

What you need to do to sell cosmetic products in Great Britain

This general guidance covers all cosmetic products that are available to a member of the public in Great Britain (GB). This includes products that are sold or given away (for example, free samples) and products used on the public by professionals. This guidance is to support understanding of Regulation (EC) No 1223/2009 on Cosmetic Products, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

All cosmetic products available to consumers must have a 'Responsible Person' who makes sure safety measures are followed and legal obligations are met.

A Responsible Person can be a business or an individual (including sole traders). A Responsible Person must have a UK established address to make cosmetic products available in GB. A UK established address does not include mail forwarding or PO box addresses.

A Responsible Person can be either:

- the manufacturer
- the importer
- the distributor, if they label the product as their own (for example, using their brand name)
- an appointed company or person (who is named by the manufacturer or the importer)

Making cosmetic products safe for users

Cosmetic products available to consumers in GB must be safe for human health. The Product Information File (PIF) contains information on how safe a cosmetic product is for human health. This is why it must be kept up to date. The PIF supports cosmetic product safety by providing:

- a safety assessment, which confirms a cosmetic product is safe and gives the scientific evidence to support this
- details on good manufacturing practice, which includes what has been done when manufacturing a cosmetic product to make sure it is safe

Making cosmetic products safe for users also covers how a cosmetic product is presented. It must:

- not be mistaken for food
- have clear labelling
- have instructions on use and disposal

The Product Information File (PIF)

The Responsible Person must keep a PIF in English for all their cosmetic products. The PIF includes:

1. a description of the cosmetic product
2. the product safety report
3. how good manufacturing practice has been followed
4. evidence for the cosmetic product's effects

The PIF must be kept for 10 years after the last batch of the cosmetic product was made available.

The cosmetic product safety report

Before making a cosmetic product available to consumers, its safety must be checked by a qualified safety assessor. The cosmetic product safety report forms part of the PIF.

The two parts of the cosmetic product safety report are:

- the cosmetic product safety information (part A). This is provided by the Responsible Person
- the cosmetic product safety assessment (part B). This is provided by the safety assessor

The cosmetic product safety information (part A) provides all the details needed to perform a safety assessment on a cosmetic product. It may be necessary to carry out or organise testing of a cosmetic product to complete this section. Part A includes information on:

- the ingredients, their concentrations, chemical names and toxicological properties
- the physical and chemical properties of ingredients and the final cosmetic product
- the product stability
- any microbial contaminants in ingredients or the final product
- how preservatives prevent microbial contamination of the product
- any impurities
- what has been used to package the product
- how the cosmetic product is likely to be used
- the quantities of the ingredients and final product the user could be exposed to

The cosmetic product safety assessment (Part B) is the safety assessor's conclusions to part A. It includes:

- an assessment of the product's safety
- any necessary warnings or instructions for the product
- the scientific reasoning for the conclusions of the safety assessment
- details of the safety assessor, including name, address, and proof of qualifications

How to get a cosmetic product safety assessed

The product safety assessment is carried out by a qualified professional. This is someone who has a university degree in pharmacy, toxicology, medicine, or a similar discipline. It is the responsibility of the Responsible Person to ensure the safety assessment is carried out by a suitably qualified safety assessor.

Good manufacturing practice for cosmetic products

The manufacture of cosmetic products must comply with 'good manufacturing practice'. This is about how the reproducibility and quality of a cosmetic product is ensured when it is made.

Good manufacturing practice can be demonstrated through compliance with the relevant designated standard ISO 22716.

Good manufacturing practice for cosmetic products is different to good manufacturing practice for pharmaceuticals.

How to comply with good manufacturing practice

ISO 22716 describes practical things that can be done to apply good manufacturing practice. Whilst ISO 22716 is commonly used, it is not the only way to demonstrate good manufacturing practice. ISO 22716 says that the company producing cosmetic products must:

