The Medical Products Agency’s provisions on the Control of Cosmetics and Hygiene Products

LVFS 2004:12

Note 1: This document has been compiled only for information purposes, and is not an official translation. In the event of any discrepancy between the English version and the Swedish original, the latter will take precedence.

Note 2: This version includes amendments up to and including LVFS 2008:3 (amending LVFS 2004:12). For information on the dates when the provisions enter/entered into force, transitional periods, and all footnotes, refer to the respective Swedish original.

Pursuant to sections three to eight and eleven of the Ordinance on Cosmetics and Hygiene Products (1993:1283), the Medical Products Agency issues the following provisions on the control of cosmetics and hygiene products.

Definitions etc.

Section 1
The terms and concepts used in Chapter 14 of the Swedish Environmental Code (SFS 1998:808) and the Ordinance on Cosmetics and Hygiene Products (1993:1283) have the same meaning in these provisions. ‘Manufacturer’ refers to the party responsible for the finished product. ‘Manufacturing’ also means reformulation and reworking as well as amendments to the labelling (the product’s designation, trademark or area of use).

Section 2
Products considered being cosmetics and hygiene products are listed in Appendix 1 of these provisions.

Section 3
Cosmetics and hygiene products must not have such properties that they under normal or reasonably foreseeable use may be harmful to human health. The following shall be considered in particular: the presentation of the product, the labelling, any user instructions and instructions for disposal, or any other instructions or information that is provided by the manufacturer or his representative, or by anybody responsible for the product being released onto the common market.

Warnings concerning these matters that are included, shall not exempt the person or persons responsible for the products from compliance with the other requirements laid down in these provisions.
Ingredient substances

Section 4
The Medical Products Agency has issued provisions on the Prohibition and Restrictions of Certain Substances from being included in Cosmetics and Hygiene Products (LVFS 2007:4, most recently amended and re-printed as LVFS 2009:14).

Notification to the Product register

Section 5
Anyone who professionally manufactures or brings into Sweden cosmetics and hygiene products shall notify the products to the Medical Products Agency for listing in the product register.

A product that is brought into Sweden by more than one importer shall be notified by each individual importer.

Section 6
The notification of a product to the Product register shall contain details of
a) product name,
b) company name and organisation/company registration number or name and civil registration (ID) number of the party manufacturing or bringing the product into Sweden,
c) product type according to the codes in Appendix 1,
d) category of use according to the codes in Appendix 1,
e) name and address of the place where the Product Information, according to Section 23, is kept.

Section 7
The notification requirement shall be fulfilled at the latest within one month after the production start or after the product has been brought into Sweden.

Section 8
Products that are no longer marketed, have been wrongly registered as cosmetics and hygiene products, or for any other reason no longer should be registered as cosmetics and hygiene products – may be deregistered by the Medical Products Agency.

Notification to the Company/Business register

Section 9
Anyone who professionally manufactures or brings into Sweden cosmetics and hygiene products – or keeps Product Information in accordance with Section 23 – shall notify his business to the Medical Products Agency.
This notification obligation also applies to those who on behalf of someone else manufacture cosmetics and hygiene products, so-called ‘outsourcing manufacturing’.

**Section 10**
The company/business notification shall contain details of
a) company name and organisation/company registration number or name and civil registration (ID) number,
b) postal address and telephone number,
c) products manufactured that should be notified in accordance with Section 5.

**Section 11**
The notification obligation shall be fulfilled before the activities commence.

**Common provisions regarding notifications**

**Section 12**
Notifications in accordance with Sections 5 and 9 shall be made on special application forms provided by the Medical Products Agency, and in accordance with instructions issued by the Agency.

**Section 13**
If any of the details notified are subsequently changed, the party liable to give notice shall notify the Medical Products Agency of the change as soon as possible, but at the latest within one month after the change has occurred.

**Labelling**

**Section 14**
When cosmetics and hygiene products are released onto the market, the product’s container and outer packaging must be labelled with the following information in indelible, easily legible and visible lettering.

