STATUTORY INSTRUMENTS

2004 No. 2152

The Cosmetic Products (Safety) Regulations 2004

Product Information

9.—(1) Subject to paragraph (8) below, where a cosmetic product is manufactured or supplied in the United Kingdom a responsible person shall for control purposes keep easily accessible to a United Kingdom competent authority at the address or registered office specified on the container or packaging of the cosmetic product in accordance with regulation 7(2)(a) above the following information—

(a) the qualitative and quantitative composition of the product, except to the extent that the product is composed of any perfume or perfume composition, in which case the responsible person shall only be required to keep the name and code number of the perfume or perfume 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 which shall be in accordance with good manufacturing practice, that is to say that the cosmetic product shall be manufactured in such a way that under normal and reasonably foreseeable conditions of use it shall not endanger human health or safety;

(d) an assessment of the safety for human health of the finished product taking into consideration the matters specified in paragraph (2) below;

(e) a specific assessment of the safety for human health of the finished product taking into consideration the matters specified in paragraph (2) below in respect of cosmetic products intended for use on children under the age of 3 and for cosmetic products intended exclusively for use in external intimate hygiene;

(f) the name and address of the person or persons, qualified in accordance with paragraph (5) below, responsible for the assessments referred to in sub-paragraphs (d) and (e) above;

(g) existing data on undesirable effects on human health resulting from use of the cosmetic product;

(h) proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product; and

(i) 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 countries which are not Member States;

(2) The assessments referred to in paragraphs (1)(d) and (1)(e) above shall be carried out in accordance with the principles of good laboratory practice referred to in Article 1 of European Parliament and Council Directive 2004/10/EC(**1**) on the application of the principles of good

(**1**) O.J. No. L50, 20.2.2004, p. 44, implemented by the Good Laboratory Practice (Codification Amendment Etc.) Regulations (S.I. 2004/994).

laboratory practice and the verification of their applications for tests on chemical substances and shall take particular account of the following—

(a) the general toxicological profile of each ingredient used;

(b) the chemical structure of each ingredient;

(c) the level of exposure of each ingredient;

(d) the specific exposure characteristics of the areas on which the cosmetic product will be applied; and

(e) the specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

(3) Subject to paragraph (4) below and without prejudice to the protection in particular of commercial secrecy and of intellectual property rights where a cosmetic product is manufactured or supplied in the United Kingdom a responsible person shall ensure that the information specified in paragraphs (1)(a) and (1)(g) above shall be made easily accessible to the public by any appropriate means.

(4) For the purposes of paragraph (3) above, the quantitative information required under paragraph (1)(a) shall be limited to information relating to dangerous substances covered by Directive 67/548/EEC as amended.

(5) The person referred to in paragraph (1)(f) must be—

(a) subject to paragraph (6) below, the holder of an appropriate European diploma within the meaning of section 4A of the Pharmacy Act 1954(**2**) or any other person who has the right, granted by a competent authority in a Member State, to take up and pursue the activities of a pharmaceutical chemist;

(b) subject to paragraph (6) below, a person who is entitled to be registered under section 3(1) of the Medical Act 1983(**3**) as a fully registered medical practitioner and who has the right, granted by a competent authority in a Member State, to take up and pursue the activities of a doctor; or

(c) the holder of a diploma within the meaning of regulation 2(1) of the European Communities (Recognition of Professional Qualifications) Regulations 1991(**4**) showing that the holder has the qualifications required to practise as a chartered biologist or that he has the qualifications required to practise as a chartered chemist or that he has the qualifications required to practise a profession equivalent to the profession of chartered biologist or chartered chemist in a Member State other than the United Kingdom.

(6) Any diploma or other evidence of qualification required for the purposes of paragraph (5)(a) or (b) above shall satisfy that requirement only if—

(a) the education and training attested were received mainly within the European Community; or

(b) the holder has spent at least three years in lawful pursuit in a Member State of the relevant profession, and such professional experience has been certified by a competent authority in a Member State (being a State which recognised a diploma or other evidence of qualification obtained in a non-Member State).

(7) Where the responsible person is the manufacturer or the person who first imports the cosmetic product into the Community he must possess appropriate experience or an appropriate level of professional qualification in accordance with the legislation and practice of the United Kingdom if it is the place of manufacture or first importation.

(**2**) 1954 c. 61.
(**3**) 1983 c. 54.
(**4**) S.I. 1991/824, to which there is an amendment not relevant to these Regulations.

(8) Where the manufacturer manufactures a cosmetic product at two or more places within the Community, and one of those places is within the United Kingdom, the responsible person may choose a single place of manufacture within the Community where the information referred to in paragraph (1) above will be kept available provided that, if requested by a United Kingdom competent authority, he informs the said authority of the location at which the said information is to be kept.

(9) Where the information referred to in paragraph (1) above is to be kept accessible to a United Kingdom competent authority it must be in English or a language readily understood by the said authority.

(10) Paragraphs 9(1)(e), 9(1)(i), 9(2)(d) and 9(2)(e) above shall not apply in respect of cosmetic products placed on the market in the Community prior to 11th September 2004.