

# Requirements for Cosmetic Products

## EU Requirements: EU Regulation

Regulation 1223/2009 on Cosmetic Products (the “EU Cosmetics Regulation) contain rules on” regulates the supply and sale of cosmetics/cosmetic products in the EU. It sets out a number of important requirements in relation to cosmetic products, including prohibitions and restrictions on certain substances, a requirement for a responsible person based in the EU and labelling requirements.

It is your responsibility to comply with the Cosmetics EU requirements if you are selling cosmetics products in the EU. You must also comply with other national requirements in the countries in which you sell these products.

Please see below for further information about EU requirements.

UK Requirements: From 1 January 2021, an amended version of Regulation (EC) No 1223/2009 applies to the supply and sale of cosmetic products in the UK as a result of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (the “UK Regulation on Cosmetic Products”). This sets out a number of important requirements in relation to cosmetic products, including prohibitions and restrictions on certain substances, a requirement for a responsible person based in the EU and labelling requirements. Different rules apply to goods you sell in: (1) Great Britain (England, Scotland and Wales); and (2) Northern Ireland. We have noted below where there will be relevant changes in the UK requirements from 1 January 2021.

It is your responsibility to comply with the UK requirements if you are selling cosmetics products in the UK. If you also sell on cosmetics products on Amazon EU website(s), then you must also comply with EU Cosmetics Regulation and with other national requirements in the countries in which you sell these products.

Please see below for further information about UK requirements.

This material is for informational purposes only. It is and you should not intended take it as a substitute for legal advice. We encourage you to consult your legal counsel if you have questions for any concerns about the laws and regulations concerning your product. This material only reflects the position at the date of writing and requirements across the EU and in the UK may change. You should refer to current UK Brexit guidance about your products (where available) to learn more about changes that may affect you from 1 January 2021 .

## I. EU Requirements

What products are in scope of the Cosmetics Regulation EU requirements for Cosmetic Products?

The [EU](#) Cosmetics Regulation applies to any cosmetic product supplied or sold ~~to~~ in the EU. A “cosmetic product” can be broadly described as a substance or mixture that is intended to be applied to the human body (including the skin, hair, nails, lips, external genital organs, teeth and mucous membranes of the oral cavity) for the purposes of cleaning, perfuming, changing its appearance, protection, keeping the body or that part of the body in good condition or correcting body odours. Examples of cosmetics products range from antiperspirants to soap, make-up to toothpaste, sun lotion to perfume.

### **What are the key requirements of the [EU](#) Cosmetics Regulation?**

The [EU](#) Cosmetics Regulation is a complex piece of legislation that has a number of important requirements that must be complied with before a cosmetic product can be sold in the EU. In particular, (i) restrictions on what a cosmetic product can contain if it is to be sold in the EU, (ii) the requirement to have a responsible person based in the EU, (iii) key labelling information that must be provided with the product and on the product packaging, and (iv) a requirement to keep a product information file detailing proof of compliance for each cosmetic.

The information provided [here](#) is not an exhaustive description of the relevant requirements, and you are encouraged to seek [specific](#) advice on ensuring compliance with the [EU](#) Cosmetics Regulation.

### **Ingredient restrictions**

The [EU](#) Cosmetics Regulation sets out certain restrictions on what a cosmetics product [sold in the EU](#) can contain. Certain substances are prohibited and cannot be used in cosmetics in the EU in any circumstances (see Annex II of the [EU](#) Cosmetics Regulation). Other substances can only be used if that use complies with the relevant restrictions (see Annex III of the [EU](#) Cosmetics Regulation). In addition:

- A cosmetic product cannot contain certain CMR (Carcinogenic, mutagenic or toxic to reproduction) substances (under the CLP Regulation (EC No. 1272/2008), unless specific exceptions apply.
- Only the colorants listed in Annex IV, the preservatives listed in Annex V, and the UV filters listed in Annex VI of the [EU](#) Cosmetics Regulation can be used. They must be used in accordance with the relevant restrictions.

Lastly, cosmetic products containing nanomaterials must be specifically notified to the European Commission.

