
 <b>MCCAA</b> MALTA COMPETITION AND CONSUMER AFFAIRS AUTHORITY	<b>REGULATORY AFFAIRS DIRECTORATE TECHNICAL REGULATIONS DIVISION MALTA COMPETITION AND CONSUMER AFFAIRS AUTHORITY</b>
<b>TRD-G-152/Rev. 0</b>	<b>RAD Guidance Document</b>

# GUIDANCE NOTES ON COSMETIC PRODUCTS

Cosmetic Product Regulations  
*L.N. 424 of 2004 (as amended)*




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## 1. Introduction

[Council Directive 76/768 of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products \("Cosmetics Directive"\)](#) has been adopted in 1976 in order to ensure the free circulation of cosmetic products in the internal market and to ensure the safety of cosmetic products placed on it. Since its adoption, the Cosmetics Directive has been amended by the European legislators seven times in order to reflect new trends and challenges concerning cosmetic products. For example, the "sixth amendment" led to the adoption of the [inventory of ingredients](#) used in cosmetic products and introduced the principle of marketing ban in relation to tests on animals. The "seventh amendment" provided inter alia for more detailed provisions on the phasing out of [animal testing](#) and introduced the ["period-after-opening labelling"](#).

Apart from these so-called 'amendments', the Commission has adopted more than fifty 'adaptations' in order to adapt to technical progress the provisions in the annexes to the Cosmetics Directive to technical progress. In order to provide guidance to Member State authorities, industry, and other stakeholders on the interpretation of various provisions of the Cosmetics Directive, a number of [guidance documents](#), for example on [borderline-products](#), have been adopted in close cooperation with the Member State authorities.

The [Cosmetics Products Regulations](#), as per Legal Notice 424 of 2004 (as amended), is the latest piece of Maltese legislation that transposes Directive 76/768/EEC.

## 2. Notification


Any cosmetic manufacturer/importer that places a cosmetic product for the first time on the market within the European Community shall notify the product with the Regulatory Affairs Directorate within the Technical Regulations Division of the Malta Competition and Consumer Affairs Authority (MCCAA). The responsible person is obliged to duly fill and sign the [Cosmetic Product Registration Form](#) (TRD-601/Rev.0) and to submit this form to the authority together with the original (or copy) label of the product. Any additional information may be requested depending on a case by case basis. The Product Information File of each cosmetic product, as per paragraph 7 of the [Cosmetic Products Regulations](#) should be made available upon request.

The cosmetic product is only notified if the label complies with the cosmetics regulations and all the requested information is submitted to the authority. Notifications issued by the authority do not constitute an approval of the cosmetic product. The responsibility for the safety of the product lies always on the person placing on the market the cosmetic product.

The notification fee per product is 40 euros.

Such notification shall not be necessary in the case of products which have already been placed on the market within the European Community and are according to LN 424 of 2004 (as amended) transposing the European Cosmetics Directive No. 76/768/EEC.

The above notification procedure should be followed until 11 July 2013, the date of entry into force of the new [Cosmetics Regulation \(EC\) No. 1223/2009](#). This EU Regulation will directly implement in all EU Member States a new notification procedure and the use of frame formulations for the notification of cosmetic product information. The European Commission will officially launch the Cosmetics Products Notifications Portal (CPNP) in January 2012.

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### 3. Legal Requirements for Cosmetics

First of all the notifier needs to decide whether the product falls within the definition of a cosmetic product, as given in the legislation:

*“any substance or mixture intended to be placed in contact with the various 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 and/or correcting body odours and/or protecting them or keeping them in good condition.”*

Example: normal toothpaste is intended to be used in contact with the teeth and is intended to clean the teeth, thus it falls within the definition of a Cosmetic. On the other hand if there is toothpaste that is primarily intended to treat a dental condition or the labelling of the product contains health related claims, this would not fall within the definition of a cosmetic product.

### 4. Labelling

All cosmetic, toiletry and perfumery products that are to be placed on the EU market need to have full ingredient labelling. The aim of this is to ensure that consumers and health professionals are given clear information about ingredients in the cosmetic products they or their clients use or may wish to purchase.