The information referred to under g only needs to be stated on the outer packaging.

The details according to b, c, d and f shall be written in Swedish.

If cosmetics and hygiene products do not have a sales packaging the details shown below shall, in another way, be provided in writing to the purchaser.

a) Name, or company name and address, or registered place of business of the manufacturer or person - established in the EU/EEA – who is responsible for the marketing of the product. This information may be abbreviated, provided the abbreviations make it generally possible for the public to identify the company/business.

b) The quantity that the product contains at the time it is packed, expressed as weight or volume.
This does not apply to packaging containing less than five grams, or five millilitres, or packaging for one treatment, or free samples. Details of weight and volume do not need to be stated on the outer packaging if the product is pre-packaged, and normally contains a certain number of units such that the weight or volume details of the entire packaging is not significant, and provided that the number of units is stated on the outer packaging. The number of units that the packaging consists of does not need to be stated if this is visible through the outer packaging without opening it, or if the product is normally sold per unit.

c) The date of minimum durability should be stated as follows: “Bäst före utgången av” (“Best before the end of”) followed by either:
– date or
– details of where the date is placed on the packaging.

The date shall be clearly stated and consist of – in the following order – month and year, or day, month and year. When necessary, this information shall be supplemented with details of the conditions required to guarantee the stated durability.

This date of durability does not need to be stated on cosmetics and hygiene products with a durability exceeding 30 months. These products, however, shall have information on how long a period the product may be used after the packaging has been opened, without risk to the consumer. This shall be done by using the symbol in Appendix 4, followed by the period of durability after opening (expressed in months and/or years).

d) Special precautionary measures that shall be observed during usage – especially such as referred to in the column “Conditions of use and warnings, which should be printed on the label” in Appendices 2, 3, 4 and 5 of the ‘Medical Products Agency’s provisions on the Prohibition and Restrictions of Certain Substances being included in Cosmetics and Hygiene Products’ (LVFS 2007:4 most recently amended and re-printed as LVFS 2009:14) – shall be labelled on container and outer packaging together with any information on precautionary measures for products used by professionals, particularly by hairdressers. If this is not possible due to the size or shape of the packaging, an enclosed folder, label, tape, or card, shall provide this information.

The consumer shall be referred to this information by a brief note or the symbol in Appendix 2 of these provisions, on the container and the outer packaging.

e) The batch number of manufacture or reference for identification of the goods. If this is not possible due to size or shape, this information need appear only on the outer packaging.

f) The function of the product, unless this is clear from the presentation of the product.

g) A list of the ingredients in descending order of weight at the time they are added. This list shall be preceded by the word “Ingredienser” or “Ingr.”. If this is not possible due to the size or shape of the packaging, details of the
ingredients shall be provided by an enclosed folder, label, tape, or card, and the consumer shall be referred to this information by a brief note or the symbol in Appendix 2, on the outer packaging.

The following shall not be regarded as ingredients:
– Impurities in the raw materials used.
– Subsidiary technical materials used in the preparation but not present in the final products.
– Substances of which only strictly necessary quantities are used, as solvents or as carriers for perfume and aromatic compositions.

Perfume, aromatic compositions and their raw materials shall be referred to by the word “parfum” or “aroma”.
However, the presence of substances referred to in accordance with the requirements in the column “Other limitations and requirements” in the ‘Medical Products Agency’s Provisions on the Prohibition and Restrictions of Certain Substances from being included in Cosmetics and Hygiene Products’, Appendix 2, Part 1 – shall be included in the list of ingredients, irrespective of their function in the product.

Ingredients that are present in concentrations of 1% or less may be listed in an optional order after the ingredients present in concentrations exceeding 1%.

Colouring agents may be listed in an optional order after the other ingredients with the colour index number or denomination used in Appendix 3 of the ‘Medical Products Agency’s Provisions on the Prohibition and Restrictions of Certain Substances from being included in Cosmetics and Hygiene Products’.

