

COSMETIC COMPLIANCE IN THE EU AND UK

SCIENTIFIC AND REGULATORY SUPPORT

Regulatory Services—Europe

Cosmetic products placed on the EU market must follow the requirements of REGULATION (EC) No 1223/2009 on Cosmetic Products; this legislation was also adopted in the UK as part of the EU Exit Regulations in 2019, with a few minor amendments.

Before a cosmetic product can be marketed, it must be notified through:

- the Cosmetic Product Notification Portal (CPNP) for the EU, or
- the Submit Cosmetic Product Notification (SCPN) service for the UK.

These notifications must be completed by a designated Responsible Person (RP). Companies established within the EU or UK may act as their own RP, while businesses based outside these regions must appoint a third-party RP.

toXcel provides Responsible Person services through:

- **toXcel Cosmetic Compliance Ltd** (EU-based RP services)
- **toXcel International Ltd** (UK-based RP services)

Product Information File (PIF)

The Responsible Person's address must appear on the product label and the RP must maintain access to the Product Information File (PIF), which may be requested by the relevant competent authority at any time.

The PIF must include:

- A full percentage breakdown of the cosmetic product ingredients.
- Information and copies/pictures of the packaging and labels. Note that the label must include the list of fragrance allergens described in Commission Regulation (EU) 2023/1545.
- A Cosmetic Product Safety Report (**CPSR**) for each product. The safety of a cosmetic is assessed based on the known properties and quality of its ingredients. The 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.
- Manufacturing details and evidence of GMP, or equivalent, compliance.
- Data to support any claims made on the label.
- Development history and confirmation of no testing of the product on animals (a range of *in silico* and *in vitro* tests can be performed, if required, and **toXcel** can provide guidance on these).

Our team of experienced scientists has over 10 years of expertise in cosmetic regulatory compliance and has completed more than 300 CPSRs for a wide range of cosmetic products.

We support companies in achieving efficient market access in both the EU and UK by providing:

- Responsible Person services
- Cosmetic Product Safety Reports
- Regulatory guidance
- Label and claims review
- PIF support
- Notification services

For further information about our cosmetic services, please contact Christine McAlinden at Christine.McAlinden@toxcel.co.uk or Olwyn Diggins at Olwyn.Diggins@toxcel.co.uk.

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