Cosmetic products may be marketed only if the **container and packaging bear the following information** in indelible, easily legible and visible lettering:


(a) the name or style and the address or registered office of the manufacturer or the person responsible for marketing the cosmetic product who is established within the Community. Such information may be abbreviated in so far as the abbreviation makes it generally possible to identify the undertaking. The country of origin shall be specified for goods manufactured outside the Community;

(b) the nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five millilitres, free samples and single-application packs; for pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging. This information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually;

(c) the date of minimum durability shall be indicated by the words: ‘best used before the end of’ followed by either:

- the date itself, or
- details of where it appears on the packaging.

The date shall be clearly expressed and shall consist of either the month and year or the day, month and year in that order. If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

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Indication of the date of durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product can be used without any harm to the consumer. This information shall be indicated by Fig. 1 followed by the period (in months and/or years). It may be indicated by a number followed by the full word "month" or, for example by the abbreviation "M", the letter "M" standing for "Menses" (i.e. months in Latin). The "period after opening" needs to be printed on primary and secondary packaging (i.e. the container and its carton if any);




**Figure 1**

(e) a list of ingredients in descending order of weight at the time they are added. That list shall be preceded by the word 'ingredients'. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %. The ingredients may be indicated on the packaging alone. Where that is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain the ingredients to which the consumer is referred either by abbreviated information or Fig. 2 which must appear on the packaging. In the case of soap, bath balls and other small products where it is impracticable, for reasons of size or shape, for the ingredients to appear on a label, tag, etc. they shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.



**Figure 2**

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(f) the function of the product, unless it is clear from the presentation of the product;

(g) particular precautions to be observed in use, especially those listed in the column 'Conditions of use and warnings which must be printed on the label' in the Third, Fourth, Fifth and Sixth Schedules, which must appear on the container and packaging, as well as any special precautionary information on cosmetic products for professional use, in particular in hairdressing. Where this is impossible for practical reasons, an enclosed leaflet, label, tape or card must contain that information to which the consumer is referred either by abbreviated information or Fig. 2, which must appear on the container and the packaging;

**Language requirements:** The particular precautions and function of the product should be present on the label in English and/or Maltese while for the other information there are no language requirements.

**Misleading consumers:** In the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs cannot be used to imply that these products have characteristics which they do not have.

**Animal Testing:** The manufacturer or the person responsible for placing the product on the Community market may take advantage, on the product packaging or in any document, notice, label, ring or collar accompanying or referring to the product, 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.


## 5. Period After Opening Symbol

The period after opening must be labelled when after its opening, the deterioration of the product may lead to harm to the consumer. The deterioration may be linked to the deleterious effect of micro-organisms and/or physico-chemical degradation that would lead to harm to the consumer or the decrease of efficacy when the modification of the efficacy can affect the safety of the product according to human health (e.g. U.V protection of sun products).

Examples of sources of information for assessing a product's PaO may include:

- microbiological challenge tests
- stability data
- analytical data (e.g. preservative analysis)
- type of packaging
- experience with similar formulations and products
- consumer habits and practices.

The opening of the product may be considered as occurring when the consumer opens the product for use for the first time. Anyway, in the case of products sensitive to deterioration by micro-organisms, the person responsible for placing the product on the Community market should consider measures to avoid the opening of the product before it reaches the final consumer.


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The mention of the period after opening seems not to be relevant when there is:

- a. 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. *sealed* pressurised containers);
- b. no period after opening as is the case for single-use products, which are designed to be used only once; and
- c. no risk of harm to the consumer, as there is no risk of deterioration that could lead to, as established in the cosmetic regulations.

