

## SCHEDULE 9

Regulation 21(3) and (5)

### PART 1

#### PARTICULARS TO BE INCLUDED WITH A REQUEST FOR CONFIDENTIALITY

1. In this Schedule, “common ingredients nomenclature” means the labelling nomenclature designated in the inventory of ingredients employed in cosmetic products, drawn up in accordance with the provisions of the Directive and contained in Commission Decision [96/335/EC](#)(1).

2. The particulars to be included with a request for confidentiality are as follows—
- (a) the name or trade name and address or registered office of the applicant.
  - (b) precise identification of the cosmetic ingredient for which confidentiality is requested, namely—
    - (i) where they exist, the CAS, EINECS and colour index numbers, the chemical name, the IUPAC name, the INCI name, the European Pharmacopoeia name, the INN as recommended by the World Health Organization and the common name as provided for in the common ingredients nomenclature;
    - (ii) the European List of Notified Chemical Substances (ELINCS) name and the official number allocated to it if it has been notified pursuant to Council Directive [67/548/EEC](#) and an indication of the decision to approve or refuse any request for confidentiality made under Article 19 of that Directive;
    - (iii) where the names or numbers referred to in sub-paragraphs (a) and (b) do not exist, for example in the case of certain ingredients of natural origin, the name of the base material, the name of the part of the plant or animal used and the names of the cosmetic ingredient’s compounds, such as solvents.
  - (c) the evaluation of the safety for human health of the cosmetic ingredient as used in the finished cosmetic product or products taking into account the cosmetic ingredient’s toxicological profile, chemical structure and the level of exposure as specified in regulation 16(1)(d) and (e) and carried out in accordance with the requirements of regulations 16(2), 16(3) and 16(4)
  - (d) the envisaged use of the cosmetic ingredient and in particular the different categories of cosmetic products in which it will be used.
  - (e) a detailed justification of why confidentiality is sought addressing for example—
    - (i) the fact that the identify of the cosmetic ingredient or its function in the cosmetic product to be supplied has not been described in the literature accompanying the cosmetic product and is unknown to other manufacturers or suppliers of cosmetic products;
    - (ii) the fact that the information is not yet in the public domain even though a patent application has been lodged for the cosmetic ingredient or its use;
    - (iii) the fact that if the information were known it would be easily reproducible, to the detriment of the applicant.
  - (f) if known, the name of each cosmetic product which is to contain the cosmetic ingredient and if different names are to be used in other Member States, precise details of each one of them.

(1) [96/335/EC](#) (O.J. No. L132, 1.6.96, p.1), as amended by Commission Decision [2006/1257/EC](#) (OJ No L97 5.4.2006, p1).

- (g) if the name of a cosmetic product is not yet known, it may be communicated at a later date, but at least 15 days before the cosmetic product is supplied.
- (h) if the cosmetic ingredient is used in several products, one request shall suffice, provided that the cosmetic products are clearly indicated to the competent authority.
- (i) a statement setting out whether a request has been submitted to the competent authority of any other Member State in respect of the cosmetic ingredient for which confidentiality is sought and particulars on the outcome of any such request.

## PART 2

### PROCEDURE FOR GRANT OF REGISTRATION NUMBER

3. The registration number referred to in regulation 21(5) shall consist of seven digits, the first two corresponding to the year of approval of confidentiality, the second two to the code assigned to each Member State, as referred to in paragraph 2, and the final three digits assigned by the competent authority.
4. The code allocated to the United Kingdom is 06.