Frequently asked questions about tattoo inks

Updated BfR FAQ of 6 January 2022

In Germany, roughly 17 percent of the population are tattooed, and the trend is rising. The group of 25 to 34-year-olds indicates more than any other group that they have several tattoos (Statista, 2021). 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. Colour tattoos typically use organic pigments capable of achieving deep and vibrant colours. Permanent make-up inks primarily consist of iron oxides and carbon black. Problematic ingredients in tattoo inks can include, for example, carcinogenic aromatic amines present as breakdown products of organic pigments or impurities, but also other impurities such as preservatives and heavy metals. 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.

Since January 4, 2022, certain substances present in tattoo inks and “permanent make-up” have been gradually restricted in the European Union. According to the European Chemicals Regulation (REACH), the use of substances with known and suspected harmful effects is regulated and maximum concentrations for these substances are specified with regard to tattoo inks. So far there are no binding criteria according to which a safety assessment of tattoo inks can be carried out. The German Federal Institute for Risk Assessment (BfR) has therefore drawn up minimum requirements for tattoo inks and test methods for manufacturers and distributors, as they are responsible for the safety of their products.

The BfR has compiled frequently asked questions and answers about tattoo inks below.

What are tattoo inks and "permanent make-ups"?
The legislator understands tattooing agents to be substances and mixtures of substances that are intended to be introduced into or under the human skin in order to influence its appearance and to remain there, in some cases temporarily. Permanent make-up is also a type of tattoo. This is regulated in the Food and Animal Feed Code as well as in the national “Ordinance on ink for tattooing including certain comparable substances and preparations made from substances” (BGBl. 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. Body painting with henna – a red-yellow dye made from the leaves of the henna bush *Lawsonia inermis* – is not permitted according to the EU Cosmetics Regulation.

While the pigments in tattoo inks are injected deep into the inner layer of the skin (dermis), permanent make-up inks are intended only for application to the top part of the dermis (the *stratum papillare*). Since the thickness of skin layers can 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 undesired health effects of pigments in the body. Accordingly, this makes it impossible to estimate whether or not their use is safe.

Substances that are currently known to pose a health risk are subject to an EU-wide restriction on use within the framework of REACH (Entry 75 of Annex XVII of the REACH Regulation (Regulation (EC) No. 1907/2006). Maximum concentration limits apply to the restricted substances.

Carefully 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 therefore be avoided. In addition, tattoo inks that contain substances that are harmful to health are reported to the EU's Safety Gate system. The following internet address offers an easy way to check whether the tattoo ink that will be used has been reported as dangerous: 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 colorants (pigments) and suspending agents acting as carrier liquids. The carrier liquid can contain thickeners, preservatives and other substances. A wide range of individual substances are used.

What is the legal position regarding tattoos?
In Germany tattoo inks are subject to the Food and Feed Code, in addition to the provisions of the Tattoo Inks Ordinance. Accordingly, the products must be safe for consumers and must not harm human health. The manufacturer is responsible for the safety of such products. Tattoo inks and "permanent make-up" have also been regulated by the German Tattoo Inks Ordinance since 2009. 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. In addition to the provisions of the German Tattoo Inks Ordinance, hazardous substances in tattoo inks and permanent make-up are also subject to the REACH restriction, harmonised at European level.

What steps have been taken to regulate the European market in recent years?
In addition to the German Tattoo Inks Ordinance, similar ordinances exist in several other EU member states that regulate tattoo ink ingredients. The European Commission has therefore commissioned the European Chemicals Agency (ECHA) to draw up a proposal for a uniform regulation of tattoo inks at European level. This is a restriction under the European Chemicals Regulation (REACH), which bans hazardous substances in consumer products or restricts their use and manufacture. According to the restriction proposal of the ECHA, which was developed together with the member states Denmark, Italy and Norway and with the participation of Germany, substances are generally prohibited that are proven to be carcinogenic, mutagenic or toxic to development and which damage reproduction. In addition, the proposal includes eye-irritating, skin-irritating and allergenic substances. It also prohibits substances in tattoo inks that are prohibited or restricted in cosmetic products by certain annexes of the EU Cosmetics Regulation. This ban is justified by the argument that substances that are prohibited from use on the skin should also be prohibited from use under the skin. All in all, the restriction proposal covers around 4,200 substances whose use will be prohibited outright or allowed only in trace quantities.

