German Federal Institute for Risk Assessment

FAQ

06 May 2025

Questions and answers about tattoo inks

→ Changes compared to the version from 16 April 2025. Updated information regarding European legislation (definition of tattoo inks).

In Germany, 17 percent of the population have tattoos, and the trend is rising. The group of 25 to 34-year-olds are most likely to state that they have several tattoos (Statista, 2021). Tattoo inks can consist of many individual substances, the potentially harmful effects of which have not been assessed for this application. The most commonly used pigments are still carbon black and white titanium dioxide. Organic pigments, which have a high colour brilliance, are usually used for colourful tattoos. Permanent make-up also frequently involves use of iron oxides. Problematic impurities in tattoo inks can include carcinogenic aromatic amines in organic pigments. Certain preservatives and traces of heavy metals, as well as microbial contamination of tattoo inks are also regarded as problematic. There are also tattoo inks with special effects, such as “glow-in-the-dark”, the ingredients of which are largely unknown. Undesirable acute consequences can occur, including infections, foreign-body reactions, scars or allergic reactions. Little is known about the long-term effects of tattoo inks.

Since 2022, the use of certain substances in tattoo inks and permanent make-up has been restricted within the European Union. This restriction regulates the use of substances with known and suspected adverse health effects and sets maximum concentrations for these substances in tattoo inks. To date, 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 developed minimum requirements for tattoo inks and test methods for manufacturers and distributors, as they are responsible for the safety of their products.

What are tattoo inks and permanent make-up?

According to European legislation, use of a mixture "for tattooing purposes" is defined as "injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body. "Temporary tattoos" that are applied to the surface of the skin are considered to be a form of body paint rather than tattoos.

While the pigments in tattoos are injected deep into the dermis, permanent make-up is only intended to reach the top layer of the dermis (stratum papillare). However, as the thickness of the skin layers can vary greatly, the depth of application is highly dependent on implementation technique.

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

Little is currently known about the undesirable health effects of colour pigments in the body. This means that it is not possible to assess whether they can be used safely.

Carefully reading the list of ingredients on the tattoo ink bottle is recommended. In case of known allergies or sensitivities to any of the declared substances, 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 *Safety Gate*.

The following address can be used to easily check whether the tattoo ink to be used has been reported:
https://ec.europa.eu/safety-gate-alerts/

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

Due to the lack of conclusive research data and testing methods, there is currently no "whitelist" of colourants which are safe to use.

What are tattoo inks made of?

Tattoo inks essentially consist of colourants (pigments), dispersants and other additives. In addition to water and alcohols, these also include various polymers, preservatives, defoamers, pH regulators and a variety of other individual substances.

How are tattoos legally regulated?

Substances in tattoo colourants or permanent make-up that are currently known to pose a health risk are subject to an EU-wide restriction on use under the REACH regulation (entry 75 of Annex XVII of the REACH Regulation (Regulation (EC) No 1907/2006)). Maximum concentration limits apply to the restricted substances. In addition, the declaration of ingredients and traces of certain metals that could trigger skin allergies are regulated.

In Germany, tattoo inks have been legally regulated by the Tattoo Inks Ordinance (*Tätowiermittelverordnung*) since 2009. It sets out general requirements for tattoo inks and permanent make-up products.

Additionally, tattoo inks are subject to the German Food and Feed Code (LFGB), which states that products must be safe for consumers and must not be harmful to human health. In Germany, manufacturers and importers are responsible for the safety of their products and must ensure compliance with the legal regulations.

What steps have been taken in recent years to regulate tattoos at the European level?

In addition to the German Tattoo Inks Ordinance, a few other EU member states also have similar regulations focused on the ingredients as well as microbiological aspects of tattoo inks. Within the scope of the European Chemicals Regulation (REACH), approximately 4,200 substances are prohibited or at least severely restricted for use in tattoo inks. This relates to substances that are proven to be carcinogenic, mutagenic or toxic to development and which damage reproduction. Furthermore, substances which are eye-irritating, skin-irritating and allergenic are strongly restricted. It also restricts substances that are prohibited or restricted in cosmetic products by certain annexes of the EU Cosmetics Regulation. The relevant regulations have been in effect since 4 January 2022. A transition period until 4 January was implemented for the pigments blue 15:3 and green 7.

