

FAQs on tattoo inks

BfR FAQ, 13 October 2017

In Germany, roughly 9 % of the population are tattooed, and this figure is set to rise in the future. In the group of 16 to 29-year-olds, as many as 23 % now have tattoos. Tattoo inks can be composed of a number of different individual substances the health effects of which have not been assessed for this particular application. For tattoos, organic pigments are typically used which are characterised by their brilliant colours. In permanent make-ups, iron oxide and soot are used. Problematic ingredients in tattoo inks include, for example, carcinogenic aromatic amines as breakdown products of organic dyes or as contamination. In addition, they contain heavy metals and preservatives as well as a number of ingredients whose function is unclear, as is the case, for example, with hexachlorobenzene, shellac and essential oils. Moreover, there are now tattoo inks with special effects, for example glow-in-the-dark tattoos, the ingredients of which are largely unknown. Unwanted acute reactions in connection with tattoos are infections, foreign body reactions, scar formation and allergic reactions. As regards the long-term effects of tattoos, little is known about them. The German Federal Institute for Risk Assessment (BfR) has now compiled questions and answers on tattoo inks.

What are tattoos and permanent make-up?

The law defines tattoos as a permanent change of appearance through substances and mixtures which are applied under the skin. This also includes permanent make-up. This is laid down in the “Regulation on inks used in tattoos including certain comparable substances and mixtures made up of individual substances”, BGBl (Federal Law Gazette) I 2008, p. 2215.

Whereas in tattoos, the pigments are inserted into the middle layer of the skin (dermis), the idea is for permanent make-up to only penetrate the superficial layer (*Stratum papillare*). Since the thickness of the skin layers differs to a great extent, however, the technical implementation can lead to great variation in the depth of application.

Whereas tattoos and permanent make-up are subsumed under the generic term of tattooing, henna tattoos, also known as temporary tattoos or temptooos, are not tattoos in the real sense of the term. Rather, they fall into the body paint category.

Are there any inks which ensure completely safe tattoos?

Little is currently known about the effects of colour pigments in the body. This means that no colour can be deemed to be safe.

Some colours which are known to pose a health risk, are covered by legislation in the “Regulation on Inks Used in Tattoos Including Certain Comparable Substances and Mixtures Made up of Individual Substances”, BGBl (Federal Law Gazette). I 2008, p. 2215. The colours listed there must not be used.

Where can I find a list of colours that are safe to use?

No positive list of colours that are safe to use currently exists.

What are tattoo inks made of?

Tattoo inks essentially consist of colourants (pigments) and suspending agents as a carrier fluid. The carrier fluid can contain thickeners, preservatives and other substances. A wide range of individual substances is used. No list of substances currently used exists.

What legal regulations exist on tattoos?

In Germany, tattoo inks are governed by the regulations of the Food and Feed Code. The Food and Feed Code lays down that products must be safe for consumers and must not have any detrimental effects on human health. The manufacturer is responsible for the safety of such products. Tattoo inks and permanent make-up have, since 2009, also been regulated by the German Tattoo Law ("Regulation on Inks Used in Tattoos Including Certain Comparable Substances and Mixtures Made up of Individual Substances", BGBl (Federal Law Gazette). I 2008, p. 2215). The regulation enumerates, in a black list, substances which must not be used, such as carcinogenic primary aromatic amines made from azo colourant pigments detrimental to health.

Are tattoo inks tested by the surveillance authorities?

As part of the country-wide Monitoring Programme 2007, tattoo inks are tested for heavy metals, preservatives and microbial contamination. A number of samples have been rejected for different reasons. The supervisory authorities of the Federal States test random samples of tattoo inks to ensure that they comply with the legal requirements.

Are tattoo inks tested and approved?

No approval procedure for tattoo inks exists. The manufacturer is responsible for the safety of such products. However, the systemic effects of many tattoo inks on the body are not known. From the viewpoint of health risk assessment, there is still a great lack of data in this area.

In what areas does the BfR see a need for research?

The BfR is of the opinion that there is a need for research particularly on the distribution, metabolism and deposition / excretion of colourants and all other components of tattoo inks in the body. It is to be assumed that the soluble components of the carrier liquid become systemically available and that they are metabolised. In contrast, pigments are usually insoluble. They are initially deposited in the skin. A recent study in which the BfR was in the lead shows that colour pigments can accumulate permanently in lymph nodes, even in nanoparticle size. Nano-sized substances and chemical combinations often show new physiochemical properties. Thus, further research is needed.

The study was published in the Scientific Reports by the Nature Publishing Group on September 12, 2017 (<https://www.nature.com/articles/s41598-017-11721-z>). The BfR-FAQ about the study lead by the BfR on the "distribution of tattoo ink as nano-sized particles in lymph nodes"

(http://www.bfr.bund.de/en/questions_and_answers_on_the_study_lead_of_bfr_investigating_the_distribution_of_tattoo_ink_as_nano_sized_particles_in_lymph_nodes-202078.html)

contains further information on the research result.

What health risks does tattooing pose?

Colourants can contain heavy metals and allergenic substances. Numerous additional ingredients such as preservatives and thickeners can be contained in the carrier fluid. No systematic testing is currently done to determine whether the ingredients of tattoos form carcinogenic aromatic amines which can build up in the body through metabolism or sun light exposure. There are still no toxicological data on whether colourants have mutagenic or carcinogenic properties and whether they are harmful to human fertility. In addition, colour pigments in nanoscale sizes could be further metabolised and distributed in the body.

Do the particle sizes of the pigments vary depending on the colour, and is the specific size of the pigment declared on the ink containers?

