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Cosmetic products: learning to read labels

Reading the labels of cosmetic products often proves difficult as mandatory labelling information is mixed with non-obligatory and sometimes misleading data, which is included on the labels according to the manufacturer's wishes. This article aims at clarifying the labelling information provided for by the new European Regulation on cosmetic products that will come into effect in 2013 and on the non-regulated but frequently seen information on the packaging of cosmetic products.

Key words: cosmetic products, European Union, glossary of common ingredient names, ingredients, labelling, regulation

Understanding the labelling of cosmetic products often proves difficult as mandatory labelling information is mixed with non-obligatory and sometimes misleading data which is included on the labels according to the manufacturer's wishes. In addition to the ingredients, the precise names of which are useful to know for allergic patients, we have to be able to decipher many other logos, symbols and information, so as to improve our knowledge of cosmetic products and be able to advise our patients as best we possibly can.

Mandatory and regulated labelling information on cosmetic products

On 30 November 2009, a new European Regulation on cosmetic products [1] was adopted. It repeals the former "Cosmetics" European directive. With this new "cosmetic products" regulation, the European Union will have strong, internationally recognised regulation, which enhances the safety of products (taking into account the latest technological developments, particularly nanomaterials). Most of the points of this new regulation will enter into force from 11 July 2013.

Statutory labelling

– **Mandatory information** (article 19 of the regulation)

Cosmetic products shall be made available on the market only where the container and packaging of cosmetic products bear the following information in indelible, easily legible and visible lettering:

a. the name or registered name and the address of the responsible person,

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,

c. the dates.

The date of minimal durability is the date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function. The date shall be either preceded by a symbol (*figure 1*, point 3) or the words "best used before the end of". The date of minimum

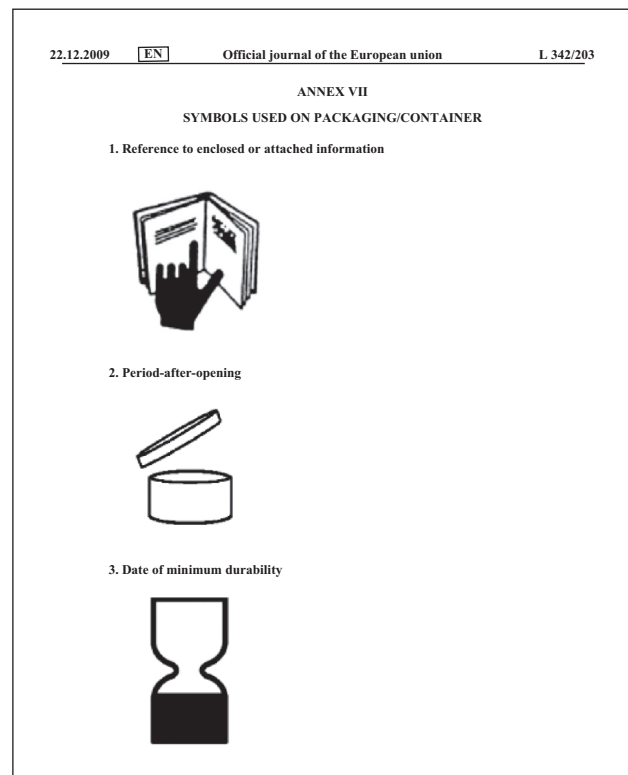


Figure 1. Mandatory symbols to be found on the packaging according to the new European Regulation on cosmetic products (Annexe VII).

durability 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. Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months.

The date of durability after opening. The products shall bear an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer. This information shall be indicated by a symbol (*figure 1*, point 2) followed by the period (in months and/or years),

d. particular precautions to be observed in use, and at least those listed in Annexes III to VI of the new cosmetic regulation (that is to say concerning substances subject to specific regulations, such as colouring agents, preservatives and UV-filters),

e. the batch number of manufacture or the reference for identifying the cosmetic product. Where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the packaging.

f. the function of the cosmetic product, unless it is clear from its presentation.

g. the list of ingredients.

This information may be indicated on the packaging alone. The list shall be preceded by the term “ingredients”. An “ingredient” means any substance or mixture intentionally used in the cosmetic product during the process of manufacturing.

The following shall not, however, be regarded as ingredients:

- impurities in the raw materials used,
- subsidiary technical materials used in the mixture but not present in the final product.

The ingredients appear under their common names set out in the *Glossary of common ingredients names* (see below). The list of ingredients shall be established in *descending order of weight*. Ingredients in concentrations of less than 1% may be listed in any order after those in concentrations of more than 1%.

Perfume and aromatic compositions and their raw materials shall be referred to by the terms “perfume” or “aroma”. Moreover, the presence of substances, the mention of which is required under the column ‘Other’ in Annex III (26 fragrance allergens requiring mandatory labelling), shall be indicated in the list of ingredients in addition to the terms “perfume” or “aroma”.