How does the BfR assess the health risk of the pigments blue 15:3 and green 7?

In light of the ECHA's restriction proposal for binding regulations for ingredients in tattoo inks, the BfR has considered possible health hazards and risks of the pigments blue 15:3 and green 7. In its Opinion No. 039/2020, issued on 8 September 2020, the BfR concluded that the data currently available for both pigments only suggest a comparatively low toxicity. However, the BfR also stresses that existing data on the harmful properties of both pigments is incomplete. A health risk assessment for use in tattoo inks is therefore currently not possible in the BfR's opinion. This applies in particular to possible health risks associated with the injection of these substances into deeper skin layers (intradermal application). The BfR recommends expanding the available data on both pigments. The complete opinion of the BfR on the risk assessment of both pigments can be accessed via the following link:

https://mobil.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 monitoring 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 German Federal Office of Consumer Protection and Food Safety (BVL) in 2013 and 2017. The monitoring 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 variety of reasons.

Are tattoo inks tested and authorised?

As is generally the case with products covered by the German Food and Feed Code, there is no actual authorisation process for tattoo inks. Instead, the manufacturer is primarily responsible for the safety of such products. However, for many substances used in tattoo inks, it's still unclear how they affect the body as a whole (systemic effects).. 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 refrain 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 or 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 in which the BfR was involved 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. Additional research is needed in the development of test systems that could be used to predict possible health risks of insoluble pigments in relation to tattoos. The applicability of tests recommended in the BfR's minimum requirements for tattoo pigments is also currently being examined.

In addition, the use of human data and targeted epidemiological studies is essential in order to map possible effects of lifelong exposure of humans to colour pigments and thus expand the data available on the fate and effects of colour pigments in the human body. In this context, the BfR is conducting various studies to obtain human data. In other collaborative studies, tattooing agent allergies are also being researched using patient samples.

What are the health risks of getting a tattoo?

The colour pigments may contain heavy metals and allergenic substances. The carrier fluid may also contain numerous other ingredients, such as preservatives or substances that ensure better distribution of the colour pigments. Health effects associated with tattoos can occur immediately, weeks or even years after tattooing. The vast majority of complications are localised skin irritation or allergic skin reactions.

However, many questions relating to the health risks of tattoos and tattoo inks are still unanswered. For example, the use of certain potentially carcinogenic aromatic amines in tattoo inks has now been severely restricted. However, there is still a need for further research into the question of whether and in what quantities metabolic processes or sunlight can release such compounds from the ingredients contained in tattoo inks. It is also

unclear to what extent various colourants have mutagenic, carcinogenic or fertility-damaging effects when used as tattoo inks.

Do tattoos pose any particular health risks during pregnancy or breastfeeding?

As the tattoo inks come into direct contact with the blood and lymphatic fluid during tattooing, tattoo inks can spread throughout the body (systemic distribution). A transfer into breast milk or to the embryo therefore appears possible.

In addition, one of the main health risks of tattooing is the transmission of viral or bacterial infections. This can occur when using non-sterile equipment or contaminated ink. After tattooing, the injured skin is also more susceptible to infection due to the impairment of the skin's barrier function. It is possible for such infections to affect the embryo. In the event of a severe bacterial infection, antibiotic treatment may be necessary. For these reasons, getting a tattoo while pregnant or breastfeeding is not recommended.

During laser tattoo removal, the pigment particles are broken down into smaller fragments to enable their removal. It can be assumed that the concentration of pigment fragments or their degradation products is increased shortly after laser treatment. It is therefore recommended to avoid tattoo removal during pregnancy or breastfeeding.

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. For specific risks posed by nanomaterials, see:

https://www.bfr.bund.de/en/nanomaterials__tiny_particles_mediate_manifold_properties-8568.html

Can tattoo inks contain carcinogenic substances?

In the past, various tattoo inks were analysed and polycyclic aromatic hydrocarbons (PAHs) and primary aromatic amines (PAAs) were detected. As some representatives of this group of chemicals are classified as carcinogenic, strict concentration limits have been set for these substances under the REACH Regulation. In addition, many heavy metals such as nickel and chromium have carcinogenic as well as allergenic properties.

