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Understanding the cosmetic product safety report

ABSTRACT

Cosmetics are regulated in the European Union by Regulation (EC) No 1223/2009. The main objectives of this regulation are to create a set of rules that all cosmetics comply with and to ensure a high level of protection for human health. One of the requirements of the regulation is that prior to placing the product on the market a safety assessment is carried out. The regulation specifies that this safety assessment should be in the form of a cosmetic product safety report. This article is intended to give an insight into what needs to be considered when carrying out a safety assessment and preparing a cosmetic product safety report.

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The main aim of Regulation (EC) No 1223/2009 is to ensure that cosmetic products placed on the market within the European Union are safe. To ensure that cosmetic products are safe, Regulation (EC) No 1223/2009 requires that the product is assessed for safety by:
"a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by a Member State".[1]
This person will be referred to as the cosmetic safety assessor in this article.

Responsible person

It is the responsibility of the responsible person to ensure that the product undergoes a safety assessment and that a cosmetic product safety report is produced before placing the product on the market in Europe. The responsible person is also required to keep the cosmetic product safety report up to date once the product is placed on the market.

What is a cosmetic product safety report?

The cosmetic product safety report is the cosmetic safety assessor's opinion that the product is safe in normal and foreseeable use and complies with the requirements of Regulation (EC) No 1223/2009.
The minimum requirements for a cosmetic product safety report are set out in Annex I of the regulation.

Ingredients

The safety of cosmetics products is based on the safety of the ingredients. The Scientific Committee on Consumer Safety evaluates the safety of ingredients listed in Annexes, II, III, IV, V and VI of Regulation (EC) No 1223/2009. The safety assessor is responsible for assessing the safety of all the ingredients not listed in the annexes.[2] From time to time the Scientific Committee on Consumer Safety amends their opinion on an ingredient and the safety assessor needs to take into consideration this opinion.

Cosmetic product safety report

The cosmetic product safety report is in two parts; Part A – Cosmetic product safety information and Part B – Cosmetic product safety assessment. Part A aims to gather all the data necessary for the safety assessment and consists of ten sections. Part B is the cosmetic safety assessor's opinion on the safety of the product and consists of four sections.

Part A

Cosmetic product safety information

- *Quantitative and qualitative composition of the cosmetic product*

The quantitative and qualitative composition of the product is essentially the product's formulation. It describes how much of each raw ingredient is in the formulation. This section should include the chemical name, INCI name, CAS number, Einecs/ELINCs or EC number where possible, and the weight percentage in the formulation. It is desirable to avoid concentration ranges but where this is unavoidable then toxicological consideration and calculations should be based on the higher concentration figure. All substances including preservatives, antioxidants, chelating agents, buffering agents, solvents, and additives which are in any of the raw ingredients should be included in the quantitative and qualitative composition of the product.

For perfumes and aromatic compositions the name and code number for the fragrance or flavour is required as well as the name of the supplier. Qualitative and quantitative information about regulated substances in the fragrance or flavour and information relevant for a safety assessment should be provided to the cosmetic safety assessor and included in the safety report. Allergens in the perfume that are listed in Annex III of the regulation should be included on the ingredient list if they exceed 0.001% in the formulation for a leave-on product and 0.01% for a rinse-off product.

- *Physical/chemical characteristics and stability of the cosmetic product*

The cosmetic product safety report needs

to take into account the physical and chemical characteristics of the raw ingredients and the finished cosmetic product. According to the guidelines from the European Commission for cosmetic product safety reports, physical and chemical properties could include chemical identification, physical form, molecular weight, solubility, partition coefficient, substance purity, and for polymers the average molecular weight and range.[3] The physical /chemical characteristics of the finished product should contain the specification for the product. Values should be in ranges where appropriate (e.g. pH 5.5-6.5.

