

## FAQ about tattoo inks

Updated BfR FAQ, 16 September 2019

In Germany, roughly 12 percent of the population are tattooed, and this figure is set to rise in the future. In the age group of 16- to 29 years old, as many as 23 percent bear a tattoo. Tattoo inks may consist of many individual substances that have not been assessed in terms of their potential to be harmful to health when used in this way. In colour tattoos organic pigments, capable of achieving deep and vibrant colours, are being used. Permanent make-up inks primarily consist of iron oxides and carbon black. Examples of problematic ingredients in tattoo inks include carcinogenic aromatic amines as cleavage products of organic colourants or as impurities; preservatives and heavy metals may also be found as other impurities. In addition, tattoo inks are now available with special effects like “glow in the dark”, whose ingredients are largely unknown. Acute problems that can occur after tattooing include infections, foreign-body reactions, scarring or allergic reactions. Little is known about the long-term effects of tattoo inks. The German Federal Institute for Risk Assessment (BfR) has answered frequently asked questions about tattoo and permanent make-up inks.

### What are tattoos - and what is permanent make-up?

The legal understanding of a tattoo is something designed to change how a person looks with substances and formulations that are intended to alter someone's physical appearance when applied under or into the human skin, where they then remain - whether on a transient or permanent basis. In that sense, permanent make-up is also considered as a type of tattoo. The law on tattoos includes the German Food and Feed Code (LFGB) and the national “Ordinance on inks used for tattooing, including certain comparable substances and formulations of substances” (Federal Law Gazette I 2008, p. 2215). Temporary tattoos, which are applied to the surface of the skin, are not classified as tattoos but as a form of body paint. The EU Cosmetics Regulation prohibits body painting with henna.

While the pigments of tattoo inks are injected deep into the inner layer of the skin (dermis), permanent make-up inks are intended only for application to the upper part of the dermis (the *Stratum papillare*). Since the thickness of skin layers may differ widely, however, the actual tattooing procedure can result in great variation in the depth of application.

### Are there any pigments that are absolutely safe to use in tattoos?

Little is currently known about the effects of pigments in the body. Accordingly, it is impossible to estimate whether or not their use is safe. According to the current available information, the pigments listed in annex IV of the EU Cosmetics Regulation have no usage restrictions in tattoo inks, which means they are not prohibited. Pigments which are forbidden to use are listed in Annex 2 of the German Tattoo Inks Ordinance (see above).

Substances currently known to pose a health risk are also covered by this German Ordinance. Use of the colourants listed there is prohibited.

Careful reading through the list of ingredients given on the tattoo ink bottle is recommended. Where an individual has known allergies or sensitivities to one of the declared substances, its use should be avoided. In addition, tattoo inks that contain substances that are harmful to health are reported to the EU's Rapid Alert system. The following internet address offers an easy way to check whether the tattoo ink that is intended for use has been reported:

[https://ec.europa.eu/consumers/consumers\\_safety/safety\\_products/rapex/alerts/?event=main.search&lng=en](https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.search&lng=en)

### **Where can I find a list of colourants that are safe to use?**

No “white list” of colourants that are safe to use currently exists, since there is not enough reliable research data available.

### **What are tattoo inks made of?**

Tattoo inks essentially consist of colourants (pigments) and suspension agents that act as a carrier fluid. The carrier fluid can contain thickeners, preservatives and other substances. A wide range of substances are used.

### **What is the legal position regarding tattoos?**

In Germany, tattoo inks are governed specifically by the provisions of the Tattoo Inks Ordinance and generally by the provisions of the Food and Feed Code. To comply with the Code, 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. Since 2009, tattoo inks and permanent make-up inks have also been governed by the German Ordinance on Tattoo Inks. The Ordinance includes a “black list” of substances that inks must not contain, such as carcinogenic primary aromatic amines originating from azo pigments and other pigments that are harmful to health.

### **What steps have been undertaken in the recent years to regulate tattoo inks on the European level?**

The European Commission has tasked the European Chemicals Agency (ECHA) with investigating the need to place restrictions on tattoo inks and permanent make-up inks, with the aim of achieving the harmonised regulation of tattoo/permanent make-up inks within the EU. Together with the EU member states Denmark, Italy and Norway - and with support provided from Germany - the ECHA has proposed initial harmonised restrictions on tattoo inks at a European level. Upon a positive vote of the EU member states, this restriction shall enter into force in 2021.

