

DECISION

laying down certain measures for keeping the confidentiality of some ingredients included in the composition of cosmetic products

(GD 560/2001)

THE GOVERNMENT OF ROMANIA

Pursuant to Article 107 of the Constitution of Romania,

HAS ADOPTED THIS DECISION:

Article 1

In order to keep the confidentiality, in the list containing the ingredients included in the composition of a cosmetic product, mentioned in Article 13 (1) (i) of Law No. 178/2000 on cosmetic products, the name of some ingredients may be marked in the form of a code consisting of seven digits.

Article 2

The manufacturer, the importer or the person on whose account a cosmetic product is manufactured, who wishes to include some cosmetic products in the conditions provided for in Article 1, shall submit a request, to the Ministry of Industry and Resources, for granting the right of confidentiality for the ingredients in question, before the cosmetic product is marketed.

Article 3

(1) The request specified in Article 2, hereinafter referred to as "*request for confidentiality*", must include the following particulars:

a) the name of the company or the name of the person and the address to which the applicant has its headquarters in Romania;

b) the specific identification of the ingredient for which the confidentiality is requested, namely: the CAS, EINECS and colour index number, the chemical name, the IUPAC name, the INCI name, the European Pharmacopoeia, the international non-patented name recommended by the World Health Organization, the name from the European Commission common nomenclature of ingredients, the ELINCS name and the official number allocated to the ingredient when it has been notified in accordance with the laws regarding the dangerous chemical substances and mixtures, as well as the reference to the approval or the refusal to approve the request for confidentiality, requested in accordance with this law:

c) where the numbers and names referred to in point (b) do not exist, as is the case of certain ingredients of natural origin, the name of the raw material, the name of the part of the plant or animal used, and the names of the components of that ingredient, solvents included, shall be indicated;

d) the evaluation of the safety for human health of the ingredients, as used in the finished cosmetic product, taking into account the toxicological profile, chemical structure and the level of exposure of the ingredient, in accordance with the good laboratory practice principles;

e) the envisaged use of the ingredient, and in particular, the different categories of cosmetic products in which it will be used;

f) for products imported from the European Union, a statement setting out whether a request similar to that specified in Article 2 has been submitted to a competent authority of an EU Member State and the outcome of any such request;

g) the name of each cosmetic product that is to contain the ingredient in question, and if different names are to be used on the market, specific details on each one of them;

h) if the name of a product is not known yet, it may be communicated at a later date, but at least 15 days before placing the product on the market;

i) if the ingredient is used in several products, one request shall suffice, provided that the cosmetic products are clearly indicated.

(2) The names provided for in paragraph (1)(b) are defined in the Annex which is integral part of this Decision.

(3) The request mentioned in Article 2 must be accompanied by a detailed justification regarding the reason for which the confidentiality is requested, for example:

a) the identity of the ingredient in question or its function in the cosmetic product to be marketed has not been described in the literature due to the fact that it is not known to the others in the field;

b) the information is not yet known in the public domain, even though a patent application has been lodged for the ingredient or its use;

c) if the information were known, it would be easily reproducible, to the detriment of the applicant.

Article 4

(1) After receipt of the request for confidentiality, the Ministry of Industry and Resources shall, within a period not exceeding four months, examine the request and inform the applicant in writing of its decision; in the event that the right of confidentiality is granted for the product in question, the applicant will also be informed of the registration number allocated to the ingredient, in the form of a numeric code consisting of seven digits, in accordance with the procedure laying down the allocation of this code, provided for in the Annex.

(2) If there are objective reasons for which the Ministry of Industry and Resources decides that an additional period is necessary for the examination of the request, the applicant shall be informed in writing of that decision; the additional period shall not exceed two months.

(3) Any refusal to grant the request for confidentiality must include a statement of the reasons based upon which the decision was taken. The applicant may appeal, in accordance with the provisions of Law no. 29/1990 laying down the administrative proceedings, as last amended.

Article 5

The registration number referred to in Article 4 (1) shall replace the name of the ingredient in the list referred to in Article 13 (1)(i) and Article 14 of Law No 178/2000.

Article 6

(1) All amendments to the information provided pursuant to Article 3 shall be communicated to the Ministry of Industry and Resources.

(2) All changes to the names of cosmetic products containing the ingredient for which the confidentiality request was granted must be communicated to the Ministry of Industry and Resources at least 15 days before these products are placed on the market under their new name.

(3) The Ministry of Industry and Resources may withdraw its approval if the amendments referred to in paragraphs (1) and (2) or other new information makes it imperative to do so,

due to reasons of public health. In this event, the applicant will be informed of the new decision within the time limits and in accordance with the procedure referred to in Article 4.

Article 7

(1) The decision of the Ministry of Industry and Resources granting the right of confidentiality for the ingredient in question shall be valid for a period of five years.

(2) If the beneficiary of the decision referred to in paragraph (1) considers that there are exceptional reasons justifying the extension of this period, he may submit a reasoned request to the Ministry of Industry and Resources, who will decide upon the new request within the time limits and in accordance with the conditions provided for in Article 1.

(3) The confidentiality period shall not be extended by more than three years.

Article 8

The National Authority for Consumer Protection, at the justified request of the consumer, shall provide information concerning the presence in the composition of cosmetic product of an ingredient whose name was established in the form of a numeric code, which may endanger his health.

Article 9

(1) Use of the numeric code without observing the provisions of Articles 2, 5, 6 paragraphs (1) and (2) and of Article 7(2) shall be considered a contravention, unless it was done in other circumstances so that, in accordance with the penal law, it shall be considered a criminal offence, and it shall be punished with fine from ROL 20 000 000 to ROL 30 000 000.

(2) The provisions of Law No 32/1968 on ascertaining and punishing contraventions, as last amended, are applicable to the contraventions referred to in paragraph (1).

Article 10

This decision shall enter into force one year after its publication in the Official Journal of Romania, Part I.

**PRIME MINISTER
ADRIAN NĂSTASE**

Countersigned by:

the Minister of Industry and Resources,
Mihai Berinde
Secretary of State
Minister of Family and Health
Daniela Bartoș

Minister of European Integration
Hildegard Carola Puwak
President of the National Authority for
Consumer Protection
Rovana Plumb

Bucharest, 14 June 2001.
No. 560.

I. Definition of identification numbers and names of ingredients

The identification numbers and names of the ingredients provided in Article 3(1)(b) of this Decision are defined as follows:

- a) CAS – Chemical Abstract Services;
- b) ELINCS – European List of Notified Chemical Substances;
- c) EINECS – European Inventory of Existing Commercial Chemical Substances;
- d) IUPAC – International Union of Pure and Applied Chemistry.

II. Methodology for granting the registration number

1. The registration number mentioned in Article 4 of this decision consists of a seven digits code, having the following signification:

- a) the first 2 digits correspond to the year of approval of the confidentiality request;
- b) the next two digits corresponding to the code number allocated by the European Commission to each EU Member State; for Romania the numeric code is 00^{*)}.
- c) the last three digits are allocated by the Ministry of Industry and Resources.

2. The following codes are allocated to the Member States:

- 01 – France
- 02 - Belgium
- 03 - Holland
- 04 – Germany
- 05 – Italy
- 06 – Great Britain
- 07 – Ireland
- 08 – Denmark
- 09 – Luxembourg
- 10 – Greece
- 11 – Spain
- 12 – Portugal
- 13 – Finland
- 14 – Austria
- 15 - Sweden

^{*)} The competent authorities in the field of cosmetic products and dangerous chemical substances and mixtures shall take the necessary measures to obtain the country code.