This section requires an assessment of the stability of the cosmetic product under reasonably foreseeable storage conditions. The testing needs to be done in the packaging that the product is going to be sold in. The aim is to evaluate the stability of the product in the packaging and to help determine the period after opening. Guidelines on the Stability of Cosmetic Products have been published by Colipa (now Cosmetics Europe) and the CTFA (now Personal Care Products Council) in March 2004.[4]

● *Microbiological quality*

The aim of this section is to determine the acceptable microbiological specifications of the raw materials and finished product. Guidelines on the microbiological quality of finished products have been published in The SCCS'S Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation 8th Revision.[5] The notes of guidance split products into two categories: Category 1 is for products specifically intended for children under three years, or for products that will be used in the eye area and on the mucous membranes. Category 2 is for all other products. For Category 1 products the total viable count for aerobic mesophyllic microorganisms should not exceed 100 cfu/g or 100 cfu/mL (cfu = colony forming unit). For Category 2 products the total viable count for aerobic mesophyllic microorganisms should not exceed 1000 cfu/g or 1000 cfu/mL. The pathogens *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* should not be detectable in 1 g or 1 mL of a cosmetic product of category 1 and in 0.1 g or 0.1 mL of a cosmetic product of Category 2.

When looking at the microbiological quality of the product the cosmetic safety assessor needs to consider whether a preservation challenge test is required. For products with a high alcohol content such as eau de toilettes, or products containing a high content of solvents and no water such as nail polishes a challenge test is not required. Products which are dispensed without coming into contact with the air such as aerosols, and single use products do not need a challenge test. They will need a microbiological quality test. A challenge test is required for all other products unless the cosmetic safety assessor can justify why it is not required.

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● *Impurities, traces, information about packaging material*

Impurities are unintended substances in raw ingredients and traces are small quantities of unintended substances in the finished product. Traces are to be evaluated for safety when the safety assessment is carried out. Traces of prohibited substances are permitted providing the product is safe and their presence is technically unavoidable.

Packaging material is the primary packaging which is in direct contact with the product. Annex I of Regulation (EC) No 1223/2009 requires that the cosmetic safety assessor considers the characteristics, purity and stability of the packaging. The cosmetic safety assessor needs to consider the possibility of substances migrating from the packaging into the product and the effect these substances may have on human health. These data may be available from the packaging supplier if the materials used in the packaging have been developed for the food industry. Alternatively the packaging may need to be tested.

● *Normal and reasonably foreseeable use*

The cosmetic product safety report needs to consider what the normal or foreseeable use of the product will be, so that the exposure to the ingredients in the product can be considered. For example it is foreseeable that a shampoo could be used as a shower gel but ingestion of a shampoo would be a misuse and is not covered by the cosmetic product safety report. When the normal and foreseeable use of the product has been determined suitable directions of use and warnings can be put on the packaging.

● *Exposure to cosmetic product*

This section of the report aims to quantify the amount of cosmetic product that comes into contact with the external parts of the human body including teeth and the mucous membranes of the oral cavity under normal and reasonably foreseeable use and the frequency of use. Secondary exposure routes should be taken into consideration when appropriate. An example of secondary exposure would be inhalation of solvents from a nail product.

The cosmetic product safety report needs to take the following parameters into consideration: the site(s) of application; the surface area(s) of application; the amount of product applied; the duration and frequency of use; the normal and reasonably foreseeable exposure route(s); the targeted (or exposed) population(s), potential exposure of a specific population shall also be taken into account (e.g. children under the age of three years, adults); and the impact of particle size on exposure.[6] The Scientific Committee on Consumer Safety give some useful information on surface areas that products are applied to, frequency of use, amount of product applied and the calculated relative daily exposure for some products.[7]

● *Exposure to substances*

The objective of this section is to calculate the amount of each substance coming into contact with the external parts of the human body, teeth and the mucous membranes of the oral cavity under normal and reasonably foreseeable use. Where substances are generated or released during the use of the product these should also be taken into consideration in the cosmetic product safety report.

● *Toxicological profile of the substances*

The aim of this section of the report is to describe the toxicological hazard of each

substance in the finished product. The cosmetic safety assessor needs to consider suitable endpoints to justify their decision as to whether an ingredient is safe. Endpoints which may be relevant include: acute toxicity, irritation and corrosivity, skin irritation and skin corrosivity, mucous membrane irritation (eye irritation), skin sensitisation, dermal/percutaneous absorption, repeated dose toxicity, mutagenicity/genotoxicity, carcinogenicity, reproduction toxicity, toxicokinetics and photo-induced toxicity.[3]

Where possible a no observed adverse effect level needs to be determined so that a margin of safety can be calculated. It is generally accepted that the margin of safety should be at least 100 to declare a substance safe for use in cosmetics.[8] If a no observed adverse effect level (NOAEL) cannot be found then the margin of safety cannot be calculated. The particle size should also be considered especially nanoparticles. Nanoparticles are covered in article 16 of Regulation (EC) No 1223/2009.