All ingredients present in the form of *nanomaterials* shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word [nano] in brackets. Such is the great novelty of this Cosmetic European Regulation.

Where it is impossible for practical reasons to label the information on the precautions of use and ingredients, the following applies:

- the information shall be mentioned on an enclosed or attached leaflet, label, tape, tag or card,

– this information shall be referred to by abbreviated information or the symbol (*figure 1*, point 1), which must appear on the container or packaging.

In the case of small products, where it is impossible for practical reasons for the information on the ingredients to appear on a label, tag, tape or card or in an enclosed leaflet, this information shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale...

Particular points

The new European Cosmetic Regulation focuses on particular points.

Nanomaterials

The latest technological developments have been taken into account, including the possible use of nanomaterials.

It is necessary to develop a uniform definition of nanomaterials at an international level; a definition that should be adapted accordingly in the new regulation.

At present, there is inadequate information on the risks associated with nanomaterials. In order to better assess their safety the SCCS (Scientific Committee for Consumer Safety) should provide guidance on test methodologies which take into account specific characteristics of nanomaterials.

Moreover, it has been agreed that the Commission should regularly review the provisions on nanomaterials in the light of scientific progress.

Potential allergens

A number of substances have been identified by the SCCS as likely to cause allergic reactions and it is necessary to restrict their use and/or impose certain conditions concerning them. In order to ensure that consumers are adequately informed, the presence of these substances should be mentioned in the list of ingredients and consumers’ attention should be drawn to the presence of these ingredients. This information should improve the diagnosis of contact allergies among consumers and should enable them to avoid the use of cosmetic products which they do not tolerate.

For substances which are likely to cause allergy to a significant part of the population, other restrictive measures such as a ban or a restriction of concentration should be considered.

Alternative methods

They have been maintained and the Commission has confirmed the prohibition to market cosmetic products whose final formulation, ingredients or combination of ingredients have been tested on animals, with an established timetable of deadlines up to 11 March 2013.

- *Since 11 September 2004* : animal testing for finished cosmetic products, that is to say products in their final

formulation as placed on the market and made available to the end user, has been prohibited.

– *Since 11 March 2009*: animal testing has been prohibited on cosmetic ingredients or combinations of ingredients, to the exception of tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics.

For the latter, the final deadline is 11 March 2013.

Hence the necessity to develop alternative methods to animal testing validated at Community level, or approved as being scientifically validated by the European Centre for the Validation of Alternative Methods (ECVAM).

Now, it appears that alternative methods for toxicity testing will not be ready, even less validated, by 11 March 2013. Maintaining the prohibition as it is means that from 2013 onwards the industry will have to do without new non-tested ingredients, as no cosmetic product can be marketed without its toxic potential being assessed.

National and European Cosmetovigilance

Effective market surveillance is necessary in order to ensure that the provisions of this regulation are respected. The cosmetovigilance system is now well-known in France as it has existed for many years among fellow dermatologists with the REVIDAL-GERDA (French vigilance network for dermatology and allergy-French study and research group in dermatology and allergy) and was institutionalised by Afssaps (French Health Products Safety Agency) in 2004. This network enables the monitoring and recording of adverse side-effects due to the use of cosmetics, thus listing and centralising the information on these adverse effects with a view to preventing them more effectively.

The new European regulation on cosmetics is planning to extend the system to the whole of Europe and to enhance its efficiency through information exchange between the different Member States. In article 23, the regulation says that any serious undesirable effects should be reported to the competent authority of the Member State where the effect occurred, that a competent authority shall immediately transmit the information to the competent authorities of the other Member States. A clear and efficient procedure for the withdrawal and recall of products may be necessary. This procedure should, where possible, build upon existing Community rules for unsafe goods.

In order to address cosmetic products which might endanger human health, a safeguard procedure should be introduced.

Glossary of common ingredient names

In article 33 of the new European regulation, it is stated that the Commission shall compile and update a glossary of common ingredient names. To this end, the Commission shall take account of internationally recognised nomenclatures. The common ingredient name shall be applied for the purpose of labelling cosmetic products placed on the market at the latest twelve months after publication of the glossary in the Official Journal of the European Union.

The list of common ingredient names of the European glossary *remains as yet unknown* and the International

Nomenclature of Cosmetic Ingredients (INCI) applies. This nomenclature was established in 1973 and has been mandatory in Europe since 1998. The listing of all ingredients was first aimed at detecting allergenic products. The biggest inconvenient of this language is that it is utterly incomprehensible for consumers [2] and sometimes for doctors as well. In order to better understand this nomenclature, a few general rules have to be known

– *a Latin name* corresponds to an ingredient extracted from a plant. The Latin name of the plant is indicated. For example, *Myroxylon pereirae* is the name of the tree from which balsam of Peru is extracted and to which it gives its name in the INCI.

