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 (SCPN).
- 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, unless they mandate a third party to take on RP obligations (article 10.3).

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 4 – Responsible Person

Article 4 as it applies to Northern Ireland under the Protocol provides that a cosmetic product cannot be placed on the Northern Ireland or EEA market unless there is a Responsible Person established in either Northern Ireland or the EU. Please note that Northern Ireland businesses that are supplied cosmetic products from GB and are distributors before 1 January 2021 will take on importer duties under the EU law from 1 January 2021. They will, therefore, also be the Responsible Person for the specific cosmetic products they place on the NI or EEA market. It is possible for a Manufacturer or Importer to designate a third party to act as the Responsible Person via a written mandate. This person must be based in NI or the EU.

There are particular provisions for Northern Ireland businesses who place products from countries outside of the UK (including the EEA) on the market in Great Britain (see GB guidance).

Where the manufacturer is not based in NI or the EEA but the product is manufactured in NI or the EEA and remains in NI or the EEA between manufacture and placing on the market (i.e. it is not exported and imported back into NI or the EEA after manufacture but before being first supplied on the NI market) the manufacturer must ensure via written mandate that there is a third party based in NI or the EEA who agrees to be the Responsible Person in respect of that product.

Northern Ireland businesses seeking to sell or supply a qualifying Northern Ireland good in GB can continue to make products in line with the EU rules that the Protocol applies to Northern Ireland (Regulation (EC) No 1223/2009 on Cosmetic Products) and sell the same product in the rest of the UK. There will be no additional approvals to sell qualifying Northern Ireland goods in the rest of the UK. If the Northern Ireland business is the Responsible Person under NI law and meets the obligations under NI law, then they will be treated as complying with most of the obligations under GB law (including labelling, safety

assessments etc.), although they will need to send certain information to the Secretary of State. If the Responsible Person for products placed on the Northern Ireland market is in the EEA, the Northern Ireland business will be the Responsible Person for the purposes of GB law but does not have to change the contact details on the product, nor will they have to undertake separate safety assessments. They will have to make sure that the product is safe for human health (see Article 3) and will have to send certain information to the Secretary of State (see Article 13).

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

<u>Cosmetic Product Safety Report – Qualifications</u>

Article 10 states - "a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by a Member State."

"Diploma or other evidence" - This is generally understood to refer to a university degree (typically lasting at least three years duration)

"Similar discipline" - As a guide, biological/biochemical subjects with some toxicological components can be argued as similar disciplines.

"Course recognised as equivalent" - Chartered Biologist or Chartered Chemist are usually accepted as 'equivalent'. Short courses such as the Brussels Free University course on cosmetic safety assessment, whilst specifically targeted, would not be 'equivalent'. A course recognised 'as equivalent' must be of an equivalent level. Assessors should provide proof of qualification and evidence of equivalence (if necessary).

For cosmetic products being sold in NI, the safety assessment should take the form of a Cosmetic Product Safety Report (CPSR) signed by a qualified safety assessor as recognised by the EU.

Northern Ireland businesses, where a safety assessment has been done under the applicable law in Northern Ireland (Regulation (EC) No 1223/2009 on Cosmetic Products),

do not have to take any further steps in relation to this Article to sell a qualifying Northern Ireland good in GB.

Micro quality – legislative basis

Article 3 Safety "… shall be safe for human health when used under normal or reasonably foreseeable conditions of use"

Annex I (Cosmetic Product Safety Report) Part A para. 3 – Microbiological quality of the raw materials and finished cosmetic product

The Cosmetic Products Enforcement Regulations 2013 [SI 2013/1478]. Reg. 12(1) Offence and Schedule 4 list of breaches of 1223/2009 (breach of Article 3)

Micro Quality of finished Cosmetics – recommended Limits are not prescribed by legislation, but specified by technical experts through CEN/ISO standards making BS EN ISO 17516: 2014.Table 1

Micro Testing - Guidance to Manufacturers

Commission Guidelines on Annex I* (Cosmetic Product Safety Report) of 1223/2009 (see 3.3.2) specify that for products other than low risk products (i.e. products not on the non-exhaustive list above), a Preservation Challenge Test and Microbiological tests on the finished product are necessary *Commission Implementing Decision 2013/674/EU

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, including Proof of Effect where justified
- Details of animal testing

(Industry Guidance: https://cosmeticseurope.eu/library/8)

The Manufacturer must make this file available to us when requested.

