

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:

EU Portal Notification

This is required for all cosmetic sales; a banded formulation is submitted via a web-based system.

Responsible Person

The responsible entity must reside in the EU and contact details must be shown on all labels; **toXcel** can fulfil this function for non-EU companies.

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 100 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.

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.

For further information, contact Christine McAlinden at Christine.McAlinden@toxcel.com.

toXcel, LLC

7140 Heritage Village Plaza
Gainesville, Virginia 20155
USA

Phone: 703-754-0248 x111
Email: Alan.Katz@toxcel.com

toXcel International Ltd.

P.O. Box 93
Ledbury, HR8 9JE
United Kingdom

Phone: +44 (0) 1531 638999
E-mail: Christine.McAlinden@toxcel.co.uk

www.toxcel.com