As regards cosmetic products that are used for aesthetic purposes and which are present in several colour shades – all colouring agents of the colour range of the product may be referred to in the list, provided the expression “may contain” or the symbol “+/−” is added.

Ingredients shall be stated with the generic denomination referred to in the inventory issued in the Official EU Journal² or, if there is none, one of the following:
INCI designation, or designation by the European Pharmacopoeia, or the international generic designation recommended by WHO, or EINECS number, or IUPAC name, or CAS number, or colour index number.

As regards soap, bath balls and other small products whose size or shape makes it impossible to include the details referred to in g on a label, tag, tape, or card, or on an enclosed folder – these details shall be shown by a sign in immediate proximity of the product’s sales container.

Section 15
The container, the outer packaging or any other presentation of the product must not carry any information that may attribute properties to the product that it does not have.

Exemptions from the labelling requirements in Section 14 g

Section 16. *If the release of a product within the EU/EEA takes place in Sweden and the party responsible wishes, due to a business secret, that one or more ingredients should not be included in the information that shall be provided according to Section 14 g, he shall submit an application on the matter to the Medical Products Agency.*

Sections 17 to 21 are omitted. *For further information on exemptions from the labelling requirements, refer to the Commission Directive 95/17/EC on rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products.*

Other product information

Section 22
If the release of a product within the EU/EEA takes place in Sweden, or if a product is manufactured and marketed in Sweden, the party liable to notify the product in accordance with Section 5 shall, to facilitate rapid and adequate medical treatment, provide appropriate and sufficient information on the substances included in the product to the Swedish Poisons Information Centre, which will release this information exclusively to facilitate such medical treatment.

Section 23
If the release of a product within the EU/EEA takes place in Sweden, or if a product is manufactured in Sweden, the manufacturer or his representative, or the party who first imported the product shall, to facilitate control, keep the information referred to below, at the address referred to in Section 14 a (labelling of the product) – so that it is immediately available to the Medical Products Agency. This information shall be written in a language that without difficulty can be understood by the competent authority in the country concerned. When the information shall be made available in Sweden, it shall be written in Swedish or English.

a) Qualitative and quantitative composition of the product. In the case of perfumes and perfume compositions, details of the name and code number of the composition and the identity of the supplier shall apply.

b) Physico-chemical and microbiological specifications of raw materials and finished product, together with purity criteria and microbiological control criteria regarding the product.

c) Manufacturing method that shall comply with good manufacturing practice. The person who is responsible for the manufacture or the first import into the EU/EEA shall have the necessary professional qualifications or such experience as required by legislation and practice in the EU/EEA country where the manufacture or the first import occurs.
d) Assessment of the safety of the finished product for human health. In this respect, the manufacturer shall take into consideration the ingredients’ general toxicological profiles, their chemical structures and their exposure levels.

Particular regard shall be paid to specific properties of the areas on which the product will be applied or the persons for whom it is intended. Among other things, a special assessment shall be made of cosmetics and hygiene products that are intended for children under the age of three and of cosmetics and hygiene products that are intended exclusively for external intimate hygiene.

If the same product is manufactured in several places within the Community, the manufacturer may choose to keep the information available at only one of these places. If this is the case, and if a request is directed to the manufacturer for the purpose of control, he shall be liable to inform the supervisory authority/authorities concerned of the place chosen. In this case, the information shall be easily available.

e) Name and address of the expert or experts responsible for the assessment referred to in d. These experts shall have a diploma in pharmacology, toxicology, dermatology, medicine or a similar discipline, as defined in Article 1 of Directive 89/48/EEC.

f) Details of undesirable effects on human health resulting from use of the product.

g) Evidence of the effect claimed of the product, if this is motivated in consideration of the nature of this effect or the type of product.

h) Details of animal experiments that are performed by the manufacturer, his representatives or suppliers in conjunction with the development or safety evaluation of the product or its ingredients, including any animal testing performed in order to comply with the legislation or regulations of non-Member States.

