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Review

Labeling of Cosmetic Products

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Abstract: The labeling of cosmetic products provides a set of obligations, as reported in the Regulation 1223/2009, which came into force in Europe in July 2013. The indications reported on the label are intended to enable the clear identification of the functionality and proper use of cosmetics, ensure the protection of the consumer from the commercial aspects and, above all, from the safety point of view. Moreover, it should allow quick tracing of the product details and all info of toxicological relevance. However, the misuse of this tool often leads, on one side, to confusion among cosmetics, pharmaceuticals, medical devices, and biocides. On the other side, it gives rise to fanciful interpretations by a huge number of web users, who pretend to be able to judge the quality of a cosmetic product just by reading the ingredients list. This article points out the concrete purpose of cosmetic labels, in order to shed light on the use of certain categories of 'controversial' ingredients and on the real quality concepts of cosmetic products. Indeed, when properly interpreted, cosmetic labels represent a good tool for the professional investigation of adverse reactions to cosmetics.

Keywords: cosmetic regulation; silicone; petrolatum; borderline product

1. Introduction

The European Regulation 1223/2009 [1], which replaced previous legislation adopted by European countries, is the physiological development of the early European directive (76/768/EEC) and its numerous updates adopted over the years. This regulation intended to eliminate the differences among the member States due to the scattered application of previous laws, which complicated proper market surveillance.

The main goal of the latest update is consumer protection. The new regulation, which has had immediate and binding application in all EU member States, quite precisely identifies some aspects:

- Specific obligations of the person responsible for the product and its suppliers, with reference to the traceability of the cosmetic product along its distribution chain;
- Detailed cosmetic vigilance procedures;
- Observance of the Good Manufacturing Practices (GMP);

Moreover, the new regulation introduced the obligation of electronic notification at the Cosmetic Product Notification Portal (CPNP). This allows companies to commercialize their products in several European States by making only one notification, and allows the supervision authorities, local health authorities, poison centers, and Ministries of Health of the different member States to access quickly the cosmetic registration portal, acquire information about products, and promptly intervene in case of emergency.

2. Hints about the New Regulation

Particularly affected by the new law is the assembly of the:

- Product Information File (PIF) and Cosmetic Safety Report (CSR)

The PIF, which should be readily available upon request by the supervising authority, is an archive of all information and documentations of the product, such as the qualitative/quantitative formula, physicochemical and microbiological specifications of the finished product and raw materials, and its manufacturing method. The new regulation underlines the necessity of complete information concerning the safety assessment of the product, data about the side effects of the cosmetic recipe, together with stability details and compatibility with packaging materials. The data and information that must be included in the CSR are described in Annex I. Specifically, the formula, physicochemical specifications, microbiological quality, application area, quantity and the frequency of use, type of consumer, quality, and toxicological profile of the ingredients are analyzed in the first part (A). Moreover, it must be verified that the product is not polluted with impurities released by the packaging materials. In the second part (B), the evaluator expresses his global opinion on all safety issues, taking into consideration all aspects examined in part A, and then provides certification if the product is safe, identifies any need for special warnings on the label, or concludes that its safety profile is not satisfactory.

- Product information: advertising claims

Together with Regulation 1223/2009, new legislation came into force on July 2013, Regulation 655/2013 [2], which sets common criteria for the claims adopted by cosmetic products. Generally, claims aim to inform the final consumers about the characteristic features and quality of a cosmetic, while taking into account the social-linguistic and cultural differences among European people. As most cosmetic products do not have an informed prescription procedure, label communication and advertising is the way by which producers introduce their formula to consumers. This creates a language gap, as the average consumer does not have an easy way to decode the claims language, which frequently are overemphasized, miracle-claiming, or obvious. Frequently, multiple evocative terms are used, such as 'natural', 'biologic', and 'organic', that are void of precise significance. This type of language is often annoying to the medical reader, unless products are sold through the pharmaceutical channel, thus requiring more balanced, physician-oriented communication. The principles for correct communication are summarized by the following six points:

1. Compliance with regulations: boasting product advantages is not possible if they are the result of the logical compliance with the legal minimum requirements (absence of forbidden ingredients, etc.);
2. Truthfulness: individual ingredient properties cannot be boasted as automatically transferred to product properties if they are not adequately demonstrated;
3. Evidential support: the claims, both explicit and implicit, must be verified by tests carried out with well-conceived methods (efficient, reliable, and reproducible) and must be accurately applied
4. Honesty: it is not possible to award the product with properties beyond those that have been experimentally proven;
5. Accuracy: claims must be objective and not denigrate competitors and/or legally used ingredients;
6. Well-informed decisions: communication should allow the average final consumer to make a well-informed choice.

