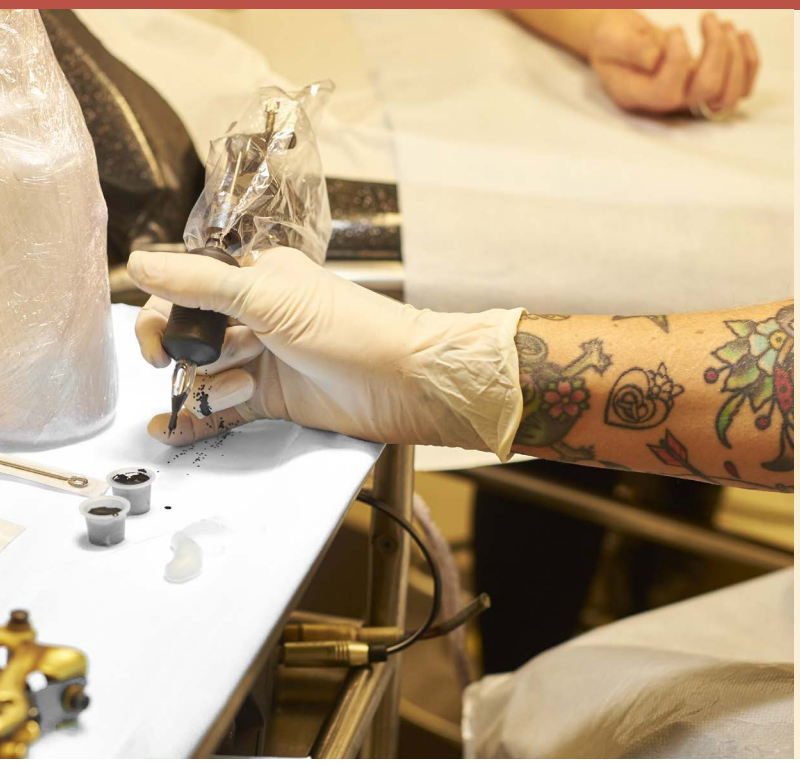
SAFER TATTOOING

Overview of current knowledge and challenges of toxicological assessment



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Compendium "Safer tattooing: overview of current knowledge and challenges of toxicological assessment"

WHAT INFORMATION DOES THE COMPENDIUM CONTAIN?

This publication is a compilation of the scientific information currently available on testing and assessing the **potential toxicity of intradermal inks** and it highlights **potential harmful effects for many of the chemicals present in inks used for tattoos and permanent make-up (PMU)**.

Experimental challenges and issues encountered when assessing toxicity are presented, along with scientific knowledge about the tattooing process and subsequent dermal tissue response. Part I details the tattooing process and biological response to tattooing. Part II gives an overview of data requirements necessary for establishing product safety.

WHY A EUROPEAN COMPENDIUM?

New behaviours or attitudes across European societies: tattooing and use of permanent make-up (tattoo/PMU inks) have become increasingly common across all sections of society but these practices still carry intrinsic risks. To place a tattoo, inks with colourants are injected into the skin. Health risks are mainly linked to chemical or microbiological contamination of these inks or to lack of hygiene during or immediately after application.

New sources and trends: in the past, tattoo inks were often crude industrial products of largely unknown origin manufactured with no consideration of the safety risks when injected into human skin. Even now, the legally responsible manufacturer, the production site and the chemical content of inks are often unknown. Many chemicals, impurities and contaminants present in inks may exert harmful effects as single ingredients or by interaction.

According to the tattoo industry, a typical tattoo ink comprises:

- up to 3 preservatives (which at present also include those not on the positive list of preservatives allowed in cosmetics);
- 1 astringent;
- up to 3 viscosity regulators;
- up to 3 solvents;
- water, and up to 6 pigments (added as powder).

The number of ingredients in a given ink is limited but there is a wide variety of substances to choose from to obtain the desired functions.

And finally, **new approaches** are needed in terms of public health protection: although the final chemical formulation of a tattoo ink may be simple and contain fewer than 15 substances, the sheer number of substances available for inks renders the task of safety assessment more complex. In addition, their intradermal, rather than dermal, route of exposure requires a different approach from that of traditional make-up and other decorative cosmetics.

Cases of tattoo inks becoming **microbiologically contaminated** are well-documented, and protocols for the **toxicological risk** assessment of tattoos and PMU require further development by the international scientific community.

With its scientific expertise in the field of public health, the EDQM – a Directorate of the Council of Europe – aims to support and guide the work of health authorities and manufacturers performing risk assessment of intradermal ink products.

Many European countries have enforced or are in the process of preparing health and safety measures, including hygiene requirements for tattoo parlours.[1] Harmonisation of national measures and of assessment requirements has been identified as a priority for the Council of Europe's intergovernmental work.

The Compendium is the result of the working group on the safety of tattoos and permanent make-up of the EDQM's Consumer Health Protection Committee. The project was initiated by the National Institute for Public Health and Environment (RIVM) in the Netherlands and a first draft prepared by a special task group. Thirty-one European countries have joined forces and expertise in this field. The publication supplements the **Committee of Ministers' Resolution ResAP (2008) 1 on requirements and criteria for the safety of tattoos and PMU**. Tattoo inks and the practice of tattooing are not covered by specific legislation at EU level; nevertheless, certain restrictions exist under the EU Chemicals (REACH) Regulation.

WHO IS THE COMPENDIUM DESIGNED FOR?

This Compendium collates scientific information and survey results to provide an overview to: **risk evaluators** and **legislators across Europe** and **authorities** responsible for overseeing consumer health protection.

PUBLICATION AND PURCHASE OF THE GUIDE

The Guide is available in book and online versions, in English. The electronic version of this Guide can be downloaded for free (www.edqm.eu/freepub) and the book version purchased at the EDQM Store (www.edqm.eu/store). For more information, please visit the EDQM website: or scan the QR code.

1 JRC Science for policy report: Safety of tattoos and permanent make-up – Final report. Paola Piccinini, Sazan Pakalin et al. JRC 101601 (2016).