Section 24

Without affecting the right to protection of, primarily, business secrets and intellectual properties, a party liable to keep information available in accordance with Section 23 a to h is also liable to keep the information referred to in Section 23 a and f available to the public by appropriate means, including electronic means. The quantitative information required in accordance with Section 23 a, which shall be made available to the public, is limited to dangerous substances covered by Directive 67/548/EEC.
Guidance list of products considered being cosmetics and hygiene products

01 Cream, emulsion, lotion, gel and oil for the skin
   A Skin cream, emulsion, lotion, gel and oil
   B Facial skin tonic
   C Cleansing cream and “scrub” cream
   D Cerate
   E Other

02 Facial masks
   A Facial masks

03 Coloured foundation
   A Make-up (liquid, cream, stick, chestnut water, bronzing gel)
   B Rouge (powder, cream, stick)
   C Other

04 Powder
   A Face powder
   B Talcum powder
   C Baby powder
   D Other

05 Soap
   A Soap (solid and liquid)
   B Liquid shower preparation and foam bath
   C Other

06 Perfume products
   A Perfume, Eau de Toilette, Eau de Cologne
   B Aftershave
   C Other

07 Bath products
   A Bath salt, bath oil
   B Other

08 Depilatory products
A  Depilatory products
B  Other

09  Perspiration agents
A  Deodorants
B  Anti-perspirants
C  Other

10  Hair-care products
A  Permanent
B  Fixation fluid
C  Hair dye with oxidation
D  Single-component hair dye (tinting)
E  Coloured setting agent
F  Bleaching products
G  Hydrogen peroxide
H  Setting agents (liquids, gels, foams and spray)
I  Shampoo
J  Conditioner, rinse, packs and other hair cures
K  Hair-tonic, -cream, -oil
L  Other

11  Shaving products
A  Shaving soap, shaving cream and shaving balsam
B  Other

12  Eye make-up and their removal products
A  Eye shadow
B  Mascara, eyeliner, kohl pencil, eyebrow pencils
C  Eye make-up remover
D  Other

13  Lipstick etc.
A  Lipstick, lip gloss, lip liner pencils
B  Other

14  Oral care products
A  Toothpaste
B  Mouthwash and spray
C  Other
15 Nail products
   A Nail polish
   B Nail polish removal agents
   C Nail strengtheners
   D Cuticle cream and nail cream
   E Other

16 Intimate hygiene products
   A Intimate hygiene cream and spray
   B Other

17 Sun protection products
   A Sun protection agent with and without sunscreen (gel, cream, lotion, stick)
   B Other

18 Products for tanning without sun
   A Tan-without-sun cream, lotion, etc.
   B Other

19 Skin bleaching products
   A Skin bleaching cream
   B Other

20 Anti-wrinkle products
   A Anti-wrinkle products
   B Other

21 Other products
   A Other products

Category of use
The primary use of the product should be specified as
E Professional use of one’s own
K Release for consumer use
Y Release for professional use
Ö Other
Appendix 3

Instructions for the issue of registration numbers

1. The registration number referred to in Section 18 comprises seven digits, of which the first two figures correspond to the year in which the secrecy classification was granted, the two following figures are the code allocated to each Member State in accordance with item 2 below, and the last three figures are issued by the competent authority.

2. The following codes have been allocated to each one of the Member States.

01 France
02 Belgium
03 The Netherlands
04 Germany
05 Italy
06 The United Kingdom
07 Ireland
08 Denmark
09 Luxemburg
10 Greece
11 Spain
12 Portugal
13 Finland
14 Austria
15 Sweden
16 The Czech Republic
17 Estonia
18 Cyprus
19 Latvia
20 Lithuania
21 Hungary
22 Malta
23 Poland
24 Slovenia
25 Slovakia
26 Bulgaria
27 Romania