Here are some details concerning the correct labeling of a cosmetic:

- Nanomaterials

The person responsible for the cosmetic product should report in the label and in the product notification to the central EU authorities the presence of nanomaterials. Nanomaterials to be communicated (since they could create safety problems if they have not been adequately evaluated) must comply with the official definition: insoluble or biopersistant and intentionally manufactured materials with one or more external dimensions, or an internal structure, in the scale from 1 to 100 nm.

Titanium dioxide, zinc oxide, and pigment CI 77266 (Carbon Black) are among the nanomaterials commonly used in cosmetic products, already evaluated as safe in such physical forms by the Scientific Committee on Consumer Safety (SCCS) [3–6], except for their use in products that can lead to inhalation of the above substances [7].

3. Label—Mandatory Information

The following information must be listed on the label (Table 1), both of the primary container (the one that contains the product, in contact with it) and of the secondary packaging (cardboard box, carton):

- The name or registered name and the address of the responsible person. If several addresses are indicated, the one where the responsible person makes the product information file readily available shall be highlighted;
- The country of origin shall be specified for imported cosmetic products;
- The nominal content;
- The date of minimum durability or Period After Opening (PAO, duration after first use);
- Particular precautions during use (if necessary to ensure safe use);
- The batch number (to ensure the traceability of the product);
- The function of the cosmetic product, unless already clear from its presentation;
- The list of ingredients (it may be indicated on the external packaging only).

Table 1. Information that must be reported on the label. In the of absence of secondary packaging, all the elements must be listed on the primary container.

Mandatory Information	Secondary Packaging	Primary Packaging
Name and function of the product	X	X
Name or business name and address (in full) of the responsible person	X	X
Nominal value	X	X
Expiration date indicated with the lettering: 'Best before' or preceded by the symbol 	X	X
If the expiration date is greater than 30 months, it may not be reported. In this case, the PAO (Period After Opening) must be reported * with the symbol of the small jar followed by the period (months/years) 	X	X
Particular cautions for use, at least those which are reported in Annex III and VI, as well as potential indications about specific cautions to be observed for professional cosmetic products	X	X
Batch number	X	
Ingredient List	X	

* This is also unnecessary if the concept of after opening conservation is not significant (e.g., single dose).

4. Ingredients of Cosmetic Products—Controversial Substances

The label should show the names of the ingredients of the cosmetic product, listed in order of decreasing content down to 1%. Under this level, the order can be random. Pigments are an exception in make-up products that are available in different shades. These ingredients, defined by an international classification of pigments called the Color Index (CI, usually a five-digit code), can be reported at the end of the ingredient list, and preceded by the indication 'may contain' or the symbol +/−. The nomenclature used to define the ingredients is the INCI (International Nomenclature of Cosmetic Ingredients) that can be freely consulted on the website of the European Community (CosIng database http://ec.europa.eu/growth/tools-databases/cosing/). This list does not define a positive list of substances allowed in the cosmetic field. Above all, it does not release the responsible person from assessing their safety of use in the finished products. Nevertheless, under EU law, lists are provided of not-permitted substances (Annex II) as well as substances that can be used only under specific conditions and/or concentrations (Annex III). Other exclusive lists (Annexes IV, V, and VI) itemize permitted pigments, preservatives, and UV filters. The disclosure of the ingredient list, available since the 90s, is linked to the increased number of cases of intolerance to cosmetics, proportional to their market expansion. Therefore, it was necessary to inform consumers and physicians about the presence of ingredients which could induce intolerance. The ingredient list does not represent a tool to evaluate the quality of a cosmetic product. Indeed, it is not possible, by a simple reading, to deduce information like the purity of each ingredient, the stability of active principles, the tolerability of use, and the existence of any quality/efficacy tests carried out on the product. Moreover, the environmental destiny of the product cannot be inferred.

Often, similarity between INCI names together with chemo-phobia effects lead to a structural, uncritical demonization of some substances.