### **Are tattoo inks tested by the surveillance authorities?**

In Germany, tattoo inks have been specifically tested for heavy metals and preservatives as well as microbial contamination, as part of the Nationwide Control Plan in 2007, and the monitoring programme run by the Federal Office of Consumer Protection and Food Safety (BVL) in 2013 and 2017. The surveillance authorities in the German federal states (“Laender”) also conduct regular tests of random samples of tattoo inks to ensure that they comply with legal requirements. Many samples have been found to be problematic for a number of reasons.

### **Are tattoo inks tested and licensed?**

As is generally the case with products covered by the German Food and Feed Code, there is no actual licensing process for tattoo inks. Instead, the manufacturer is responsible for the safety of such products. Nevertheless, the systemic effects of many tattoo ink ingredients on the body are not known. From the viewpoint of health risk assessment, substantial data is still missing here. However, the core principle of the German Food and Feed Code still applies, namely that products that are used must be safe. In case of doubt, the manufacturer must prohibit tattooists from using substances according to the duty of care principle.

### **Where does the BfR see a need for further research?**

The BfR believes that more research is needed in particular concerning the distribution, metabolism and deposition/excretion of pigments and other ingredients contained in tattoo inks in the human body. One may assume that the soluble components of the carrier liquid become systemically available and are therefore metabolised. Pigments are typically insoluble

and hence remain deposited in the skin initially. A recent study to which the BfR also contributed shows that pigments may accumulate permanently in lymph nodes, even as nanoscale-sized particles. Nano-sized substances and combinations of chemicals exhibit often new physiochemical properties. Further research is therefore needed here.

The study was published in the Scientific Reports journal by the Nature Publishing Group on 12 September 2017 (<https://www.nature.com/articles/s41598-017-11721-z>). The BfR FAQ about this study reporting on the detection of tattoo ink pigments as nano-sized particles in lymph nodes contains further information about the research findings: [https://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](https://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)

### **What are the health risks of having a tattoo done?**

Colourants may contain heavy metals and allergenic substances. Many other ingredients such as preservatives and thickeners can also be contained in the carrier fluid. Effects on health that result from being tattooed may occur immediately after the tattooing session or only after several weeks. Most of these complications are related to localised skin rashes or allergic reactions triggered in the individual's skin.

While the Tattoo Inks Ordinance does contain provisions concerning potentially carcinogenic aromatic amines, more research is still needed to understand whether metabolic processes or exposure to direct sunlight can lead to a breakdown of tattoo ink ingredients and a release of these compounds in the human organism. Furthermore, there is a lack of toxicological data about the potential of colourants to have mutagenic, carcinogenic or teratogenic effects when used as tattoo ink ingredients. In addition, pigments in nanoscale sizes could be further metabolised and distributed in the body.

### **Are there any particular risks to health if someone gets a tattoo while pregnant or breastfeeding?**

During a tattooing session, the tattoo ink comes into direct contact with blood and lymphatic fluid in the body. As a result, tattoo inks are distributed systemically in the body. It is therefore reasonable to assume that a transition into breast milk or to the embryo is possible.

The inks and needles used in tattooing also harbour another key health risk, namely exposure to a viral or bacterial infection. This can happen if tattooing equipment has not been sterilised or the ink itself is contaminated. After the tattooing, the skin is injured: its natural barrier function is weaker, making the skin more prone to infection. These infections could be passed on to a baby or unborn child. In severe cases, a course of antibiotics might even be necessary. For these reasons, getting a tattoo throughout pregnancy or breastfeeding is not recommended.

During tattoo removal, a laser may be used to break the pigment particles into smaller fragments that are given to transportation and excretion. One may assume that the concentration of these pigment fragments or their degradation products is higher shortly after laser treatment. Postponing any planned tattoo removal until after pregnancy and after breastfeeding is therefore also recommended.

### **Do the particle sizes of the pigments vary depending on the colour? Is the specific size of the pigment particle given on the pigment containers?**

Pigment sizes are not stated on the pigment containers and their sizes have not been investigated to date. It is therefore possible that nanoparticles, understood as particles smaller than 100 nm in diameter, may be present in the colourants. It is very likely that these nano-

particles could be transported into the lymph nodes. Studies have shown that black colourants in particular contain tiny particles of around 50 nm. Data from a joint study conducted with the BfR demonstrated that a green organic pigment also contains particles as small as 50 nm.

