

Safety of tattoo inks

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What are the Hazards and Risks?

Lack of hygiene

Infection – dirty needles can pass infections, non-sterile water to dilute the inks
using tattoo inks past their expiration date.

use of unhygienic practices that contaminate ink bottles or mixing with contaminated colors

use of manufacturing processes that introduce contaminants or allow contaminants to survive

use of contaminated ingredients

Allergic and toxic reaction

due to additives, chemical composition of the colourant, but also due to impurities

Scarring – Unwanted scar tissue may form when getting or removing a tattoo

Granulomas – These small knots or bumps may form around material that the body perceives as foreign, such as particles of tattoo pigment

MRI complications – People may have swelling or burning in the tattoo when they have magnetic resonance imaging (MRI)

Some risks, such as the spread of infections through the use of unsterilized needles, have long been known.

But what isn't clear is the safety of tattoo inks

Theory

- **Tätowiermittelverordnung**

- **Resolution ResAP(2008)1**
on requirements and criteria for the safety of tattoos and permanent make-up
(superseding Resolution ResAP(2003)2 on tattoos and permanent make-up)

- **COUNCIL DIRECTIVE of 27 July 1976**
on the approximation of the laws of the Member States relating to
cosmetic products (76/768/EEC)

- **REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND**
OF THE COUNCIL of 30 November 2009 on cosmetic products

Tätowiermittelverordnung



Cosmetic DIRECTIVE (76/768/EEC)

Annex I: (76/768/EEC) negative list,
list of substances which must not form part of the products

Annex III: (76/768/EEC) positive list

Tätowiermittelverordnung

Annex I (76/768/EEC)

LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF THE PRODUCTS

CI 74160: (CAS 147-14-8; EINECS 205-685-1)
when used as a substance in hair dye products

Annex III (76/768/EEC)

CI 74160: no special application conditions: colouring agent allowed in all cosmetic products.

Resolution ResAP(2008)1

on requirements and criteria for the safety of tattoos and permanent make-up
(superseding Resolution ResAP(2003)2 on tattoos and permanent make-up)

Example:

Nickel As low as technically achievable

Method

Bioavailability



Specifications

Safety data required for the assessment of substances used in tattoos and PMU

- Data on physico-chemical properties:

purity;
impurities (heavy metals, amines, etc.);
auxiliary ingredients;
stability (UV, laser, enzymes, bacteria);
cleavage products (aromatic amines, etc.).

- Toxicological data:

corrosion;
irritation (skin, mucous membranes);
phototoxicity;
immunotoxicity (sensitisation, photo-sensitisation, etc.);
genotoxicity *in vitro* including test of cleavage products; photo - genotoxicity.



Reality

No or insufficient labelling

Insufficient quality of the raw material

No or insufficient test methods for the raw materials and finished products



Requirements

➤ **Evidence of competence for tatoois**

➤ **Safety assessment for all tattoo inks on the market**

like **Safety Assessment Reports for cosmetics (Annex I, Regulation (EC) No 1223/2009)**

support by an expert (Safety Assessor)

➤ **Validated standard methods**

Pro Tattoo

- **Many years of experience**
- **Special trainings for tatoois**
- **Transparency**
- **Public relations**
- **Seminars**