Ards and North Down Borough Council

Product Safety Advice for Cosmetic Manufacturers

For further advice and information on supplying safe goods, contact the Environmental Health Service at:

T: 0300 0133333

E: consumerprotection@ardsandnorthdown.gov.uk

W: www.ardsandnorthdown.gov.uk

Product Safety

If you sell products to the public, you have a legal duty to ensure that the products are safe and meet relevant regulations.

A product is safe if it presents no risk (or almost no risk) to consumers if they use the product in the intended way.

This duty applies to small scale home-based suppliers in the same way it applies to larger scale manufacturers/suppliers.

About Us

Officers from the Environmental Health Service carry out a range of activities aimed at protecting customers and helping businesses meet their legal obligations. Officers may request information about your business and products, including technical documentation.

White Label/Own Branded Products

A cosmetic product is generally considered **white-label or own-branded** where:

- The product is **made by another company**
- It is supplied as a **finished product**
- The business sells the product under **its own name, brand or packaging**

However, this does not mean you do not have legal responsibilities under Cosmetic Legislation.

UK Government guidance states a 'Manufacturer' is any person or business who manufactures a cosmetic product or *has the product designed or manufactured and markets it under their name or trademark*.

Therefore, where a business does not physically make the product but places it on the market under its own brand name, it is classed as the **manufacturer** for the purposes of cosmetic legislation and takes on the manufacturer responsibilities set out in this guidance.

NI Trading Standards – Counterfeit Goods

If you require information relating to counterfeit goods please contact the Northern Ireland Trading Standards Service on 03001236262 or via their website https://www.economy-ni.gov.uk/articles/trading-standards-service

Cosmetic Products

Regulation (EC) 1223/2009 on Cosmetic Products

The Cosmetic Products Enforcement Regulations 2013

What is a cosmetic?

Regulation (EC) No. 1223/2009 Article 2

"A cosmetic product shall mean any substance or mixture intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to…

• clean

• perfume

• change the appearance

• correct body odours

• protect

• keep in good condition

Manufacturer's obligations

- Place on the market a safe product
- Implement Good Manufacturing Practices
- Carry out a safety assessment
- Have a Product Information File (PIF) to include:
    - Product description
    - Method of manufacture
    - Statement of GMP
    - Cosmetic Product Safety Report
    - Proof of claims made
    - Details of animal testing Industry
- Place product details onto the Cosmetic Products Notification Portal (CPNP). If selling to GB, also need to place products onto the UK Submit a Cosmetic Product Notification (SCNP).
- Ensure no restricted/prohibited substances are in the product
- Label the product in accordance with the Regulation
- Record and assess any undesirable effects of the cosmetic product

Manufacturer's Obligations

As the Manufacturer, they are the Responsible Person for all areas.

Article 3 – Safety

A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular, of the following:

(a) presentation including conformity with Directive 87/357/EEC;
(b) labelling;
(c) instructions for use and disposal;
(d) any other indication or information provided by the responsible person defined in Article 4.

Article 8 - Good Manufacturing Practice

1. The manufacture of cosmetic products shall comply with good manufacturing practice with a view to ensuring the objectives of Article 1.

2. Compliance with good manufacturing practice shall be presumed where the manufacture is in accordance with the relevant harmonised standards, the references of which have been published in the *Official Journal of the European Union*.

Good Manufacturing Practice is about having a system to control quality and safety in the manufacturing environment. Regulation 1223/2009 makes GMP a prerequisite in Article 8 in order that cosmetics businesses ensure that they meet the objectives of Article 1, i.e. a high level of protection of human health (which is also the broad objective of Article 3 – Safety). GMP is not defined in the Regulation but can be interpreted through the harmonised standard ISO EN 22716. Compliance with the ISO standard is not mandatory, but if a manufacturer does comply with ISO 22716 they are legally presumed to comply with Article 8

Article 10 - Safety Assessment

1. In order to demonstrate that a cosmetic product complies with Article 3, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I.

The responsible person shall ensure that:

(a) the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment;
(b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources;
(c) the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market.

Cosmetic Product Safety Report

Part A:

There are 10 points to be considered:

1. Quantitative & qualitative composition
2. Physical/chemical characteristics and stability
3. Microbial quality
4. Impurities, traces, information about the packaging material
5. Normal & foreseeable use
6. Exposure to the product
7. Exposure to the ingredients
8. Toxicological profile of the ingredients
9. Undesirable effects (ratio) and serious undesirable effects
10. Information on the cosmetic product Cosmetic Product Safety Report

Part B:

There are 4 areas to be considered:

1. Assessment Conclusion
2. Label warnings/instructions for use
3. Reasoning
4. Assessor's credentials and approval of part B

Article 11 - Product Information File

1. When a cosmetic product is placed on the market, the responsible person shall keep a product information file for it. The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.