### **Responsible person**

[For every cosmetic product](#), there must be a responsible person, based in the EU, ~~for every cosmetic product~~. The responsible person is responsible for ensuring that each cosmetic product complies with the requirements of the [EU](#) Cosmetics Regulation. They may be a natural or a legal person and will either be the manufacturer, importer or [a mandated and authorised person or entity](#), depending on the circumstances. In limited circumstances, a distributor can be the responsible

person if they modify a cosmetic product in a way that could affect the cosmetic product's compliance with the [EU Cosmetics Regulation](#), [or sell a cosmetic product in the EU under their name or trademark](#). The contact information of the responsible person (name and ~~EU~~ address) must be on the container and packaging of each cosmetic product.

### ~~Key labelling information~~

~~There are mandatory labelling requirements that set out the information that must be included on the product and its packaging. This information includes: name or registered name and the EU address of the responsible person, country of origin information (if imported), nominal content/, date of minimum durability, precautions for use, batch number, function (unless clear) and ingredients.~~

~~Certain Key information must be translated into the language(s) of the EU countries in which the cosmetics products will be sold.~~

~~In addition, some specific information must be submitted into the Cosmetic Product Notification Portal before a cosmetic product can be sold in the EU.~~

### **Product information file**

The responsible person must keep a product information file for a period of ten years from the date on which the last batch of the cosmetic product was supplied or sold ~~on~~<sup>in</sup> the EU ~~market~~. The product information file must also be readily accessible in electronic or other format at the responsible person's address. This address must be indicated on the label. The product information file should contain: (i) a description of the cosmetic product; (ii) the cosmetic product safety report; (iii) a description of the manufacturing method and a statement on compliance with good manufacturing practice; (iv) proof of the effect claimed for the cosmetic product, where justified by the nature or the effect of the cosmetic product; and (v) data on any animal testing. This information should be updated as necessary.

### **What should I do if a cosmetic product does not comply with the Cosmetics Regulation?**

Where a responsible person considers or has reason to believe [that](#) a product is not in conformity with the [EU Cosmetics Regulation](#), [they](#) must immediately take the necessary corrective measures to bring the product into conformity, withdraw it or recall it, as appropriate. Where that cosmetic product presents a risk to human health, the responsible person must immediately inform the competent authority where the product has been made available and where the product information file is accessible, giving details of, in particular, the non-compliance and corrective measures taken.

Responsible persons are under an obligation to cooperate with the competent authorities and, if requested to, cooperate on any action to eliminate the risks posed by products that they have made available. Responsible persons must respond to a reasoned request from an authority to provide

the information and documentation necessary to demonstrate conformity with the requirements that they were under an obligation to check.

Amazon does not allow the sale of professional use only cosmetics. Please check with the manufacturer or product label to see if your product is professional use only.

### **What are the cosmetic product labelling requirements?**

Cosmetic products must, on the container and packaging, include the following information. This must be in indelible, easily legible and visible lettering:

- The name or registered name and the address of the responsible person. This information can be abbreviated as long as the responsible person and their address can be identified. If more than one address is indicated, the address where the product information file is made available should be highlighted.
- If the product is imported, the country of origin.
- The nominal content at the time of packaging (by weight or by volume) or the number of items in case of pre-packages normally sold as a number of items, unless an exception applies.
- The date of minimum durability. On the packaging, these must be preceded with the relevant symbol or the words “best used before end of”. This is not mandatory for cosmetic products with a minimum durability of more than 30 months.

Cosmetic products must, on the container and packaging, include certain information, including the information set out below. If it is not possible for this information to be on the container and packaging, it must be included on a leaflet, label, tape, tag or card enclosed or attached to the product. Unless impracticable, abbreviated information or an applicable symbol can also be used.

- Particular precautions to be observed in use, and in particular, at least those listed in Annexes III to VI of the [EU Cosmetics Regulation](#).
- The batch number of manufacture or the reference for identifying the cosmetic product. If it is impossible for practical reasons for this information to appear on the product, it can appear on the packaging only.
- The function of the cosmetic product, unless it is clear from its presentation.
- A list of ingredients as prescribed by the [EU Cosmetics Regulation](#)- [on Cosmetic Products](#). The list must at least appear on the packaging.

Key information must be translated into the language(s) of the EU countries in which the cosmetics products will be sold.

### **Notification requirements**

Prior to selling a cosmetic product in the EU, the responsible person (and in certain circumstances the distributor), must submit information to the European Commission (via the Cosmetic Product Notification Portal).

