 PIF, for example, if 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.

10.4 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 information on warnings. The safety assessment should also identify precautions which should appear on the label taking into account the product's method of use and presentation, for example, restricting a product to professional use only (see section 10.5).

10.5 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 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 Annex III of Regulation 1223/2009 (as amended) and should be taken into consideration in the safety assessment. A search for each ingredient on the [CosIng](#) database will provide 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.

10.6 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 barcode 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.

10.7 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'.

10.8 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 if 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 VII of Regulation 1223/2009) 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.

10.9 Suitable languages

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

11 SAMPLING AND ANALYSIS

Quality control checks including sampling and analysis must be performed in a reliable and reproducible manner. A number of test methods are provided in Commission Directives 80/1335/EEC, 82/434/EEC, 83/14/EEC, 85/490/EEC, 93/73/EEC, 95/32/EC & 96/45/EC. In the absence of a legislative method, test methods are presumed reliable and reproducible if they are in compliance with the relevant ISO or CEN standards.

12 NON-COMPLIANT PRODUCT

In the event of a non-compliance being identified, the RP must take all appropriate measures to bring the product into conformity. If a cosmetic product poses a risk to consumers, measures must be taken to prevent risk to the consumer, such as adequate and effective warning of the risk to consumers, recall of the product or affected batch from consumers or withdrawal of the product from the market. Market action including recall and withdrawal should take place when other measures are not considered adequate to prevent the risk to the consumer. Where a decision is taken by the RP to take market action on the Irish market, the HPRA should be informed by contacting cosmetics@hpra.ie.

12.1 Corrective and preventative actions

Corrective actions required to address non-compliance(s) can vary in terms of severity. Measures taken to bring the product into conformity may include but are not limited to:

- Re-labelling or over-labelling
- Marketing the product with appropriate warnings
- Making the marketing of the product subject to prior conditions
- Reformulation

The PIF should be updated to reflect any changes made to the product. Substantial changes such as reformulation generally require a new PIF.

12.2 Recalls and product withdrawals

There should be established written procedures, regularly checked and updated as required, in order to organise any recall or withdrawal activity. For further information refer to [ISO 22716](#) and HPRA's 'Guide to Distribution of Cosmetic Products in Ireland'.

13 NOTIFICATION

Prior to placing on the market the RP must notify the cosmetic product to the European Commission (EC). The EC launched the Cosmetic Product Notification Portal (CPNP) in January 2012. This is a centralised database for the notification of cosmetic products which replaces national notification requirements. Further information on the CPNP is available on the [European Commission website](#).

The information submitted by RPs (and in some cases distributors) via the CPNP is made available electronically to the Competent Authorities (for the purposes of market surveillance, market analysis, evaluation and consumer information) and to the Poison Centres (for the purposes of medical treatment). The National Poisons Information Centre has been appointed as the body responsible for receiving emergency health response information relating to cosmetic products. For further information on the National Poisons Information Centre visit their [website](#).

14 FURTHER INFORMATION

Further guidance on cosmetic products is available on our website www.hpra.ie, under the 'Publications and Forms' section. For queries relating to the responsible person for cosmetic products, you may contact the Health Products Regulatory Authority at the following address:

Compliance Department
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