All information must be in English.

Check all the information in detail to ensure it contains everything, that it is for the product you requested and that it has been produced since the change in Legislation (2013).

Use Annex I of Reg 1223/2009 as a detailed checklist.

Product Description

" a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product"

- Exact product name
- Unique internal formulation reference
- Product notification reference
- Language variations
- Product function

Method of Manufacture

“a description of the method of manufacturing and a statement on compliance with good manufacturing referred to in Article 8”

Should include:

- a general overview (including bulk storage/filling)
- Summary of the process
- Cross-references to documentation (e.g. specific sites)
- Can provide a demonstration of a controlled process at every stage

Statement of GMP (Article 8)

Provide a statement of compliance. This is not necessarily a certificate as it does not require third party verification. Statement should include reference to guide/standard used (e.g. ISO 22716)

Cosmetic Product Safety Report

“the cosmetic product safety report referred to in Article 10 (1)” (& Annex I)

(As detailed above.)

Check it has been signed by someone who is qualified to be an assessor. Check the assessors recommendations for e.g. labelling and if they have been implemented (this also shows that the label has been reviewed as part of the assessment).

Proof of Claims

“where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product”

As a minimum there should be a short summary. Full technical data may be external to PIF, for novel or complex claims only e.g. SPF or teeth whitening shade change claims. It is not for obvious effects, such as cleaning (e.g. if containing SLS, an accepted cleaning ingredient).

Check the evidence, is it relevant to the product?.

Common Criteria for Cosmetic Claims

Evidential support = one of six Common Criteria

1. Legal compliance – e.g. that a product is Government approved
2. Truthfulness – e.g. claims on an ingredient imply the product has the same characteristic
3. Evidential support – e.g. adequate and appropriate evidence must be available
4. Honesty – e.g. performance is based on use of two products combined
5. Fairness – e.g. denigration of safe and legal ingredients
6. Informed decision-making – e.g. consideration of the average consumer

Focus on 'free-from'. Some 'free-from' may be acceptable e.g. aiding consumers to make an informed choice. However, 'Free-from' claims may breach one or more of the Common Criteria e.g. Free from a prohibited ingredient (legal compliance) that all similar products will also be free from. 'Free-from' includes claims with a similar meaning e.g. 'zero', 'without', 'does not contain'.

Further guidance:

Common Criteria Regulation – Justification of Cosmetic Claims: Regulation (EU) No.655/2013

Common Criteria Guidelines • Commission Technical Document on Cosmetic Claims (inc. 'free-from' and hypoallergenic claims)

Animal Test Data

Animal Testing is prohibited, unless there are reports from before this was introduced, companies shouldn't have anything for this.

13-SANCO-COS-CO
SCOM-19 Article 18

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.

https://webgate.ec.europa.eu/cpnp/public/tutorial.cfm

*EU Exit – Products sold in NI will continue to be notified on the CPNP. Products sold in GB will need to be notified on the UK's Submit Cosmetic Notification Portal (SCPN). Regardless of where the Manufacturer/Responsible Person is located.

Submit Cosmetic Product Notifications (SCPN) for Businesses

Search Submit Cosmetic Product Notifications (SCPN) - Market Surveillance Authorities

Article 13 requires that the responsible persons and, under certain circumstances, the distributors of cosmetic products submit some information about the products they place or make available on the European market through the CPNP.

This must be done before placing the product on the market

The CPNP is making this information available electronically to:

- competent authorities (for the purposes of market surveillance, market analysis, evaluation and consumer information)
- poison centres or similar bodies established by EU countries (for the purposes of medical treatment)

The CPNP is accessible to

- competent authorities
- European poison centres
- cosmetic products responsible persons
- distributors of cosmetic products

Products containing nanomaterials
The CPNP also contains a separate module (Article 16) for cosmetic products containing nanomaterials. This notification has to be done in addition to the notification under Article 13. If the European Commission has concerns regarding the safety of a nanomaterial, it may request the scientific committee on consumer safety to perform a risk assessment.