Pigment sizes are not stated on the ink containers and neither tested so far. Therefore it is possible that nanoparticles - generally considered of being smaller than 100 nm in diameter - can be present in the inks. Especially black colours contain small particles around 50 nm as other studies showed. Data from a BfR collaboration show that the green organic pigment in the sample also contains particles as low as 50 nm which are more likely to be transported to the lymph nodes. The toxic elements that sometimes are present in the inks as impurities are tested in national market surveys among Europe. If the concentrations in the inks reach levels that might affect human health, then they are likely listed in the Rapid Alert System (RAPEX) of the European Commission. Tattooists and people seeking a tattoo can get this kind of information online.

Can tattoo inks contain carcinogenic substances?

In the past, black tattoo inks have been tested and polycyclic aromatic hydrocarbons (PAH) were detected. Since some representatives of this group of chemicals are classified as carcinogens, the BfR recommends limiting the use of PAH in tattoos to the lowest level that can be achieved by technological means.

Chronic health effects like cancer usually do not emerge before years or decades after exposure and are thus difficult to link to tattoos or certain tattoo ingredients. Without epidemiological data that track large cohorts for decades and investigate whether people are tattooed or not, a connection between tattoo ingredients and chronic adverse effects can hardly be uncovered. This also holds true for the pigments and toxic elements that were found in the lymph nodes in the BfR study. To this end, no full risk assessment of these compounds in terms of their application in tattoo inks has been carried out so far. Thus, this question to what extent the analyzed elements may harm the health of tattooed individuals currently cannot be answered. The long-term health effects of this deposition are unknown, so far.

Further information can be found in the BfR opinion "Some Tattoo Colours Contain Carcinogenic PAH" (<http://www.bfr.bund.de/cm/349/some-tattoo-colours-contain-carcinogenic-pah.pdf>) and in the FAQ about the BfR-Study on the distribution of tattoo ink as nano-sized particles in lymph nodes.

Should tattoos be protected from the sun?

Increased light sensitivity of tattooed areas of the skin is common. Exposure to light can lead to swelling, itching, stinging sensations, pain and reddening of the skin. These reactions are not limited to certain colours or pigments and can flare up within seconds and then disappear again.

Can tattooing lead to infections?

Tattoos have long been known to cause inflammation and infections. Inflammations are the result of defence reactions of the body when the skin is injured. Infections can ensue, since the skin barrier, which provides protection against germs entering the body, is damaged. In some cases, bacteria (e.g. streptococci, staphylococci or mycobacteria), viruses (e.g. papilloma, herpes or hepatitis viruses) or fungi can get into the wound and subsequently cause serious infections.

Can nickel be contained in tattoo inks?

Nickel has been detected in tattoo inks. This poses a potential health problem, because nickel is the contact allergen with the highest sensitisation rate. People with a nickel allergy can therefore develop a serious skin disease following tattooing.

In contrast to cosmetic products which must not contain nickel except for traces, the use of nickel in tattoos is only partially subject to regulation to date. In the opinion of the BfR, however, it is especially important that tattoos and permanent make-up do not contain any nickel, since the skin cannot act as a barrier offering protection as the substances are directly injected into the skin. The BfR recommends reducing nickel in tattoo inks to the greatest extent technically possible.

What is the BfR's recommendation to make tattoo inks safe?

When the Tattoo Ink Regulation came into force in 2009, the BfR recommended that the regulation shall be supplemented by a positive list for colourants. This list should name all colourants which may be used in tattoo inks without having adverse effects on human health. (http://www.bfr.bund.de/cm/349/requirements_for_the_safety_assessment_of_tattooing_agents.pdf).

To ensure that colourants are included in a positive list, manufacturers must prove, on the basis of certain safety criteria, that they are safe. The BfR has compiled criteria which are to be applied when assessing the safety of tattoo inks and which can serve as a basis for making decisions for the inclusion of individual substances in positive lists. In addition to the positive list for colourants, lists for the remaining components are conceivable.

From a health point of view, is it advisable to remove existing tattoos?

Several procedures are currently available that make it possible to remove tattoos to a large extent. However, these methods themselves pose health risks such as scar formation, skin alterations, and allergic reactions. Whereas removal by laser can lead to toxic breakdown products, surgical removal is associated with the risk of an infection of the affected skin area. Pigments and carrier fluids as well as breakdown products which have made their way from the tattoo into other parts of the body can remain in the body even after removal of the tattoo.

The BfR recommends that only recognised procedures are used for tattoo removals and that they are only carried out by trained personnel with access to the required facilities. Under all circumstances, consumers should be given comprehensive information on the potential risks of tattoo removal.

The BfR does not have a comprehensive list of procedures that can be used to remove tattoos. New methods continue to be developed, but they are not required to be registered with the authorities, nor do the authorities test such methods. Where recent events make it necessary, the BfR assesses these methods. For example, a chemical process involving a liquid tattoo remover was assessed in Opinion No. 033/2011, 1 August 2011 (in German). (http://www.bfr.bund.de/cm/343/tattoo_entfernung_einsatz_waessriger_milchsaeure_ist_mit_gesundheitlichen_risiken_verbunden.pdf)

BfR Opinion No. 013/2013 "Requirements for tattoo inks" from 28 August 2012 also contains, under item 6, a description of different tattoo removal methods and associated health risks. (<http://www.bfr.bund.de/cm/349/requirements-for-tattoo-inks.pdf>)

Do henna tattoos pose a health risk as well?

So-called temptoos or henna tattoos are temporary tattoos which are painted on the skin. They are popular among children and young adults and are often available in holiday destination countries. Often henna is used which has been made darker with the substance *para*-phenyldiamine (PPD). PPD is a known contact allergen which can cause strong allergic reactions. The use of this substance in henna tattoos is banned in Europe (EU Regulation 1223/2009). Unlike tattoo inks, temptoos are governed by the European Cosmetics Directive.

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the Federal Government and Federal Laender on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.