COSMETIC PACKAGING MIGRATION: HOW TO INTERPRET AND COMPLY WITH EU COSMETIC REGULATION (EC) NO 1223/2009?

EU Cosmetic Regulation (EC) No 1223/2009 introduced a requirement to report on packaging materials, impurities and traces within a product's safety information. What it doesn't do is set a standard, an official guideline or specify evaluation methods.

WHAT DOES REGULATION (EC) NO 1223/2009 SAY ABOUT PACKAGING MIGRATION?

Article 3 of the new EU Cosmetic Regulation states that:

"A cosmetic product made available on the market shall be safe for human health."

More specifically for the packaging industry Chapter IV, Article 17 says:

"Traces of Prohibited Substances. The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3."

WHAT IS THE ISSUE FOR PACKAGING?

An already complex topic, packaging migration is no clearer under this new Regulation. In effect, manufacturers must now comply with regulations that fail to specify what a 'small quantity of a prohibited substance' is, or how it should be tested and measured.

Cosmetic products are sold in the widest variety of packaging, which only compounds the issue: tubes, bottles (glass, plastic, capsules, aerosols), pots (plastic, glass, metal tins), pouches, films, multi-layers. All these materials may contain additional coatings, inks and glues amongst others.

INFORMATION COLLATION AND SAFETY ASSESSMENT PROVIDES A SOLUTION

Safety assessors conducting each Cosmetic Product Safety Report (CPSR) must collate a broad range of data from suppliers and manufacturers in order to make an effective risk assessment of the product, its packaging and any potential risk. To focus on packaging migration and according to the guidelines to Annex 1 of Cosmetic Regulation (EC) No 1223/2009, the CPSR must contain key information as listed below.

1 - Data from suppliers, at the earliest possible stage in the supply chain, is preferred for the analysis of impurities that may exist, their quantity and potential for migration.

2 - Beyond examination of the raw ingredients and impurities, customers must also supply the assessor with challenge test reports demonstrating the primary results of interaction between the product and its packaging, answering key questions:

- What is the potential for migration when the formulation (product) is in contact with the primary packaging?
- What is the potential impact on the quality and efficacy of the product?

3 - To ensure compliance with Chapter IV, Article 17 of the Cosmetic Regulation (EC) No 1223/2009, SGS advises companies operating in the cosmetic industry to consider providing the following information about packaging for the CPSR:

- Food grade certificate and test reports according to the Regulation (EC) No 1935/2004 on Food Contact Materials[1]; declaration/certificate of compliance according to annex IV of Regulation (EU) No. 10/2011 (plastic materials and articles). This recommendation is based on the assumption that if packaging is safe for food, it should also be safe for cosmetic products.
- Composition, through the specification/technical data for each raw material, based on knowledge of the process for manufacturing the raw material (origin of substance, production process, synthesis route, extraction process, solvent used, etc.); and through a physical & chemical analysis of possible impurities in raw materials and, if necessary, in the final product (e.g. nitrosamines).
- SVHCs (Substances of Very High Concern) declaration/certificate and test report to comply with REACH regulation (packaging being considered an article under REACH).

4 - It is the assessors' responsibility to evaluate the risk posed by packaging materials based on information supplied by the client and their whole supply chain (suppliers, manufacturers, importers). The safety assessor must be sure that, based on the above information, the packaging is suitable. If any doubts exist they can request more detail, such as:

- Additional chemical composition (polymer and residual monomer, impurities in the packaging, etc.).
- Specific migration data based on the packaging type (PE, PET, PP, glass, stainless steel, rubber/silicon, etc.), or on the type of formulation (oil, water based, alcoholic, etc.).
- Targeted SVHC analysis, beyond what is already included on the candidate list, or listed in Annex XVII of REACH.

Close co-operation along the supply chain is required to ensure that accurate product data is available at the right time and in the right place.

COSMETIC PACKAGING EXPERTISE

Packaging migration evaluation is just one area of expertise at SGS. With extensive experience in cosmetics and packaging our technical experts and toxicologists can help you to achieve compliance with the EU Cosmetic Regulation. Documentation reviews, safety assessments and even food contact compliance are just some of the ways we can help. If data is missing/unavailable we can also conduct the necessary testing, thereby ensuring your product file is complete.

For more information please contact your local SGS representative or our global team: consumer.products@sgs.com.

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