- *Undesirable effects and serious undesirable effects*

The aim of this section is to monitor the safety of the product after it has been placed on the market and to take corrective measures when necessary. The responsible person should set up a system to collect, document and establish the cause of any undesirable effects. Information on any undesirable effects and serious undesirable effects should be included in the cosmetic product safety report. The responsible person needs to investigate any undesirable effects to ascertain whether they are very likely, likely, not clearly attributable or not attributable to the product and to pass on this information to the cosmetic safety assessor so that they can consider revising their opinion or use this information when assessing similar products. For serious undesirable effects the competent authority should also be informed by the responsible person and the notification forms sent to the competent authority should be attached to the cosmetic product safety report.

- *Information on the cosmetic product*

This section allows inclusion of any other information which is relevant to the safety assessment not covered by the other sections in Part A. For instance any studies on human volunteers should be included here.

Part B

Cosmetic product safety assessment

Part B is the actual assessment of safety of the product by the cosmetic safety assessor. It is the cosmetic safety assessor's reasoned opinion of the safety of the product.

- *Assessment conclusion*

In this section the cosmetic safety assessor states whether the product is safe, safe with restrictions or not safe for human health under normal and foreseeable use. If the cosmetic safety assessor concludes that the product is not safe then the product must not be placed on the market.

- *Labelling warnings and instructions of use*

Labelling of cosmetics is covered in article 19 of Regulation (EC) No 1223/2009. In this section of the cosmetic product safety report the cosmetic safety assessor needs to list any warnings for ingredients listed in annexes III to VI of Regulation (EC) No 1223/2009 and any precautionary information on products intended for professional use.

- *Reasoning*

In order to reach a conclusion as to whether a cosmetic product is safe for human health and compliant with Regulation (EC) No 1223/2009 the cosmetic safety assessor should ensure that they have all the relevant information. They need to explain how they reach their conclusion based on the information in Part A. The cosmetic safety assessor is required to consider the safety of the ingredients in the formulation and the safety of the finished product.

Safety assessments should be reviewed and if necessary updated if one of the following occurs: new scientific findings and toxicological data on the substances are available which could modify the result of the existing safety assessment; changes occur in the formulation or specification of raw materials; changes occur in the conditions of use; a rising trend in terms of the nature, severity and frequency of undesirable effects, both under reasonably foreseeable conditions of use and in the case of misuse.[3]

The cosmetic safety assessor is able to accept, reject, or accept under specific conditions that a formulation is safe in terms of human health.

The guidelines on annex I recommend that a mechanism is put in place to ensure that relevant information is efficiently exchanged between the responsible person and the safety assessor so that the safety assessor is in a position to intervene where an update to the cosmetic product safety report is required.[3]

- *Assessor's credentials and approval of Part B*

Regulation (EC) No 1223/2009 in Annex I states that this section should include the name and address of the safety assessor, proof of their qualifications, the date the cosmetic product safety report was completed and the cosmetic safety assessor's signature.

SCCS opinions and safety assessments

From time to time the Scientific Committee on Consumer Safety amends their opinion on specific ingredients. In December 2013 the Scientific Committee on Consumer Safety amended their opinion on methylisothiazolinone.[9] The cosmetic safety assessor should use the most up to data when assessing the safety of a cosmetic product.

Conclusion

This article has been written as a guide to what cosmetic safety assessors need to consider when assessing the safety of a cosmetic product and what they may include in the cosmetic product safety report. Cosmetic product safety reports from different cosmetic safety assessors will differ in style and content as cosmetic safety assessors will use different databases and software to prepare the cosmetic product safety report. The safety assessment of the cosmetic product can only be as accurate as the information that is provided to the cosmetic safety assessor. PC

References

1 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast): Article 10, paragraph 2.
2 The SCCS'S Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation 8th Revision. SCCS/1501/12: 12.
3 Commission Implementing Decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU).
4 Guidelines on Stability testing of Cosmetic Products (COLIPA/ CTFA) March 2004.
5 The SCCS'S Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation 8th Revision. SCCS/1501/12: 77.
6 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast): Annex I.
7 The SCCS'S Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation 8th Revision. SCCS/1501/12: 70-73.
8 The SCCS'S Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation 8th Revision. SCCS/1501/12: 48.
9 The SCCS Opinion on Methylisothiazolinone (P94) Submission II. SCCS/1521/13.