## 6. Ingredients

1. All ingredients have to be listed on the label, whatever their concentration is, however there are some exceptions:
  - Impurities in the raw materials used, subsidiary technical materials used in the preparation but not present in the final product or materials used in strictly necessary quantities as solvents or as carriers for perfume and aromatic compositions shall not be regarded as ingredients.
  - Perfumes, aromatic compositions and their raw materials should not be written on the label as they only should be referred to as '*parfum*' or '*aroma*'. However for 26 entries (from 67 to 92), their presence should also be mentioned, in addition to the generic mention of '*parfum*' or '*aroma*', when it is specified under the relevant entries in the Third Schedule of the cosmetics regulations. This requirement is linked with presence limit of the substance in the product (limit of 0.001 % in leave-on products and of 0.01 % in rinse-off products). It concerns the use of those substances as perfumes, aromatic compositions and their raw materials in order to avoid that only the generic mention '*parfum*' or '*aroma*' for this type of use is mentioned.
  - The same logic applies for cases where ingredients are not supposed to be labelled. It is the case for substances which are parts of a mixture (for example botanical extracts and essential oils). Their presence should be mentioned when it is specified under the relevant entries of the Third Schedule to the cosmetics regulations. This requirement is again linked with presence limit of the substance in the product. It concerns the presence of those substances in mixtures in order to avoid that only the name of the mixture is mentioned.
2. Colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination adopted in the Fourth Schedule. For decorative cosmetic products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the words 'may contain' or the symbol '+/-' are added.
3. In order to facilitate the free movement of goods within the EU internal market a system of ingredient labelling was developed, and this was called the International Nomenclature for Cosmetic Ingredients (INCI). INCI is a common nomenclature for each ingredient used in a cosmetic product and is independent of language. It has been developed by the European and American cosmetic industries. Under INCI, plant materials are listed according to the internationally agreed nomenclature known as the Linné system, for example *Centella asiatica*.

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*Examples of INCI names:*

	INCI
Water	Aqua
Bees Wax	Cera alba
Glycerol	Glycerin
Trolamine	Triethanolamine

The names and regulatory information concerning the ingredients can be searched on the CosIng website <http://ec.europa.eu/consumers/cosmetics/cosing/>. You can choose to search either in the Cosmetics Directive or in the Cosmetics Regulation. Please notice, that the annexes for the Regulation are not yet complete.

Please note that ingredients assigned with an INCI name which appear in CosIng (Inventory Section) are not necessarily actually used in cosmetic products nor are they approved for such use. For ingredients used in cosmetic products as colorants, preservatives and UV filters, only those authorized in Annexes IV, VI, respectively VII to Directive 76/768/EEC are listed in CosIng.

In addition, CosIng may contain ingredients known to be used in medicinal products. If, due to such ingredients, a product restores, corrects, or modifies physiological functions by exerting a pharmacological, immunological or metabolic action, the product shall be qualified as a medicinal product. However, products that, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions, may be qualified as cosmetic products.

## 7. Animal Testing


The Cosmetics Directive establishes a prohibition to test finished cosmetic products and cosmetic ingredients on animals (testing ban), and a prohibition to market in the European Community, finished cosmetic products and ingredients included in cosmetic products which were tested on animals (marketing ban).

The testing ban on finished cosmetic products applies since 11 September 2004 while the testing ban on ingredients or combination of ingredients applies since 11 March 2009.

The marketing ban applies since 11 March 2009 for all human health effects with the exception of repeated-dose toxicity, reproductive toxicity and toxicokinetics. For these specific health effects the marketing ban will apply step by step as soon as alternative methods are validated and adopted in EU legislation with due regard to the OECD validation process, but with a maximum cut-off date of 10 years after entry into force of the Directive, i.e., 11 March 2013, irrespective of the availability of alternative non-animal tests.

*Review of the 2013 Implementation Deadline of the Marketing Ban:* During 2011 the Commission is analyzing whether for technical reasons one or more of the tests referred to in Article 4a 2.1 (repeated-dose toxicity, reproductive toxicity and toxicokinetics) will not be developed and validated before March 2013.

In order to establish the availability of alternatives by 2013 the Technical Report "*Alternative (non-*

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*animal) Methods for Cosmetics Testing: Current Status and Future Prospects - 2010'* has been elaborated by a group of experts.

[http://ec.europa.eu/consumers/sectors/cosmetics/documents/animal-testing/index\\_en.htm](http://ec.europa.eu/consumers/sectors/cosmetics/documents/animal-testing/index_en.htm)


In order to decide whether or not a legislative proposal should be made the Commission is working on an impact assessment. To this end it has carried out a targeted stakeholder consultation between 7 December 2010 and 15 April 2011.