– *scientific names of molecules and common names* are most often in English. – *colouring agents* are given a “Colour Index” or *C.I.* (C.I. + 5 digit number). For example, C.I. 75810 is the code for chlorophyll used as a green colouring agent. Colouring agents may be listed randomly at the end of the ingredient list.

– *INCI names* are published in the International Cosmetic Ingredient Dictionary and Handbook and are recognised for labelling in the United States, the European Union and many other countries. In practice, the best database to use to find the chemical name of an INCI ingredient on a label is CosIng [3], the European Commission Cosmetic Ingredients database.

Non-regulated cosmetic labelling information

“...free” labels

These are increasingly frequently found on the packaging of cosmetic products. “Preservative-free”, “paraben-free”, “fragrance-free”... Whether it applies to one or several ingredients, the term “free” is in general conspicuous.

Non-regulated information

The regulation on cosmetic products does not mention nor regulate this type of information. Mentioning what such products do not contain depends on the manufacturer’s initiative and they shall be the responsible person. However, there may be some rare control by health services such as Afssaps or DGCCRF (General Directorate of Competition, Consumption and Fraud Repression) in France. Thus, during the 2nd and 3rd quarters of 2008, a joint survey by both services was carried out concerning cosmetic products marketed as “preservative free”. It showed that out of the 43 products they analysed, 13 contained compounds that are classified as preservatives in the International Nomenclature of Cosmetic Ingredients (INCI). Three of them were clearly cases of fraud as the percentages found in tests showed that these compounds had been voluntarily introduced as preservatives. For the other 10, the amounts detected were very low and were probably substances that had not been added by the manufacturers themselves but had been used as preservatives for the ingredients used. Nevertheless such preservatives were present in the finished product and the “preservative free” label could not be

considered as truthful. The same findings were observed in Denmark by the Environmental Protection Agency which published a report on the subject following a survey on 93 cosmetic products labelled as “preservative free” [4].

Does “free” imply “better” ?

Indirectly the “free” mention must be considered as a “plus”, thus it is a marketing argument as the ingredients of the “-free” list are generally considered by consumers as toxic on a human, animal or environmental level. Such is the reason why this label is often used for natural or organic cosmetic products. Its only interest is to help choose products with ingredients the consumer absolutely wants to avoid but it can be misleading for allergic patients, for example the “fragrance free” label on cosmetics containing essential oils [5].

“Not tested on animals”

Until the 2013 deadline, whether it is respected or not, animal testing of raw materials in cosmetic products, particularly regarding toxicity, is still allowed.

– A product with a “*finished cosmetic product not tested on animals*” label barely states it respects the regulation since this has been mandatory for all finished cosmetic products since 2004 (see above). This is not distinctive information as such as all manufacturers marketing in Europe must meet this requirement.

– Furthermore, the “*not tested on animals*” label is ambiguous as it does not state clearly what exactly is not tested. Is it only the finished product or does it also include its ingredients?

– It is to be noted that, today, cosmetic products whose final formula or ingredients are not tested on animals can be found on the market. In this case, it is mentioned on the packaging, either explicitly: “*formula and ingredients not tested on animals*” (extremely rare), or with the new label of the *One Voice association* that came out in June 2011 (figure 2, point 1). Moreover, this label prohibits any extracts or substances from animals and, and this is also new, will only be attributed to biological products in order to “highlight products that are harmless for the living and the planet” [6].

Organic/Bio labels

It is hard to find one’s way in the jungle of organic/bio labels. These labels are confusing for consumers who think that natural products, not derived from petrochemicals are harmless. In reality we know the allergenic or even toxic potential of plants. Moreover the eviction of ingredients deemed at risk (rightly or wrongly) does not mean they do not contain chemicals preservatives or antioxidants.

There is no French or European legislation concerning such labels or their equivalents (certified products) and the criteria vary greatly from one accreditation body to another. Thus can be found certifications from national private bodies such as Ecocert in France or private industrial labels