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****

CBD

CBD in cosmetics must not be derived from:

- flowering or fruiting tops of the plant; or
- whole plant, where top remains during processing

Misuse of Drugs Act 1971 / Regulation 2001 states that Cosmetic products must meet ALL three limbs of exempt product definition:

- [controlled substance] is not designed for administration to a human being

- controlled substance cannot be recovered

- component or product contains <1mg controlled substance

Article 19 – Labelling

Mandatory Labelling

- RP Name and Address
- Function of the product
- Country of origin
- Net content
- Warnings/Precautions
- Batch Code
- Best Before Date
- Period After Opening (PAO)
- Ingredients list

NB.No CE mark – Cosmetics Regulation is not a ‘New Approach’ Directive.

Best Before / Period After Opening

3 scenarios

1. Date of minimum durability (BB) (< 30M)

2. PAO (> 30M) Exemptions: aerosols, single use products, products which do not cause harm

3. Some products may not need either BB or PAO NB. BB relates to safety and efficacy PAO relates to safety only

Ingredients list

“INGREDIENTS”

• INCI names

• Colour Index (CI)

• Order

• “may contain” / +/- exemption

• “Parfum” and “Aroma”

• 26 Allergens

• (nano)

Primary and Secondary Pack

Indelible, Easily Legible & Visible

Labelling Requirement	Primary Container (inner)	Secondary Container (outer)
Name, EC address of manufacture or importer/distributor	Yes	Yes
Country of origin	Yes	Yes
Declared quantity of contents	Yes	Yes
'Best before...' date	Yes	Yes
Period After Opening (PAO)	Yes	Yes
Warning statements and precautionary information	Yes	Yes
Batch code	Yes*	Yes
Function of the product	Yes	Yes
Declaration of the ingredients	**No****	**Yes**

**Where it is impossible for reasons of size for the lot code to appear on both the primary container and outer packaging, it may appear on the outer packaging alone.*

*** required on the primary packaging where there is no secondary packaging*

No requirement regarding where this information should be labelled on pack.

Labelling Exemptions

Small packs: Each pack should be considered on a case-by-case basis taking into consideration:

• size

• whether there is outer packaging

• shape/labelling area available;

• length of the ingredient list and the amount of warnings and precautions.

Difficult shape packs: Products that are not particularly small, but their shape makes labelling in the normal way difficult

Alternative Options

1. Leaflet or nearby tag/card + ‘hand and book symbol’ The Regulation allows alternative solutions to be found for the labelling of both the precautions/warnings and ingredient labelling (only). An enclosed leaflet, label, tape or card must contain the ingredient list and / or warnings information to which the consumer is referred either by abbreviated information or which must appear on the pack. Where the symbol replaces: Warnings: the symbol should appear on the primary and secondary packaging. Ingredients: the symbol should appear only on the secondary packaging

2. Notice in the immediate proximity The Regulation allows when it is impracticable for reasons of size or shape for the ingredients list to be given, or to be displayed on a notice in the immediate proximity to the container in which the product is being sold.

Non Pre-packaged Products

Where a cosmetic is supplied in neither a container nor packaging, the Regulation allows all the labelling requirements to appear either:

• on the container in which the product is exposed for supply or

• on a notice in immediate proximity to that container

Refillables

Key considerations:

• Hygiene – is the consumer responsible for washing and drying the bottle

• Good Manufacturing Practice (in store)

• Fill weight controls – ok if using companies own bottles, but consider if consumers are bringing their own. Are these bottles suitable for numerous refills.

• Labelling

• Safety assessment

• Formulation robustness (preservation)

Most companies are just offering shower gels as the bottles are easy to clean out. Lotions and oil based products are more difficult to wash out.

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. Within the EU, the competent authorities of the EU countries share information about undesirable effects to try and reduce the occurrence of future effects. However, as the UK has left the EU, the UK will now not be taking part in information sharing.

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 carries 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.