This information that needs to be notified includes the following:

- The category of cosmetic product and its name or names, enabling its specific identification.
- The name and address of the responsible person where the product information file is made readily accessible.
- The country of origin of the import.
- The member state where the cosmetic product is being sold.
- The contact details of a physical person to contact, if needed, should be provided.
- The presence of substances in the form of nanomaterials, their identification and foreseeable exposure conditions.
- The name and the Chemical Abstracts Service or EC number of certain CMR substances.
- The frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

The information above is not an exhaustive list of notification obligations. Therefore we encourage you to seek advice to ensure full compliance with the regulatory regime.

### **Additional Information**

We strongly encourage you to visit the European Commission’s website for more information on cosmetics products in the EU:

- [http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance\\_en](http://ec.europa.eu/growth/sectors/cosmetics/market-surveillance_en)
- [https://ec.europa.eu/growth/sectors/cosmetics/legislation\\_en](https://ec.europa.eu/growth/sectors/cosmetics/legislation_en)

## **II. UK Requirements**

### **What products are in scope of the UK requirements for Cosmetic Products?**

The UK requirements for cosmetic products apply to any cosmetic product supplied or sold in the UK, but the provisions apply differently to Great Britain (England, Scotland and Wales, “GB”) and Northern Ireland. You can read more about the position in Northern Ireland (“NI”) below. A “cosmetic product” can be broadly described as a substance or mixture that is intended to be applied to the human body (including the skin, hair, nails, lips, external genital organs, teeth and mucous membranes of the oral cavity) for the purposes of cleaning, perfuming, changing its appearance, protection, keeping the body or that part of the body in good condition or correcting body odours. Examples of cosmetics products range from antiperspirants to soap, make-up to toothpaste, sun lotion to perfume.

UK Regulation on Cosmetic Products has a number of important requirements that must be complied with before a cosmetic product can be sold in GB. These include, in particular:

- (i) restrictions on what a cosmetic product can contain if it is to be sold in GB; and
- (ii) the requirement to have a “responsible person” based in GB; and

- (iii) key labelling information that must be provided with the product and on the product packaging; and
- (iv) a requirement to keep a product information file detailing proof of compliance for each cosmetic product.

The information provided here is not an exhaustive description of the relevant requirements, and you are encouraged to seek specific advice on ensuring compliance with the UK's requirements for cosmetic products.

### **Ingredient restrictions**

There are certain restrictions on what a cosmetics product sold in GB can contain. Certain substances are prohibited and cannot be used in cosmetics in GB in any circumstances (see Annex II of the EU Cosmetics Regulation, ~~visit the~~ and UK Regulation on Cosmetic Products), other substances can only be used if that use complies with the relevant restrictions (see Annex III of the EU Cosmetics Regulation and UK Regulation on Cosmetic Products). In addition:

- A cosmetic product cannot contain certain CMR (Carcinogenic, mutagenic or toxic to reproduction) substances (under the CLP Regulation (EC No. 1272/2008), unless specific exceptions apply.
- Only the colorants listed in Annex IV, the preservatives listed in Annex V, and the UV filters listed in Annex VI of the EU Cosmetics Regulation and UK Regulation on Cosmetic Products can be used. They must be used in accordance with the relevant restrictions.

Lastly, cosmetic products containing nanomaterials must be specifically notified to the UK authorities (via the UK Submit Cosmetic Product Notification (SCPN) service)

### **Responsible person**

For every cosmetic product, there must be a responsible person, based in GB.

The responsible person is responsible for ensuring that each cosmetic product complies with the requirements for cosmetic products. They may be a natural or a legal person and will either be the manufacturer, importer or an authorised person, depending on the circumstances. In limited circumstances, a distributor can be the responsible person if they modify a cosmetic product in a way that could affect the cosmetic product's compliance with the EU Cosmetics Regulation / UK Regulation on Cosmetic Products or sell a cosmetic product in GB under their name or trademark. The contact information of the responsible person (name and address) must be on the container and packaging of each cosmetic product.

### **Product information file**

The responsible person must keep a product information file for a period of ten years from the date on which the last batch of the cosmetic product was supplied or sold in GB. The product

information file must also be readily accessible in electronic or other format at the responsible person's address. This address must be indicated on the label. The product information file should contain: (i) a description of the cosmetic product; (ii) the cosmetic product safety report; (iii) a description of the manufacturing method and a statement on compliance with good manufacturing practice; (iv) proof of the effect claimed for the cosmetic product, where justified by the nature or the effect of the cosmetic product; and (v) data on any animal testing. This information should be updated as necessary.

