

Requirements for the safety assessment of tattooing agents

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Unlike cosmetics, the inks for tattoos and permanent make-up are not applied to the surface of the skin but are consciously introduced into the skin. This overrides the skin's barrier function that normally protects against the intake of ingredients (ink pigments, solvents and preservatives) and possible impurities in the inks. Hardly any research has been done on whether the substances are metabolised and how they act in the human body. Hence, it is all the more important that agents used for tattooing and permanent make-up do not contain any substances that could constitute a health risk for consumers. The Federal Institute for Risk Assessment (BfR) had, therefore, recommended that until there was statutory regulation only those inks should be used for tattoos and permanent make-up which comply with the requirements set out in the European Cosmetics Directive and the German Cosmetics Ordinance and which have been tested and approved for use in cosmetics.

The Tattooing Agents Ordinance was adopted on 13 November 2008 and it enters into force on 1 May 2009. This means that, for the first time, tattooing agents are regulated in Germany. They must now meet health requirements and be correspondingly labelled.

In order to be able to develop an approval procedure for tattooing agents in the long term, BfR recommends drawing up a positive list of safe substances for tattooing agents. The precondition is that the safety of the ingredients in tattooing agents and permanent make-up can be assessed on the basis of generally recognised test criteria. In the opinion of BfR, these criteria should contain details of purity, contamination and auxiliary substances and should also consider data from toxicological studies. Furthermore, the findings from the latest scientific research and information from the industrial associations involved should be documented in a test catalogue.

The full version of the BfR Opinion in German is available on

http://www.bfr.bund.de/cm/206/anforderungen_fuer_eine_sicherheitsbewertung_von_tatowiermitteln.pdf