Many ingredients are mistakenly accused on the web to be toxic or generally dangerous to human health, whereas they are freely usable in cosmetic product because are considered toxicologically safe by health authorities. Among these substances are silicones. The word 'silicone' includes an almost infinite set of possible structures, with totally different applications, associated only by the presence of chains of silicon and oxygen atoms as the main units. In most cases, they are inert and stable substances, with good toxicological profiles, particularly for dermal application. For example, many studies mention the positive effects of the application of semi-occlusive films, mainly silicone-based, on the healing of scars [8–10]. Currently, the only class of silicone substances under observation that undergoes a forthcoming regulation of use is that of volatile cyclic siloxanes, particularly the pentamer and tetramer (D5 and D4) molecules. From an assessment of the Scientific Committee, it comes to light that the volatile silicone with five oxygen atoms has a Margin of Safety (MoS) lower than 100 only at high levels of exposure. Therefore, its use is considered safe except in body lotions, hair-styling products, and all products that may give rise to long consumer exposure through inhalation (aerosol, pressurized sprayer, powders, etc.). Furthermore, considering that the D4 silicone has been evaluated to be toxic for reproduction, the purity levels of the pentamer, which contains impurities of the tetramer, must be higher than 99% [11].

Another class of ingredients constantly on trial, because they are considered not eco- and dermo-compatible, includes paraffins and most oil-derived substances. Over the years, a growing presence of products boasting claims like 'OIL FREE' has arisen, in reponse to the outburst of the concept of 'natural' and/or 'organic'. This demands the respect of strict protocols (through certifications created by private associations) and the restricted use of selected natural or organic ingredients in the formulae. Often, products formulated in a non-scientific way hide behind the 'natural' adjective, with a reduction of safety standards, in comparison to 'non-natural' products. Possible tolerability problems linked to a 'simple' natural formulations are not few:

(1) The oxidation of unsaturated vegetable oils with the formation of peroxides (sensitizing) [12];

(2) The destabilization of fragrances with the formation of peroxides and their decomposition products, aldehydes, because of the absence of synthetic stabilizers;
(3) Tolerability problems due to high percentages of so-called 'alternative preservatives' (not listed in the EU positive list);
(4) The possible presence of a high percentage of impurities of pesticides or heavy metals, due to the almost exclusive use of vegetal ingredients. Many companies do not invest in the verification of the purity of each batch of raw materials.

The dislike for some petroleum derivatives is mainly linked to the introduction of CAS number 8009-03-8 into the CMR substance list, formerly type 3 (Annex I of the old Directive 67/548/EEC) and now type 2 (Annex VI of the new Regulation CLP 1272/2008), as a probable carcinogen for humans. Actually, CAS number 8009-03-8 describes a mix of substances including paraffin (Vaseline or petrolatum) but does not describe a specific purity. Therefore, this CAS number refers to both refined Vaseline and the non-refined grade. Indeed, pharmaceutical grade petrolatums (USP) are not carcinogenic, mutagenic, or toxic to reproduction because they satisfy all purity requirements of the legislation FDA 21 CFR 172.880, including the analytical procedures aimed to verify the total amount of aromatic polycyclic hydrocarbons impurities. This type of refined petrolatum conforms to FDA legislation and can also be used in the food field.

The IARC report (International Agency of Research on Cancer), Vol. 33, 1984 [13] concluded that there were not adequate proofs of carcinogenicity in humans and animals for very refined oils. In particular, Vaseline has been included in class 5 ('White oils and petrolatums suitable for food and/or medicinal use').

The second negative shadow for this category of substances is the apparent high occlusive power and the consequent comedogenic properties. The pharmaceutical grade mineral oil (or Vaseline oil or paraffinum liquidum—CAS 8012-95-1), similar to paraffin, is a complex mix of very refined saturated hydrocarbons, derived from petroleum through a sequence of refining and purification steps. In skincare products, mineral oil is used in cleansers, lubricants, and for massage. Abundant papers focus on the safety of cosmetic products containing mineral oil, even in high percentages [14–16]. On the other hand, mineral oil has far higher moisturizing, emollient, and skin-renovating properties than many vegetal origin emollients, thanks to its inertia and chemical stability [17]. These two examples (silicones and petrolatums) demonstrate that often it is not easy to define 'good' or 'bad' ingredients without an in-depth knowledge about substances. Rather, it is said that 'the overdose makes the poison'.

5. Ingredients of Cosmetic Products—Regulated Substances

Ingredients used in the cosmetic field are continuously monitored by the European authorities and, in case of suspect harmful effects to human health, the Scientific Committee on Consumer Safety (SCCS) assesses the risk size. This is especially the case of substances classified as preservatives, UV filters, and pigments. For example, the list of intermediate colorants usable in oxidative permanent hair dye products was significantly reduced in recent years due to the elimination of substances that did not have sufficient proof of safety of use or were no longer used by the industry because they were suspected to be sensitizing.

