

# **Guidance for Importing Cosmetic Products**

## **Responsible Person**

**Regulation (EC) No 1223/2009 on cosmetic products**, states that only a responsible person can place a cosmetic product on the GB market. A responsible person instead can be one of the following:

- A person in the UK designated by written mandate by a manufacturer outside of the UK
- A distributor, where they place a cosmetic product on the market under their name or trademark, or modify a product already placed on the market in such a way that compliance with the applicable requirements may be affected - for example, repackaging or relabelling
- The importer (established in the UK who places a product from a country outside the UK on the UK market)

In the absence of a UK based manufacturer or authorised representative, the duties of the responsible person will fall to you as the importer. If this is the case, then you will need to fulfil the legal duties below.

#### **Duties of the Responsible Person**

- Ensure that the cosmetic product has undergone a safety assessment and that a cosmetic product safety report is produced
- Keep certain product information (see Compliance section) at the registered office address or the address detailed on the product. This information must be easy for Trading Standards authorities to access and can be requested if needed. The information must be in English
- Collate the Product Information File (PIF). This should contain information about the finished product, including evidence of safety and efficacy
- Produce a copy of the Cosmetic Safety Report (CSR). This document may also be requested by a Trading Standards Authority
- Ensure the cosmetic product is registered on the Submit Cosmetic Products Notifications portal (SCPN). Each new cosmetic product needs be registered using the link <u>Submit a cosmetic product notification - GOV.UK (www.gov.uk).</u> The information below needs to be provided:



- the category of cosmetic product and its name or names, enabling its specific identification
- the name and address of the responsible person
- the contact details of a physical person to contact in the case of necessity (if the cosmetic product has been imported into the UK)
- the presence of substances in the form of nanomaterials and their identification
- the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties
- o a legible photo of the final packaging

### Labelling

The following information must be present on the packaging or, if the packaging is too small by a leaflet, label, tag, tape or card enclosed with or attached to the product. This information must be visible, indelible and easily legible:

- The name and address of the UK responsible person must be on the container (such as a tube, bottle or jar) and the packaging (for example, the box or outer carton). Where the product is manufactured outside the UK, the country of origin must also be given
- Durability, where a cosmetic product has a minimum durability of 30 months or less, it must be marked on the container and the packaging with a best-before date or the symbol shown below



The indication must be in the form 'Best used before the end of', followed by the date (day / month / year or month / year) or an indication of where the date appears on the packaging. If any particular conditions must be observed to guarantee the stated durability, these must also be described

Where a product has a shelf life of more than 30 months, it must instead be marked with the symbol shown below together with an indication (in months, or years and months) of the period after opening for which the product can be used without harming the consumer





- Precautions to be observed in use must be printed on the label (see warnings section below). If the product is for professional use only, such as in hairdressing, this must appear on the container and packaging
- The batch number of manufacture or the reference for identifying the goods
- The function of the product if not otherwise obvious from design and packaging
- Ingredients List: This must be clearly highlighted as 'INGREDIENTS' on the packaging. The ingredients must be listed in descending order of weight. This includes products for professional use and free samples
- The ingredient name must be that listed in the International Nomenclature of Cosmetic Ingredients (INCI) or, if no such name is listed, one of the following:
  - o chemical name
  - European Pharmacopoeia name
  - International Non-proprietary Name (INN), as recommended by the World Health Organisation
  - European Inventory of Existing Commercial chemical Substances (EINECS), International Union of Pure and Applied Chemistry (IUPAC), or Chemical Abstracts Service (CAS) identification reference
  - o colour index number

#### **Warnings and Instructions**

The Preamble to Annex II in the Regulations defines different types of cosmetic product. Check the Preamble, to see which category of cosmetic the product falls into, as this will affect the substances allowed and the warnings to be applied.

Annex II, III, IV, V and VI contain a list of substances, colourants, preservatives and UV filters prohibited or restricted in cosmetic products. Check this list to make sure the ingredients of the product don't contain substances not allowed.

Check the tables in Annexes III to VI to find the correct wording for conditions of use, warnings and symbols.



All cosmetic products must include clear instructions for use, so that the product can be used safely.

Below are some of the examples of the warnings and conditions of use by product type, depending on the substance used:

- Hair products: not to be used by children under 3, avoid contact with eyes and rinse eyes immediately if the product comes into contact with them
- Hair dyeing products: can cause an allergic reaction, wear suitable gloves, follow instructions
- Certain nail products: keep out of reach of children, can cause blindness

#### **Compliance Documentation**

As an importer of cosmetic products into GB, you must ensure the products you place on the market are safe for human health under normal or reasonably foreseeable conditions of use. The Responsible Person section at the top of this document states in certain circumstances you may be defined as the responsible person. Therefore, you must ensure you can provide the relevant safety documents listed below to a Trading Standards Authority on request.

- Product Information File (PIF). This must be kept at the address of the responsible person, and it must contain the following information:
  - A description of the product
  - A copy of the Cosmetic Product Safety Report
  - Details of methods of manufacture in accordance with good manufacturing practice
  - Proof of the effect claimed for the cosmetic product, where justified by the nature or the effect of the cosmetic product
  - Data on animal testing if conducted.
- Cosmetic Product Safety Report (CPSR) forms the safety assessment of the product. The report must be compiled by a qualified safety assessor and signed off by the responsible person. The report must:
  - Consider the intended use of the cosmetic product and the anticipated exposure to each ingredient in the final formulation



- Apply an appropriate weight-of-evidence approach for reviewing all sources of data
- Ensure the report is kept up to date in view of any new information received.
- The report is split into part A and part B.
- Part A covers gathering the data required to identify and quantify from the identified hazards, the risk that a cosmetic product may present to human health.
- Part B will provide a conclusion as to why the safety assessor believes the cosmetic product is safe.
- Part A
  - o Quantitative and qualitative composition of the cosmetic product
  - Physical/chemical characteristics and stability of the cosmetic product
  - Microbiological quality
  - o Impurities, traces, information about the packaging material
  - Normal and reasonable foreseeable use
  - Exposure to the cosmetic product
  - Exposure to the substances
  - Toxicological profile of the substances
  - Undesirable effects and serious undesirable effects
  - Information on the cosmetic product
- Part B
  - Assessment Conclusion
  - Labelled warnings and instructions for use
  - o Reasoning
  - o Assessor's credentials and approval of part B



#### When sourcing your products, you should:

- Buy from a reputable supplier and always obtain an invoice
- Make sure the product/packaging is marked with the name and address of the responsible person
- Ask to see proof that the product is safe (a copy of the cosmetic product safety report)

The UK government provides further guidance on <u>Placing manufactured goods on</u> the market in Great Britain - GOV.UK (www.gov.uk)