The restriction proposal was supported by the EU member states and adopted by the European Commission on December 14, 2020. The new regulations have been in effect in the EU since January 4, 2022. For the pigments blue 15:3 and green 7, the European Commission and the EU member states have agreed on a transition period, so that the restriction applies to both pigments from January 4, 2023.

How does the BfR assess the health risk of the pigments blue 15:3 and green 7?
In light of the ECHA restriction proposal for binding regulations pertaining to ingredients in tattoo inks, the BfR has considered possible health hazards and risks posed by the pigments blue 15:3 and green 7. In its Opinion No. 039/2020 of September 8, 2020, the BfR came to the conclusion that the data currently available for both pigments only suggest a comparatively low level of toxicity, but the existing data on adverse health effects of both pigments is incomplete. Therefore, the BfR is of the opinion that a comprehensive health risk assessment of their use in tattoo inks is currently not possible. In particular, no assessment can be provided for the potential health risks involved in injecting these substances into deeper layers of the skin (intradermal application). The BfR recommends improving the available data sets for both pigments. The full BfR Opinion on the risk assessment of both pigments is available via the following link:
https://www.bfr.bund.de/cm/349/tattoo-inks-risk-assessment-for-pigment-blue-15-3-and-pigment-green-7.pdf

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 primarily responsible for the safety of such products. However, it is not fully understood how many substances used in tattoo inks interact throughout the entire body (i.e. systemically). From the viewpoint of health risk assessment, a substantial amount of 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 also be safe. In case of doubt, the manufacturer must therefore 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. It can be assumed that the soluble components of the carrier liquid are systemically available and metabolised. The pigments, on the other hand, are mostly insoluble. They are initially deposited in the skin. A study to which the BfR also contributed shows that, after tattooing, pigments accumulate not just in the skin, but also permanently in lymph nodes, even as nanoscale-sized particles. Nano-sized substances and combinations of chemicals can often exhibit new physiochemical properties. Further research is therefore needed here.

The study was published on September 12, 2017 in the scientific journal "Scientific Reports" (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

The use of human data and targeted epidemiological studies are essential in order to map possible effects of lifelong exposure of humans to pigments and thus to improve the available data on the fate and effect of pigments in the human body. The BfR is already working on the acquisition of human data. In cooperation with the Clinical Research Center for Hair and Skin Science at Charité Berlin, for example, blood and urine samples from people are analysed shortly after tattooing.

What are the health risks of having a tattoo done?
Inks can contain heavy metals and allergenic substances. The carrier liquid can contain numerous other ingredients such as preservatives or thickening agents. Effects on health resulting from tattooing may occur immediately after the tattooing session or first after several weeks. Most of these complications are related to localised skin rashes or allergic reactions triggered in the individual's skin.

Although the REACH restriction contains regulations on potentially carcinogenic aromatic amines, there is still a need for further research on the question of whether metabolic processes or solar radiation can release such compounds in the human organism from tattoo ink ingredients. Furthermore, there is a lack of toxicological data on whether inks, when used as tattoo inks, have mutagenic, carcinogenic or reprotoxic effects. In addition, nanoscale-sized pigment particles may be further metabolised and distributed within the body.

Are there any particular risks to health if someone gets a tattoo while pregnant or breastfeeding?
Since tattoo inks come into direct contact with the blood and lymphatic fluid during tattooing, the tattoo inks can spread throughout the body (i.e. systemic distribution). It is therefore reasonable to assume that inks could be passed on via breast milk or the placenta.

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 is itself contaminated. After the tattoo is finished, 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. Antibiotic treatment may be required in the event of severe bacterial infection. For these reasons, getting a tattoo during pregnancy or breastfeeding is not recommended.

During laser tattoo removal, the pigment particles are broken up into smaller fragments that are then removed by bodily processes. 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 (the term is generally understood to mean particles smaller than 100 nm in diameter) may be present in the ink. These nanoparticles are more likely to be transported to the lymph nodes. Studies have shown that black inks in particular contain small particles around 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 also being one of the proposal authors. 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 establish. 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?
Increased sensitivity of tattooed skin areas to sunlight is common. This leads to swelling, itching, stinging, pain and reddening of the skin. These reactions are not limited to specific colour tones or pigments and can flare up and subside within seconds. Protecting tattoos from exposure to the sun is therefore recommended.