(a) Formaldehyde and related molecules

Since 15 April 2015, formaldehyde has been classified as CMR 1B, and since 1 January 2016 products containing formaldehyde cannot be introduced on the market and made available to the final consumer. Still under discussion, the potential extension of this limitation that might also affect formaldehyde-releasing preservatives (Table 2): Imidazolidinyl and Diazolidinyl Urea, DMDM Hydantoin, Sodium Hydroxymethylglycinate, Benzylhemiformal, 2-Bromo-2-Nitropropane-1,3-diol, Quaternium 15.

Table 2. Preservatives in Annex V that can release formaldehyde by decomposition.

Reference Number	INCI Name	Maximum Allowed Concentration
21	2-Bromo-2-Nitropropane-1,3-diol	0.10%
27	Imidazolidinyl Urea	0.60%
31	Quaternium 15	0.20%
33	DMDM Hydantoin	0.60%
46	Diazolidinyl Urea	0.50%
51	Sodium Hydroxymethylglycinate	0.50%
55	Benzylhemiformal	0.15%

(b) Parabens

Recently, a further restriction was applied to parabens. In particular, Phenylparaben, Benzylparaben, Pentylparaben, as well as the two branched Isobutyl- and Isopropyl-paraben and their salts have been removed from Annex V and introduced in Annex II (prohibited substances) [18]. The maximum percentage of use for Propyl- and Butyl-paraben has been reduced to 0.14% (as the sum of the two ingredients). They cannot be used in leave-on products designed for application on the nappy area of children under 3 years of age. The regulation of use for all the other parabens has not changed [19].

(c) Fragrance and essential oil allergens

Since these substances can be sometimes irritating and allergenic, a list of 26 (Table 3) substances that must be identified on the products to inform consumers was defined in 1999. Regulated by Directive 2003/15/EC, they must be indicated on the label if their percentage is higher than 0.01% in rinse-off products, and higher than 0.001% in leave-on products. Under discussion is the potential extension of the list of allergens that must be indicated in the product label, when present at specific percentages, that are introduced in cosmetics through fragrances/flavoring and essential oils. More than 2500 fragrant ingredients are used in perfumed consumer goods such as cosmetics, cleansers, softeners, and other household products. In 2012, the Scientific Committee on Consumer Safety identified a total of 54 fragrant substances and 28 natural extracts (essential oils) as 'contact allergens verified in humans'. The Scientific Committee defined also 18 ingredients and one natural extract as 'contact allergens verified in animals'. For these 127 substances, the SCCS suggests indication on the label. Moreover, another 35 substances and 13 natural extracts classified as 'potential contact allergens' were identified, for which label indication is not required [20].

Table 3. List of 26 allergens that must be reported on the label if their percentage is up to 0.01% in rinse-off products and 0.001% in leave-on products.

CAS Number	INCI Name
127-51-5	Alpha Isomethyl Ionone
122-40-7	Amyl Cinnamal
105-13-5	Anise Alcohol
100-51-6	Benzyl Alcohol
120-51-4	Benzyl Benzoate
103-41-3	Benzyl Cinnamate
118-58-1	Benzyl Salicylate
80-54-6	Butylphenyl Methylpropional
104-55-2	Cinnamal
104-54-1	Cinnamyl Alcohol
5392-40-5	Citral
106-22-9	Citronellols
91-64-5	Coumarin

Table 3. *Cont.*

CAS Number	INCI Name
97-53-0	Eugenol
90028-67-4	Ervenia Furfuracea
90028-68-5	Ervenia Prunastri
4602-84-0	Farnesol
106-24-1	Geraniol
101-86-0	Hexyl Cinnamal
107-75-5	Hydroxycitronellal
31906-04-4	Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde
97-54-1	Isoeugenol
5989-27-5	Limonene
78-70-6	Linalool
111-12-6	Methyl 2-Octynoate

6. Borderline Products

For the definition reported in the Regulation, a cosmetic product is: "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 odors".

Therefore, products that have other main scopes, for example to cure or to prevent disease, cannot be considered as cosmetics. Often it is important to discriminate clearly among cosmetics, drugs, and medical devices, independently from the presence of some substances that may appear in products of all three categories. They have different functions, answering to different needs. For this reason, it is necessary to specify that they are three different, well-differentiated typologies of product. The respective legislations define them as follows.

6.1. Medicinal Product

- "Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;"
- "Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting, or modifying physiological functions by exerting a pharmacological, immunological, or metabolic action, or to making a medical diagnosis."

(Art. 1 paragraph 2 Directive 2001/83/EC).

6.2. Medical Device

- "Any instrument, apparatus, appliance, software, . . . material or other article intended . . . to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

  . . . diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease/disability, . . . investigation, replacement, or modification of the anatomy, . . . providing information by means of in vitro examination, . . . and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means."