[http://ec.europa.eu/consumers/sectors/cosmetics/documents/animal-testing/stakeholders\\_consultation\\_en.htm](http://ec.europa.eu/consumers/sectors/cosmetics/documents/animal-testing/stakeholders_consultation_en.htm)

## 8. Product Information File

The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the following information (in English or Maltese or Italian) readily accessible to the competent authority at a specified address:

- (a) the qualitative and quantitative composition of the product; in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier;
- (b) the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product;
- (c) the method of manufacture complying with the good manufacturing practice. The person responsible for manufacture or first importation into the Community must possess an appropriate level of professional qualification or experience;
- (d) assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredients (which can be generally obtained from the Safety Data Sheet, although further data may sometimes be necessary), their chemical structure and their level of exposure. It shall take particular account of the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended. There shall also be a specific assessment 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.
- (e) the name and address of the qualified person or persons responsible for the assessment referred to in (d). That person must hold a diploma as defined in Article 1 of Directive 89/48/EEC in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline;
- (f) existing data on undesirable effects on human health resulting from use of the cosmetic product;
- (g) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product;


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(h) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety evaluation of the product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of non-member countries.


Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be available. In this connection, and when so requested for monitoring purposes, it shall be obliged to indicate the place so chosen to the monitoring authority or authorities concerned.

## 9. Annexes and Schedules

	Legal Notice 424/2004	Cosmetics Directive 76/768/EEC
<b>Illustrative list by category of cosmetic products</b>  <i>Non-exhaustive list of cosmetic products grouped by category; this gives an indication of what products are thought to fall within the definition of a cosmetic product.</i>	First Schedule	Annex I
<b>List of substances which must not form part of the composition of cosmetic products</b>  <i>List of substances that are banned from forming part of a cosmetic product; these could be medicinal substances, substances that are classified as carcinogenic, etc.</i>	Second Schedule	Annex II
<b>List of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down</b>  <i>List of substances which are not allowed to be present in the cosmetic except subject to restrictions and conditions found in the schedule/annex. For example, d-limonene is not allowed to be used in the product at concentrations above 0.001% in leave-on products and 0.01% in rinse-off products unless the presence of this substance is specifically indicated in the label, this is because d-limonene is known to cause allergies.</i>	Third Schedule Part 1	Annex III Part 1
<b>List of substances provisionally allowed</b>  <i>List of substances which are provisionally allowed to be used, provided that the conditions of the schedule/annex are followed with.</i>	Third Schedule Part 2	Annex III Part 2
<b>List of colouring agents allowed for use in cosmetic products</b>  <i>List of colouring agents that are allowed to be used in cosmetic products.</i>	Fourth Schedule	Annex IV

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<b>List of preservatives which cosmetic products may contain</b>  <i>List of allowed preservatives.</i>		Fifth Schedule	Annex VI
<b>List of UV filters which cosmetic products may contain</b>  <i>List of allowed UV-filters.</i>		Sixth Schedule	Annex VII
<b>Symbols to be used</b>	<b>Reference to enclosed or attached information pictogram</b>  <i>Symbol that has to be used when there is information available which is not found on the label.</i>	Seventh Schedule	Annex VIII
	<b>Symbol indicating the durability of cosmetic products</b>  <i>Symbol to be used for the period after opening requirement for those products that have a durability date greater than 30 months and when the deterioration after the opening of the product may lead to harm to the consumer.</i>	Ninth Schedule	Annex VIIIa
<b>Methods of Analysis necessary for checking the composition of cosmetic products</b>  <i>List of testing methods that have to be used for checking the composition of a cosmetic product.</i>		Eight Schedule	
<b>List of validated alternative methods to animal testing</b>  <i>List of validated alternative methods.</i>		Tenth Schedule	Annex IX

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## 10. The New Cosmetic Products Regulation

On 30 November 2009, the new Cosmetic Products Regulation, [EU Regulation 1223/2009](#), replacing the Cosmetics Directive, was adopted.

With the new Cosmetics Regulation, Europe is having a robust, internationally recognised regime, which reinforces product safety taking into consideration the latest technological developments, including the possible use of nanomaterials.

The regulation simplifies the rules and procedures for the marketing and safety of cosmetics by grouping the existing 55 directives and more into a single regulation. The regulation represents a common European code of law on cosmetic products, reducing the uncertainties arising from differentiated implementation of the previous directives in the 27 member states.

The regulation will enable more streamlined Europe-wide procedures and safety rules, thereby reducing administrative burdens and costs. Consumers will benefit through the uniform application of rules, the enhanced coordination of market surveillance activities as well as the increased responsibilities placed on economic operators with a view to ensuring a higher level of consumer protection, notably with the introduction of a product information file.

Most of the provisions of this new regulation will be applicable as from 11 July 2013. The ban and the strict regime aiming at phasing out animal testing were not modified.