

Decree of the EDI (Swiss Department for Inside Matters) about commodities with contact to mucosa, skin and hair

This decree about commodities with contact to mucosa, skin and hair is a new decree.

1. Subject and scope

Art. 1

This decree regulates:

- a) the requirements to nickelous objects
- b) the requirements to tattoo colours and colours for Permanent Make-up as well as their identification
- c) the requirements to apparatusology and instruments for Piercing, Tattoo and Permanent Make-up
- d) the requirements to afocal, cosmetic contact lenses and their identification

2. Nickelous objects

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3. Piercing, Tattoo, Permanent Make-up and similar practices

Art. 3 Definitions

- a) Piercing is the penetration of body parts like for example earlaps in order to fix a decorative object
- b) Tattoo is the implantation (Microimplantation) of colour pigments in the dermis of the skin with special needles and special machines for tattoo. The pictures and ornaments stay forever.
- c) Permanent Make-up is the implantation (Microimplantation) of colour pigments in the epidermis of the skin. Due to photo-sensibility, the permanency of the colour pigments is more little than that for tattoo. Permanent Make-up is mainly used in order to accentuate facial contours like eyebrows and lips.

Art. 4 General requirements

- a) Sterile with regard to the products mentioned here means the non-existence of viable organisms, viruses included.
- b) Persons who do piercings, tattoos and Permanent make-up to other persons are obliged to do all possible preparations in order to avoid infections.

Art. 5 Requirements to Piercings, tattoo colours and colours for Perm. Make-up

- a) Tattoo colours and colours for Permanent Make-up should not – if applied according to regulations - have any risk to the health of the customer.
- b) The following ingredients are forbidden:
 - aromatic amines according to attachment 1
 - colorants according to attachment 2
 - colorants according to attachment 2, column 2-4 of the decree of the EDI about cosmetics
 - substances according to attachment 3 (Decree about cosmetics)
 - substances according to article 3, paragraph 3, letters gI, of the decree about protection from dangerous substances and preparations
 - flavours
- c) The total of preserving agents should not exceed 5 g/kg.
- d) Piercing should not imply a resting colouration of the skin.

Art. 6 Requirements to packagings of tattoo colours, colours for Perm. Make-up and initial clips

- a) Filled containers with colours for Permanent Make-up and Tattoo must be closed so that the sterility is guaranteed until use.
- b) Initial clips must be packed so that they are sterile until their use.

Art. 7 Requirements to apparatusology and instruments for Piercing, Tattoo and Permanent Make-up

- a) Apparatusology and instruments must be sterile if they come into contact with the skin of the customer
- b) If available, materials for disposal use are to be used.

Art. 8 Identification

- a) Containers with colours for Tattoo and Permanent Make-up must bear at the least the following information:
 - Name and address of the manufacturer as well as name and address of the importer for Switzerland
 - Composition in quantity-decreasing order according to a usual nomenclature (IUPAC; CAS OR CI)
 - Batch number
 - Minimum durability described as “to be used until end of X” (X = month and year which are to be given open and uncoded); if necessary, the storing conditions are to be indicated
 - If necessary, instructions for use and warning notices
- b) The indications according to paragraph 1 are to shown, if desired, to the customer.

Art. 9 Professional Guidelines

The Swiss Health Department (BAG) can investigate and recommend professional guidelines for “well working practice” for Tattoo, Piercing and Permanent Make-up.

4. Afocal cosmetic contact lenses

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5. Adjustment of the attachments

The Swiss Health Department (BAG) adjusts the attachment of this decree regularly to the updating of technology and science. It looks about developments of foreign legislation.

6. Final ordinances

Art. 14 Provisional ordinances

- a) Colours for Tattoo and Permanent Make-up can only until(1 year after coming into effect) be manufactured, marked and imported according to present law. They can be used for customers only until(2 years after coming into effect)

Art. 15 Coming into effect

This decree comes into effect on.....