Chronic health effects such as cancer usually occur years or decades after exposure and are therefore difficult to link to tattoos or specific tattoo ingredients. Without epidemiological data that tracks and studies large cohorts over decades and records people's tattooing, it is difficult to establish a link between tattoo ingredients and chronic adverse effects. This also applies to the pigments and toxic elements found in lymph nodes.

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 results in swelling, itching, stinging, pain and reddening of the skin. These reactions are not limited to certain colour shades or pigments. Protecting tattoos from the sun is therefore recommended. In addition, certain pigments, known as azo pigments, can be split by sunlight. This not only leads to rapid fading of the tattoo, but also to the release of primary aromatic amines, some of which have carcinogenic and allergenic properties.

Can getting a tattoo lead to infection?

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 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?

The use of nickel in tattoo inks is prohibited by the REACH restriction regulations. Even if it is present in the colour below the limit value specified in REACH, the mixture must bear the label “Contains nickel. May cause allergic reactions”.

Nickel is the contact allergen with the highest sensitisation rate. It is not known at what concentration of nickel in the tattoo can trigger an allergy in sensitised people. Despite the high sensitisation rate to nickel and the presence of small traces of nickel in tattoo inks, nickel allergies to tattoo inks are rarely reported. The BfR recommends limiting nickel in tattoo inks to the lowest possible technical level.

Further information can be found in the BfR Opinion “Nickel in tattoo ink can trigger allergies” (in German): https://www.bfr.bund.de/cm/343/nickel-in-taetowiermitteln-kann-allergien-ausloesen.pdf.

How does the BfR assess the health risk posed by tattoos?

The BfR deals with the health risks of tattoo inks as part of toxicological and analytical research activities. It is also involved in regulatory activities at the national and the European level. For the health risk assessment of tattooing products, parameters relevant to exposure, such as the entry of various components into the skin and the tattooed skin area, are first considered. Subsequently, the specific properties of the ingredients are combined with the exposure parameters in order to carry out a risk assessment.

In 2023, a new international BfR commission for tattoo inks was established. The commission advises the BfR on issues relating to the composition of tattoo inks and the assessment of health risks. The commission for tattoo inks is made up of experts from various disciplines and fields of activity. These include the fields of medicine, toxicology, chemistry and hygiene, and tattoo ink manufacturers are also represented. The work of the commission is intended to contribute to new findings and recommendations on the safety of tattoo inks. The Commission's scientific expertise is advisory in nature and is separate from the BfR risk assessment, in which it is not involved.

What measures does the BfR recommend in order 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, only sterile water should be used when diluting 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 to reduce the risk to human health posed by tattooing products as much as possible in accordance with the current state of science and technology.

Due to a lack of data, the BfR has not yet issued any recommendations for use.

Are there criteria for the safety assessment of tattoo inks?

To date, there are no binding criteria for the safety assessment of tattoo products. 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 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). For the toxicological requirements, test methods are proposed that are assumed to be feasible with colour pigments. 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.

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

In regards to health, 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 and changes to the skin as well as release of hazardous substances. While removal by laser can lead to toxic cleavage products, surgical removal is associated with a pronounced risk of infection and scar formation on 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 doctors with the relevant expertise. Since 31 December 2020, laser tattoo removal has been subject to qualified doctor's proviso, which means that only licensed doctors with the appropriate additional specialised medical training are allowed to remove tattoos. Consumers must be comprehensively informed about the possible health risks posed by tattoo removal according to the Ordinance on Protection against the Harmful Effects of Non-ionising Radiation in Human Applications (NiSV).

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 issued on 1 August 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 28 August 2012 (see Section 6): https://www.bfr.bund.de/cm/349/requirements-for-tattoo-inks.pdf

Do henna tattoos also pose a health risk?

Also known as "temptoos", henna tattoos are not actually tattoos, but instead a type of body painting. In this case, the colours are painted onto the skin and lead to a colour reaction on the top-most layer of 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 subject to the EU Cosmetics Directive.

Further information on tattoos

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

Tattoos: even parting with them is not without risks (press release issued on 13 August 2015)
https://www.bfr.bund.de/en/press_information/2015/21/tattoos__even_parting_with_them_is_not_without_risks-194972.html

“Safer Tattoo” – Information portal of the German Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV):
https://www.bmuv.de/safer-tattoo

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. The BfR advises the Federal Government and the States ('Laender') on questions of food, chemicals and product safety. The BfR conducts independent 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.

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