11(2) states what the file should contain

The Required Information

- Product description
- Method of manufacture
- Statement of GMP
- Cosmetic Product Safety Report
- Proof of claims made
- Details of animal testing

(Industry Guidance: https://cosmeticseurope.eu/wp-content/uploads/2024/10/Updated_Cosmetics_Europe_PIF_Guidelines_-_2015_-_Update.pdf)

Article 13 – Notification

1. Prior to placing the cosmetic product on the market the responsible person shall submit, by electronic means, the following information to the Commission:
   (a) the category of cosmetic product and its name or names, enabling its specific identification;
   (b) the name and address of the responsible person where the product information file is made readily accessible;
   (c) the country of origin in the case of import;
   (d) the Member State in which the cosmetic product is to be placed on the market;
   (e) the contact details of a physical person to contact in the case of necessity;
   (f) the presence of substances in the form of nanomaterials and:
      i. their identification including the chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI to this Regulation;
      ii. the reasonably foreseeable exposure conditions;
   (g) the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1A or 1B, under Part 3 of Annex VI to Regulation (EC) No 1272/2008;
   (h) the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

The cosmetic products notification portal (CPNP) is a free of charge online notification system created for the implementation of Regulation (EC) No 1223/2009 on cosmetic products. When a product has been notified in the CPNP, there is no need for any further notification at national level within the EU.

Products sold in NI continue to be notified on the CPNP. Products sold in GB will need to be notified on the UK's Submit Cosmetic Notification Portal. Regardless of where the manufacture/Responsible Person is located.

This must be done before placing the product on the market

Article 14 – Restrictions for substances listed in the Annexes

Substances contained in Cosmetics products must only be included in line with the Annexes

Annex II - Prohibited substances

Annex III - Restricted ingredients

Annex IV - Cosmetic colorants

Annex V – Preservatives

Annex VI - UV filters Carcinogenic Mutagenic Reprotoxic

Note also - CLP Regulation: (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures

**** Annexes are updated regularly, check for most current version before providing advice or taking any action****

Article 19 – Labelling

Mandatory Labelling	**Ingredients List**
• RP Name and Address • Function of the product • Country of origin • Net content • Warnings/Precautions • Batch Code • Best Before Date, or • Period After Opening (PAO) • Ingredients list	"INGREDIENTS" • INCI names • Colour Index (CI) • Order • "may contain" / +/- exemption • "Parfum" and "Aroma" • Allergens • (nano)

ALLERGENS UPDATE 2026

Commission Regulation (EU) 2023/1545 amends **Annex III** of Regulation (EC) No 1223/2009 by significantly expanding the list of fragrance allergens that must be individually declared in the ingredient list of cosmetic products. The number of fragrance allergens requiring individual declaration has increased from **26 to over 80 substances.**

The Regulation introduces phased implementation dates:

- All **new cosmetic products** placed on the Northern Ireland market after **31 July 2026** must comply.
- All **existing cosmetic products already on the market** must comply by **31 July 2028**

Cosmetovigilance

A consumer may experience an 'undesirable effect' after use of a cosmetic product. These effects need to be monitored by companies and in some cases, the authorities.

Understanding 'Undesirable Effects'

Definitions in the Cosmetics Regulation:

'undesirable effect' means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product

'serious undesirable effect' means an undesirable effect [adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product] which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death

Undesirable Effects don't normally result in medical intervention. A consumer may experience a UE or an SUE.

Why UEs/SUEs Occur

Sometimes an individual may have an allergy or sensitivity. E.g. PPD in hair colorants = the product is safe for the general population. Sometimes things go wrong, e.g. formulation error, contamination during manufacture, insufficient instructions

What happens to customer complaints?

Verification by Causality Assessment

The company must carry out an assessment using either the decision tree or table

Very Likely, Likely, Not Clearly Attributable, Unlikely, Excluded

Undesirable Effects are cases deemed as 'likely' or 'very likely' and are recorded in the PIF (as a ratio).

Serious Undesirable Effects are anything other than 'excluded' cases and are reported to Environmental Health and recorded in the PIF.

Environmental Health Officers may request a copy of your PIF for the purposes of Market Surveillance.