### **Can tattoo inks contain carcinogenic substances?**

In the past, black tattoo inks have been tested and polycyclic aromatic hydrocarbons (PAHs) were detected. Since some members of this group of chemicals are classified as carcinogens, the BfR recommends limiting the use of PAHs in tattoo inks to the lowest concentration that can be achieved by technological means. This has been taken into account by the restriction proposal on hazardous substances in tattoo inks that was drawn up in the context of the REACH Regulation, with the BfR contributing to its preparation. Long-term effects on health such as developing cancer typically emerge only years or decades after exposure and are therefore difficult to link to a specific tattoo or specific tattoo ingredients. Without epidemiological data that track, examine and represent large cohorts for many years while recording whether or not people have tattoos, a connection between tattoo ingredients and chronic adverse effects is unlikely to be elucidated. This also holds true for the pigments and toxic components found in the study demonstrating the detection of tattoo pigments as nano-sized particles in lymph nodes. To date, no risk assessment has been carried out on the health effects of these compounds in relation to their use in tattoo inks. Accordingly, the question of the extent to which the components analysed could harm the health of tattooed individuals cannot be answered at present. The long-term health effects of such deposits in the body are as yet unknown. Further information can be found in the BfR Opinion “Some Tattoo Colours Contain Carcinogenic PAH”:

<https://www.bfr.bund.de/cm/349/some-tattoo-colours-contain-carcinogenic-pah.pdf>

### **Should tattoos be protected from the sun?**

One common problem is that tattooed areas of the skin are more sensitive to sunlight. Sun exposure can lead to swelling, itching and stinging sensations, pain and reddening of the skin. These reactions are not limited to certain colours or pigments, and may flare up quickly but then resolve themselves without further intervention. Protecting tattoos from exposure to the sun is therefore recommended.

### **Can I get an infection by having a tattoo done?**

Tattoos have long been known to cause inflammation and infections. Inflammations are the result of a skin injury triggering the body's natural defences. An infection may also occur because the skin, normally a natural barrier that stops germs entering the body, has now been damaged. In a worst-case scenario, bacteria (e.g. streptococci, staphylococci or mycobacteria), viruses (e.g. papilloma, herpes or hepatitis viruses) or fungi could get into the wound and thereby cause a serious infectious illness.

The new EU standard “Tattooing - Safe and hygienic practice” is an evidence-based document that offers guidelines on protecting both the consumer and the tattoo artist from infections (draft standard prEN 17169:2017). This standard is due to be adopted and published by the European Committee for Standardisation (CEN) in 2019. While not legally binding, this document considers important aspects of tattooing practice and communication with the health authorities. Issues the standard covers include training staff in infection avoidance practices, requirements for sterility and take-home information for customers. The BfR recommends visiting tattoo studios that follow the guidelines as described in this standard.

### **Can tattoo inks contain nickel?**

Nickel is prohibited by the provisions of the Cosmetics Regulation (Annex 2). The element has been detected in some tattoo inks, however. This is a potential health hazard, because, as a contact allergen, nickel also has the highest sensitisation rate. People with a nickel allergy can therefore develop potentially serious skin disorders after getting a tattoo. The BfR recommends reducing nickel in tattoo inks to the greatest extent technically possible. Further information (in German only) is provided by the BfR Opinion "Nickel in tattoo inks can trigger allergies" (<https://www.bfr.bund.de/cm/343/nickel-in-taetowiermitteln-kann-allergien-ausloesen.pdf>).

### **How does the BfR assess health risks posed by tattoos?**

The BfR conducts toxicological and analytical research in order to assess the health risks posed by tattoo inks. In addition, the BfR is also involved in regulatory activities within Germany and Europe. In performing a health risk assessment for tattoo inks, the first step is to determine the parameters relevant for exposure, such as the injection of the various components into the skin and the area of skin that is tattooed. Following this, the specific properties of the ingredients are then combined with the exposure parameters to assess the level of risk. The current German Tattoo Ink Ordinance is based on a black list of substances whose use in cosmetics is prohibited or restricted: accordingly, these substances are likewise prohibited or restricted in tattoo inks as well. A black list of this kind can naturally deal only with known substances.