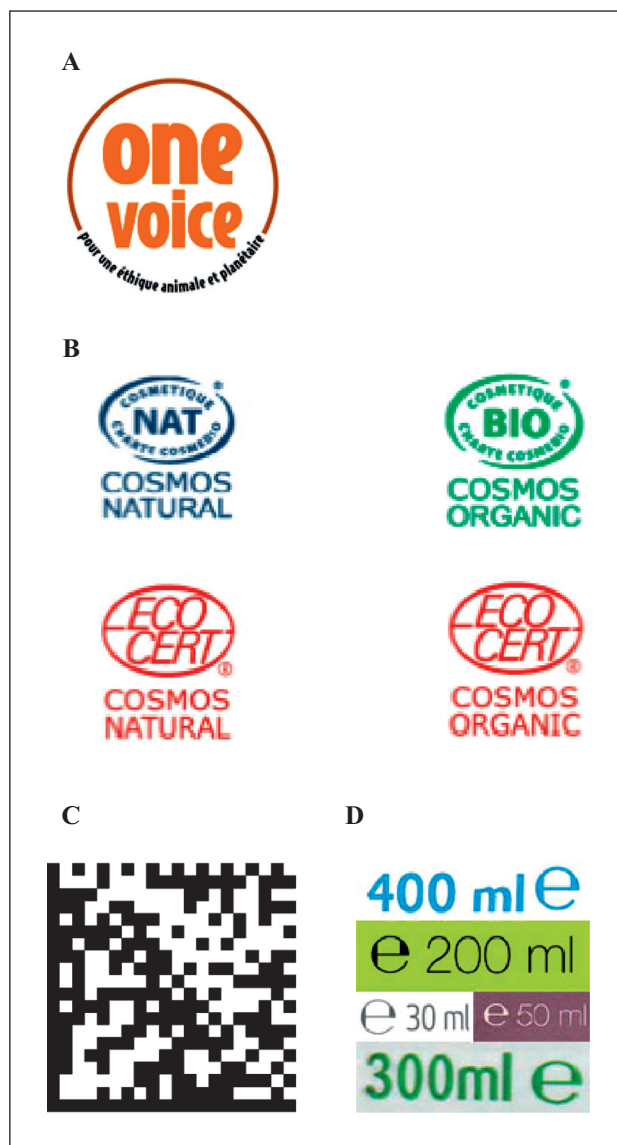


Figure 2. Miscellaneous logos. A) New One Voice logo. B) Examples of cosmos-standard logos (national signature and below cosmos organic or natural signature). C) Flashcode. D) e-mark.

with a European cooperation such as NaTrue. It is also important to be able to tell the difference between natural and organic labels – which indicate that the product is made from plants, animals or minerals... – from Ecolabels which concern “green” products, *i.e.* biodegradable and recyclable products. An attempt to achieve European harmonisation of private labels had been debated since 2002 and resulted in the publication of Cosmos-standard on 31 January 2011 [7]. The aim of Cosmos-standard is to set up higher requirements compared to the already existing national standards. It is based on a precautionary principle stating that “where there is scientific evidence that an ingredient, technology or process could pose a health problem or environmental risk”, it will not be allowed. Thus, nanomaterials, GMOs and irradiation are forbidden.

In order to calculate the percentages of organic ingredients in the product, Cosmos-standard classifies ingredients in

five categories (water, minerals and ingredients of mineral origin, physically processed agro-ingredients, chemically processed agro-ingredients and other ingredients) and each category is subject to specific requirements.

In practice, *nothing is going to change on the labels* as national logos will remain, only to be completed by a “Cosmos organic” or “Cosmos natural” terms depending on the degree of certification (*figure 2*, point 2). Notwithstanding this attempt, a unique and universal organic label is not yet a reality due to conflicts of interests that have led to the creation and use of other labels, particularly the NaTrue label.

“Under dermatological control”

It is found under different names on labels but whether it is referred to as “formula elaborated” or “tests carried out” “under dermatological control”, it should be known that neither its presence nor its name is regulated and that it only depends on the manufacturer’s initiative. In general, the presence of this label is for marketing reasons and aims at providing a serious scientific caution in the consumer’s mind [8].

Flash code

Flashcode or QR code or Datamatrix. . . is a bar code but a two-dimensional one (*figure 2*, point 3). It is in fact a way to access immediate information through a mobile phone with internet access. It is already used in many applications and has just made its appearance on the packaging of cosmetic products. It can be useful on condition that the information it provides is considered with a critical eye. Nonetheless, it is a way of knowing a little more before buying a cosmetic product compared to what the packaging has the space to mention (regarding its ingredients, its qualities or its indications. . .).

The e mark (or estimated symbol)

This symbol is often seen alongside the net weight statement (*figure 2*, point 4). The “e” mark is in fact an additional guarantee from the manufacturer, under its sole responsibility, that its products will meet the regulation requirements. But such requirements legally allow a margin of error on the minimum stated contents of the product. Thus the e mark is not a guarantee of purchasing the exact contents stated on the label but that the contents meet the requirements of

the regulation. European control authorities consider that cosmetic products bearing the e mark have a presumption of conformity as the manufacturer that uses it has to carry out self-assessment tests in the course of the production process [8].

In conclusion, the study of all the information on the packaging of cosmetic products shows that one has to read the labels properly and to remain updated on the changes in regulation. As regards the information, statements and logos displayed by the manufacturers themselves, it is important to be able to take a critical distance and to encourage regulations on the subject. ■

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