### **What should I do if a cosmetic product does not comply with the Cosmetics Regulation?**

Where a responsible person considers or has reason to believe that a product is not in conformity with the UK Regulation on Cosmetic Products they must immediately take the necessary corrective measures to bring the product into conformity, withdraw it or recall it, as appropriate. Where that cosmetic product presents a risk to human health, the responsible person must immediately inform Trading Standards, giving details of, in particular, the non-compliance and corrective measures taken.

Responsible persons are under an obligation to cooperate with Trading Standards and, if requested to, cooperate on any action to eliminate the risks posed by products that they have made available. Responsible persons must respond to a reasoned request from Trading Standards to provide the information and documentation necessary to demonstrate conformity with the requirements that they were under an obligation to check.

Amazon does not allow the sale of professional use only cosmetics. Please check with the manufacturer or product label to see if your product is professional use only.

### **What are the cosmetic product labelling requirements?**

Cosmetic products must, on the container and packaging, include the following information. This must be in indelible, easily legible and visible lettering:

- The name or registered name and the address of the responsible person. This information can be abbreviated as long as the responsible person and their address can be identified. If more than one address is indicated, the address where the product information file is made available should be highlighted.
- If the product is imported, the country of origin.
- The nominal content at the time of packaging (by weight or by volume) or the number of items in case of pre-packages normally sold as a number of items, unless an exception applies.
- The date of minimum durability. On the packaging, these must be preceded with the relevant symbol or the words "best used before end of". This is not mandatory for cosmetic products with a minimum durability of more than 30 months.

Cosmetic products must, on the container and packaging, include certain information, including the information set out below. If it is not possible for this information to be on the container and

packaging, it must be included on a leaflet, label, tape, tag or card enclosed or attached to the product. Unless impracticable, abbreviated information or an applicable symbol can also be used.

- Particular precautions to be observed in use, and in particular, at least those listed in Annexes III to VI of the EU Cosmetics Regulation / UK Regulation on Cosmetic Products.
- The batch number of manufacture or the reference for identifying the cosmetic product. If it is impossible for practical reasons for this information to appear on the product, it can appear on the packaging only.
- The function of the cosmetic product, unless it is clear from its presentation.
- A list of ingredients as prescribed by the UK Regulation on Cosmetic Products. The list must at least appear on the packaging.

Key information must be in English for cosmetics products sold in GB.

### **Notification requirements**

Prior to selling a cosmetic product in GB, the responsible person (and in certain circumstances the distributor), must submit information to the UK authorities (via the UK Submit Cosmetic Product Notification (SCPN) service).

This information that needs to be notified includes the following:

- The category of cosmetic product and its name or names, enabling its specific identification.
- The name and address of the responsible person where the product information file is made readily accessible.
- The country of origin of the import.
- The contact details of a physical person to contact, if needed, should be provided.
- The presence of substances in the form of nanomaterials, their identification and foreseeable exposure conditions.
- The name and the Chemical Abstracts Service or EC number of certain CMR substances.
- The frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

The information above is not an exhaustive list of notification obligations. Therefore we encourage you to seek advice to ensure full compliance with the regulatory regime.

### **Northern Ireland**

Please note that different rules apply in NI from 1 January 2021 as a result of the Northern Ireland Protocol. In particular:

- You should ensure that products meet EU requirements, including notification to the EU Portal (CPNP).
- The responsible persons can be based in NI or the EU.

- [“Qualifying Northern Ireland goods” will be able to be sold in GB. The UK Government is issuing guidance on how this will work.](#)

[Brexit guidance can be found here:](#)

[GB:](#)

- [Placing manufactured goods in Great Britain from 1 January 2021](#)
- [Product Safety and Metrology in GB from 1 January 2021](#)

[NI:](#)

- [Placing manufactured goods in Northern Ireland from Great Britain](#)
- [Placing manufactured goods in Northern Ireland from the EU](#)
- [Product Safety and Metrology – NI](#)

### [\*\*Additional Information\*\*](#)

[For more information on the requirements for cosmetics products in the UK, we encourage you to visit the following site:](#)

- <https://www.businesscompanion.info/en/quick-guides/product-safety/cosmetic-products>

[The following websites contain information about changes in relation to Brexit:](#)

- <https://www.ctpa.org.uk/brexit-advice>