### **What does the BfR recommend to make tattoo inks safer?**

Tattoo inks must be safe when used on consumers. This means that proper care and attention must be given to hygiene and microbiological risks, as well as potentially toxicological aspects of production and application. In relation to potential infection risks, this would ideally be achieved by maintaining minimum standards for hygiene and sterility. In particular, tattoo inks should be used only if they have been labelled as sterile by the manufacturer. Only sterile water should be used when diluting any colourants. In 2009, with the entry into force of the Ordinance on Tattoo Inks, the BfR argued that due to the special nature of tattoo ink application - namely injection into skin well-supplied with blood - the criteria set out by the European Council's Committee of Experts on Cosmetic Products shall be applied in order to assess tattoo inks and permanent make-up inks with a view to creating a test catalogue: [https://www.bfr.bund.de/cm/349/requirements\\_for\\_the\\_safety\\_assessment\\_of\\_tattooing\\_agents.pdf](https://www.bfr.bund.de/cm/349/requirements_for_the_safety_assessment_of_tattooing_agents.pdf)

This would enable manufacturers to minimise the potential toxicological risks of colourants and other ingredients in tattoo inks.

### **From the point of view of health risks, is it advisable to remove an existing tattoo?**

Several procedures are now available for the extensive removal of tattoos. However, these methods pose health risks such as scar formation, changes to the skin and allergic reactions. While removal by laser can lead to toxic cleavage products, surgical removal is associated with the risk of an infection of the affected area of skin. Pigments and carrier fluids, as well as cleavage products that have migrated from the tattoo into other parts of the body, can remain in the body even after the tattoo has been removed.

The BfR recommends removing tattoos only with recognised medical procedures, performed only by trained personnel with access to the required facilities. In all cases, consumers must be provided with full information about the health risks involved in the specific tattoo removal method.

The BfR does not maintain a comprehensive list of procedures for removing 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. The BfR carries out a health assessment of these procedures on a case-by-case basis. As one example, a chemical procedure using a liquid tattoo removal agent was assessed in Opinion no. 033/2011, dated 1 August 2011 (only available in German):

[http://www.bfr.bund.de/cm/343/tattoo\\_entfernung\\_einsatz\\_waessriger\\_milchsaeure\\_ist\\_mit\\_gesundheitlichen\\_risiken\\_verbunden.pdf](http://www.bfr.bund.de/cm/343/tattoo_entfernung_einsatz_waessriger_milchsaeure_ist_mit_gesundheitlichen_risiken_verbunden.pdf)

A description of various methods for removing tattoos and the associated health risks is also included in BfR Opinion no. 013/2013 “Requirements for Tattoo Inks”, dated 28 August 2012 (see section 6): <https://www.bfr.bund.de/cm/349/requirements-for-tattoo-inks.pdf>

### **Are henna tattoos also a health risk?**

Also known as “temptoos”, henna tattoos are temporary tattoos that are painted onto the skin. Popular with children and teenagers, henna tattoos are often part of a holiday experience. The henna used is often made darker by mixing with the substance *p*-phenylenediamine (PPD). PPD is a known contact allergen that can cause severe allergic reactions. The use of this substance in henna tattoos is banned in the European Union (EU Regulation 1223/2009). Unlike tattoo inks, “temptoos” are regulated by the EU Cosmetics Directive.

### **Further information on the subject from the BfR website:**

Half of all Germans regard tattoo inks as safe (BfR Consumer Monitor 2018):

[https://www.bfr.bund.de/en/press\\_information/2018/42/tattoos\\_are\\_popular\\_half\\_of\\_all\\_germans\\_regard\\_tattoo\\_inks\\_as\\_safe-207850.html](https://www.bfr.bund.de/en/press_information/2018/42/tattoos_are_popular_half_of_all_germans_regard_tattoo_inks_as_safe-207850.html)

FAQ for the study showing the detection of tattoo pigments as nano-sized particles in lymph nodes for titanium dioxide (12 October 2017):

[https://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](https://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)

Tattoos: even parting with them is not without risks (press release 13 August 2015)

[https://www.bfr.bund.de/en/press\\_information/2015/21/tattoos\\_even\\_parting\\_with\\_them\\_is\\_not\\_without\\_risks-194972.html](https://www.bfr.bund.de/en/press_information/2015/21/tattoos_even_parting_with_them_is_not_without_risks-194972.html)

### **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.

*This text version is a translation of the original German text which is the only legally binding version.*