

# Medical Products Agency's Code of Statutes

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## **The Medical Products Agency's provisions on the Prohibition and Restrictions of Certain Substances from being included in Cosmetics and Hygiene Products**

**LVFS 2007:4**

**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 document includes only the introductory part, sections one to six. Appendices 1 to 5 are not included. For information on the contents of the appendices 1 to 5, refer to the corresponding annexes of the Cosmetics Directive 76/768/EEC. (Conditions of use and warnings to be printed on the label must be in Swedish, refer to LVFS 2009:14 below.)

**Note 3:** The Swedish original, LVFS 2007:4, has been amended and re-printed as LVFS 2009:14. For information on the dates when the provisions enter/entered into force, transitional periods, and the footnotes, refer to the respective Swedish original.

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

### **Section 1**

These provisions apply to cosmetics and hygiene products that are offered for sale or used professionally.

### **Section 2**

The substances referred to in Appendix 1 of these provisions must not be included in cosmetics and hygiene products.

However, the presence of traces of these substances is permitted if such presence cannot technically be avoided in good manufacturing practice.

### **Section 3**

The substances referred to in Appendix 2 of these provisions must not be included in cosmetics and hygiene products if the substances exceed the stated limits or are used under circumstances other than those referred to in the Appendix.

### **Section 4**

Cosmetics and hygiene products must not contain colouring agents other than those referred to in Appendix 3 of these provisions. The colouring agents that are permitted must not be used under circumstances other than those referred to in the Appendix.

The first paragraph does not apply to colouring agents that are exclusively intended for hair colouring.

## **Section 5**

Cosmetics and hygiene products must not contain preservatives other than those referred to in Appendix 4 of these provisions. The preservatives that are permitted must not be used under circumstances other than those referred to in the Appendix, unless other concentrations are used for specific purposes apparent from the presentation of the product.

## **Section 6**

Cosmetics and hygiene products must not contain UV-filters other than those referred to in Appendix 5 of these provisions. The UV-filters that are permitted must not be used under circumstances other than those referred to in the Appendix.

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## **Appendix 1**

List of substances which cosmetics and hygiene products must not contain.

*(Corresponds to Annex II of the Cosmetics Directive 76/768/EEC: List of substances which must not form part of the composition of cosmetic products.)*

## **Appendix 2**

List of substances which cosmetics and hygiene products must not contain, except when complying with stated restrictions and conditions.

*(Corresponds to Annex III of the Cosmetics Directive 76/768/EEC: List of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down.)*

## **Appendix 3**

List of colouring agents allowed for use in cosmetics and hygiene products.

*(Corresponds to Annex IV of the Cosmetics Directive 76/768/EEC: List of colouring agents allowed for use in cosmetic products.)*

## **Appendix 4**

List of preservatives which cosmetics and hygiene products may contain.

*(Corresponds to Annex VI of the Cosmetics Directive 76/768/EEC: List of preservatives which cosmetic products may contain.)*

## **Appendix 5**

List of UV-filters which cosmetics and hygiene products may contain.

*(Corresponds to Annex VII of the Cosmetics Directive 76/768/EEC: List of UV filters which cosmetic products may contain.)*