Can I get an infection by having a tattoo done?
It has long been known that tattoos can cause inflammation and infection. Inflammation is the result of a skin injury triggering the body’s natural defences. Infections can develop as the skin barrier, which acts as a natural protector preventing germs from penetrating the skin, is destroyed. In the worst case, bacteria (e.g. streptococci, staphylococci or mycobacteria), viruses (e.g. papilloma, herpes or hepatitis viruses) or fungi can get into the wound and subsequently lead to serious infectious diseases.

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 (DIN EN 17169:2020-05). This standard was officially adopted by the European Committee for Standardization (CEN) and published in the final German version in May 2020. While not legally binding, this document considers important aspects of tattooing practice and communication with the health authorities. It describes, among other things, the details of staff training in infection avoidance practices, requirements for sterility and after-care information for customers. The BfR recommends only using tattoo studios that follow the guidelines as described in this standard.

Can tattoo inks contain nickel?
Nickel is prohibited by the provisions of the REACH Regulation. The element has nevertheless been detected in tattoo inks. This poses a potential health hazard, because, as a contact allergen, nickel also has the highest sensitisation rate. People with a nickel allergy can therefore also develop severe skin diseases after receiving a tattoo. The BfR recommends reducing nickel in tattoo inks to the greatest extent technically possible. Further information is contained in the BfR Opinion “Nickel in Tattoo Inks Can Trigger Allergies” (in German):

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 REACH restriction is based on a negative list of substances that have been proven to be harmful to health.

What does the BfR recommend to make tattoo inks safer?
Tattoo inks should be safe when used on humans. 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. With regard to possible toxicological risks, tattoo inks should comply with the provisions of the REACH restriction. Furthermore, the BfR recently formulated minimum requirements and test methods as part of an opinion (see also the following question). The recommendations contained here are intended, among other things, to help identify tattoo pigments that are not suitable for tattoos.
This, the BfR argued, would enable manufacturers to minimise the potential toxicological risks of colourants and other ingredients in tattoo inks. Due to a lack of data, the BfR has not yet issued any recommendations for use.

Are there any criteria for safety assessment of tattoo inks?
As yet no binding criteria exist for the safety assessment of tattoo inks. There is also a lack of suitable test methods and data for a health risk assessment. The BfR has therefore drawn up minimum requirements for tattoo inks and test methods for manufacturers and distributors, who are primarily responsible for the safety of their products. Test methods are already available for the analytical and toxicological minimum requirements so that they can be used immediately. The necessary specifications for tattoo ink ingredients include precise information on the chemical and physical properties as well as the identification of impurities (contaminants). With regard to the minimum toxicological requirements, *in vitro* tests are proposed for tattoo pigments for the following endpoints: Eye irritation / eye corrosion, skin irritation / skin corrosion, phototoxicity, skin sensitisation, genotoxicity and photogenotoxicity. In addition, the BfR shows requirements for which further research is necessary or for which methods must be developed.

The minimum recommendations are intended, on the one hand, to help identify tattoo pigments that are not suitable for tattoos. On the other hand, through the use of pigments that meet the minimum toxicological requirements, possible health risks are reduced in line with the current state of science and technology. Further information can be found in BfR Opinion No. 031/2021 under the following link: https://www.bfr.bund.de/cm/349/tattoo-inks-minimum-requirements-and-test-methods.pdf

From the point of view of health risks, is it advisable to remove an existing tattoo?
Several procedures are now available for removing tattoos. However, these methods themselves pose health risks such as scar formation, changes to the skin and allergic reactions.

Whereas 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 liquids, 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. Since December 31, 2020, laser tattoo removal has been subject to doctor's proviso, which means that only licensed doctors with the appropriate training are allowed to remove tattoos. Further information can be found here:
https://www.bfs.de/EN/topics/opt/application-medicine-wellness/tattoo/tattoo-removal.html;jsessionid=94DBED0139D7614C009E19567A89C5E3.2_cid391

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. However, the BfR does carry out occasional health assessments of these methods. For example, a chemical process with liquid tattoo remover was assessed in Opinion No. 033/2011 of August 1, 2011 (in German):
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 August 28, 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 often form part of a holiday experience. The henna used is often made darker by mixing with the substance p-phenylenediamine (PPD). PPD is a well-known contact allergen that can cause severe allergic reactions. The use of this substance in henna tattoos is banned in the European Union (Regulation (EC) No. 1223/2009). Unlike tattoo inks, “temptoos” are governed 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

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

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

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https://de.statista.com/statistik/daten/studie/1253983/umfrage/umfrage-in-deutschland-zu-tattoos-nach-altersgruppen/

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 the States ('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.