

Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (76/768/EEC) (repealed)

[<sup>F1</sup>Article 7a

1 The manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market shall for control purposes keep the following information readily accessible to the competent authorities of the Member State concerned at the address specified on the label in accordance with Article 6 (1) (a):

- a the qualitative and quantitative composition of the product; in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier;
- b the physico-chemical and microbiological specifications of the raw materials and the finished product and the purity and microbiological control criteria of the cosmetic product;
- c the method of manufacture complying with the good manufacturing practice laid down by Community law or, failing that, laid down by the law of the Member State concerned; the person responsible for manufacture or first importation into the Community must possess an appropriate level of professional qualification or experience in accordance with the legislation and practice of the Member State which is the place of manufacture or first importation;
- [<sup>F2</sup>d assessment of the safety for human health of the finished product. To that end the manufacturer shall take into consideration the general toxicological profile of the ingredients, their chemical structure and their level of exposure. It shall take particular account of the specific exposure characteristics of the areas on which the product will be applied or of the population for which it is intended. There shall be *inter alia* a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.

Should the same product be manufactured at several places within Community territory, the manufacturer may choose a single place of manufacture where that information will be available. In this connection, and when so requested for monitoring purposes, it shall be obliged to indicate the place so chosen to the monitoring authority or authorities concerned. In this case this information shall be easily accessible;]

- e the name and address of the qualified person or persons responsible for the assessment referred to in (d). That person must hold a diploma as defined in Article 1 of Directive 89/48/EEC in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline;
- f existing data on undesirable effects on human health resulting from use of the cosmetic product;
- g proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product[<sup>F2</sup>;]
- [<sup>F3</sup>h data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety evaluation of the product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of non-member countries.

Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, Member States shall ensure that the information required under (a) and (f) shall be made easily accessible to the public by any appropriate

---

*Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.*

---

means, including electronic means. The quantitative information required under (a) to be made publicly accessible shall be limited to dangerous substances covered by Directive 67/548/EEC.]

2 The assessment of the safety for human health referred to in paragraph 1 (d) shall be carried out in accordance with the principle of good laboratory practice laid down in Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances<sup>(1)</sup>.

3 The information referred to in paragraph 1 must be available in the national language or languages of the Member State concerned, or in a language readily understood by the competent authorities.

4 The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing imported cosmetic products on the Community market, shall notify the competent authority of the Member State of the place of manufacture or of the initial importation of the address of the place of manufacture or of initial importation into the Community of the cosmetic products before the latter are placed on the Community market.

5 Member States shall designate the competent authorities referred to in paragraphs 1 and 4 and shall send details thereof to the Commission, which shall publish that information in the *Official Journal of the European Communities*.

The Member States shall ensure that the abovementioned authorities continue to cooperate in areas where such cooperation is necessary to the smooth application of this Directive.]

---

#### **Textual Amendments**

- F1** Inserted by [Council Directive of 14 June 1993 \(93/35/EEC\)](#).
- F2** Substituted by [Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products \(Text with EEA relevance\)](#).
- F3** Inserted by [Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products \(Text with EEA relevance\)](#).

---

**Status:** EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

---

(1) [<sup>F1</sup>OJ No L 15, 17. 1. 1987, p. 29.]

.....  
**Textual Amendments**

**F1** Inserted by [Council Directive of 14 June 1993 \(93/35/EEC\)](#).