

THE EU COSMETIC REGULATION

SCIENTIFIC AND REGULATORY SUPPORT

Regulatory Services—Europe

The Cosmetic Regulation (EC) No 1223/2009 came into force across the EU in July 2013. Whilst retaining much of the old Directive, the new Regulation is more specific about the contents of the Cosmetic Product Safety Report, product labelling, appropriate claims and the need to retain a Product Information File.

toXcel is a group of experienced regulatory scientists offering tailored services to small and large cosmetic companies. We are pleased to provide assistance in the following major areas:

Cosmetic Product Safety Report (CPSR)

The safety of a cosmetic is assessed based on the known properties of its ingredients. **toXcel** provides literature based hazard assessments and reviews suppliers specifications and data, taking into account any impurities. Our overall assessment is based on the properties of the product and anticipated human exposure. The stability, microbial quality, packaging, and labelling are also taken into consideration. The report must be signed by a suitably qualified person; **toXcel** scientists include Registered Toxicologists (DABT, ERT) and Chartered Biologists (CBiol). **toXcel** has completed over 300 CPSRs.

Product Information File

This file must be available via the Responsible Person if requested by a competent authority. It contains the CPSR, manufacturing details including compliance with GMP, efficacy data, and development history (limitations apply to the types of test allowed for safety testing).

Label Compliance

This must include the INCI ingredients list, allergen listing, durability, and special instructions. In 2026, Commission Regulation (EU) 2023/1545 comes into place, expanding the list of fragrance allergens that must be included on the label. **toXcel** can help you prepare for this change.

Achieve success in your marketing goals as we guide you through the regulatory requirements ensuring cost-effective compliance of your cosmetic products in the EU.

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