(Art. 2 paragraph 1, REGULATION (EU) 2017/745 on medical devices).

Both medical products and medical devices have no limitations concerning the application area or administration route. It is thus necessary to specify that a product might fall under the drug legislation merely due to its presentation or claimed functions. Moreover, the Art. 2, paragraph 2, Directive 2004/27/CE highlights that: 'In cases of doubt, where, taking into account all its characteristics, a product may fall simultaneously within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation ... ' the dispositions of medical products legislation shall be applied. Because of the difficulty, in many cases, to define in a clear way the boundary lines between certain categories of products, the European Community developed (also based on the judgements of the Court of Justice) three guideline documents (Table 4) for the distinction between cosmetics and drugs [21], cosmetics and biocides [22], and for the management of borderline cosmetics [23]. It is very interesting the close interpretation of a part of the definition of medical product: 'restoring, correcting or modifying physiological functions', because it specifies that almost all products generally considered as cosmetics can also, one way or another, modify physiological functions. Examples include moisturizing products that can modify the water content of cells, or anti-wrinkle creams that carry out effects on skin cells. Mentioning an explicative example:

Question: Are products that plump up the lips considered cosmetics?

Answer: Products that make lips more voluminous may in principle fulfil the definition of cosmetic products because they are intended to be placed in contact with the lips 'with a view to exclusively or mainly changing their appearance'.

However, these products may also meet the definition of medicinal products 'by virtue of function', whereby the product is used or administered with a view 'to restoring, correcting, or modifying physiological functions by exerting a pharmacological, immunological, or metabolic action, or to making a medical diagnosis'.

Considering the principle of 'significant modification' of physiological functions earlier described, the European Court of Justice affirmed that, if these products act through inflammation and/or irritation (e.g., products containing capsaicin), the deliberate induction of a swelling effect could be perceived as a significant modification of one or more physiological functions in the lips, thus bringing the products under the definition of medicinal products.

Table 4. Main legislations and guidelines references that set the production, transport, and marketing of cosmetic products.

Field of Application	Regulation/Guideline
Cosmetic Products	REGULATION n. 1223/2009/EC
Claims	REGULATION n. 655/2013/EC
Classification, labeling, and packaging of substances and mixtures	REGULATION n. 1272/2008/EC
Borderline cosmetic product	Manual on the scope of application of the Cosmetic Regulation 1223/2009, VERSION 1.0 (November 2013)
Differences between cosmetics and medicinal products	Guidance document on the demarcation between the cosmetic products DIRECTIVE 76/768 and the medicinal products DIRECTIVE 2001/83, as agreed between the commission services and the competent authorities of member states
Differences between cosmetics and biocides	Guidance document agreed between the Commission services and the competent authorities of Member States for the biocidal products Directive 98/8/EC and for the cosmetic products Directive 76/768/EEC (2004)

7. Quality Concept of Cosmetic Product

As described above, the ingredients list cannot be used to assess the quality of a cosmetic product. Formulation in a modern way, mixing natural and synthetic raw materials, requires various delicate, precise, and systematic procedures that cannot be trivially minimized. This means choosing and

mixing ingredients in a smart way, while taking into consideration the stability, safety, and efficacy of the formulation. This is also dependent on the ability of the product to repair the dermal ecosystem, with the goals of avoiding/reducing all intolerance events by removing any substance with sensitizing effects or limiting its action through quenching. A cosmetic product, through a system of ordinary epidermal maintenance, works by limiting dehydration events, repairing the barrier damages, rebalancing lipid alterations, and avoiding protein denaturation, etc. The value of a well-formulated cosmetic product is in its formulation simplicity, that is to say, in the ability to combine limited amount of ingredients in synergic ways while avoiding, if possible, the trite way of using communication ingredients. For example, the use of vegetal extracts would be correct when their purity levels are closely monitored (absence of pesticides, extraction solvents, unknown substances). Likewise, while it is true that even traces of allergens must be avoided, such an omission cannot stimulate the advertisement of products as having a nickel content lower than its legally allowed limit in wine [24].

Quality means certified purity and low level of known impurities, with the lowest functional amount of antibacterial ingredients and anti-contaminant packaging, but without microbiological risks for the consumer, and well-controlled stability standards. Indeed, these are the real parameters truly representing the source of harmlessness when associated with properly recorded measures of efficacy. A cosmetic product is a complex system, the project and the result of a multifactorial assembly, founded on a strategy of choices of substances and mixing methods, quality assurance, and careful testing of the compatibility, stability, and reproduction of the results obtained with models, including manufacturing methods and transport systems.

Conflicts of Interest: The authors declare no conflict of interest.

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