- make sure all people employed know their roles and responsibilities for production, control, storage, and shipment of cosmetic products
- make sure staff have appropriate training and skills for cosmetic product manufacture
- ensure the place cosmetic products are manufactured is regularly maintained and cleaned
- make sure the place cosmetic products are manufactured is set up to reduce the risk of products and raw materials mixing
- make sure equipment used for manufacturing is regularly maintained and avoids cosmetic product contamination
- know comprehensive information on supply chains for raw materials so any problems can be traced
- make sure any water used for cosmetic product manufacture is adequately treated and tested routinely for microbes and impurities
- have detailed information on how the cosmetic product has been produced
- know where in the manufacturing process to test cosmetic product quality
- give a cosmetic product a batch number and label
- check any equipment and the place the cosmetic product is being manufactured before manufacture, to minimise contamination
- make sure the quality of the product is maintained in storage, when being shipped and also when being returned
- record and justify changes to the manufacturing process
- use quality control as a way to find if a cosmetic product, raw materials, or items used for packaging change unexpectedly
- know and define the different types of waste generated during manufacture
- identify and dispose of waste in a controlled and sanitary way
- investigate any complaints or problems with a cosmetic product. This includes looking at measures which need to be taken to prevent problems happening again. It also includes verifying batches which have been affected by problems
- perform internal audits to ensure these steps (defined in ISO 22716) are being correctly implemented
- ensure there is up to date documentation in place to show what happens during manufacture, quality control, storage, and shipment of cosmetic products. Examples would include protocols and methods

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The two parts of the cosmetic product safety report are:

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The cosmetic product safety information (part A) provides all the details needed to perform a safety assessment on a cosmetic product. It may be necessary to carry out or organise testing of a cosmetic product to complete this section. Part A includes information on:

- the ingredients, their concentrations, chemical names and toxicological properties
- the physical and chemical properties of ingredients and the final cosmetic product
- the product stability
- any microbial contaminants in ingredients or the final product
- how preservatives prevent microbial contamination of the product
- any impurities
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The cosmetic product safety assessment (Part B) is the safety assessor's conclusions to part A. It includes:

- an assessment of the product's safety
- any necessary warnings or instructions for the product
- the scientific reasoning for the conclusions of the safety assessment
- details of the safety assessor, including name, address, and proof of qualifications

Labelling cosmetic products

The labelling for cosmetic products must be easy to read. The container and any packaging must be labelled with:

- the name and address of the Responsible Person
- the country of origin if the product is imported to the UK
- the weight or volume
- the date which the cosmetic product can be used until
- any precautions for use
- an identification number (for example batch number)
- what the cosmetic product does
- the ingredients - these can be provided solely on the packaging. Note that nanomaterial ingredients must be followed by '(nano)'

In some cases, the usage date and the weight or volume may not be required, for example where the contents are less than 5 grams or 5 millilitres. This may apply to free samples and single-application packs.

It may not be practical to include precautions and ingredients for certain cosmetic products, for example due to available space on packaging. If this is the case it is important to include this information within the packaging, for example on a leaflet. A symbol should be used to indicate where this information is.

Making claims about what a cosmetic product does

The labelling and advertising of cosmetic products must not imply they have characteristics or functions which they do not have.

Keeping users of cosmetic products safe

Adverse reactions to cosmetic products

If a user of a cosmetic product has a reaction which results in them being temporarily or permanently unable to carry out their usual day-to-day tasks this must be reported to OPSS immediately as a serious undesirable effect (SUE). Examples of the effect that must be reported include disability, hospitalisation, congenital abnormalities, risk to life, and death.

Forms to fill out for SUEs can be found on the [Cosmetic products: reporting SUEs page](#). Further details must be provided on:

- the Responsible Person
- all serious effects the user experiences
- the name and batch number of the cosmetic product
- any corrective measures taken

All SUE forms must be submitted to seriousundesirableeffects@beis.gov.uk.

Effects on users that do not prevent them from doing their day-to-day tasks do not need to be reported. For example, allergic reactions, irritation, and cosmetic acne.

Safety concerns about substances in cosmetic products

There may be situations where there are serious concerns about the safety of substances in cosmetic products. If this is the case the Responsible Person may be asked by OPSS to provide:

- the cosmetic products containing this substance
- the concentrations of this substance in associated cosmetic products

Making information accessible to the public

If requested by a member of public, the Responsible Person must provide:

- the list of ingredients of the product - this is sometimes called the qualitative composition
- information on amounts per unit weight or volume for any hazardous ingredients such as CMRs - this is sometimes called the quantitative composition
- data on undesirable effects and serious undesirable effects (SUEs)