

FAQ

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Cosmetic products: All ingredients must be tested Questions and answers on the risk assessment of cosmetic products

Shampoo, deodorant, toothpaste, lipstick or sunscreen: cosmetic products are part of everyday life for both children and adults. Some ingredients in cosmetic products, in particular preservatives or UV filters, are frequently the subject of public controversy regarding their safety. As a result, consumers often wonder whether cosmetics can pose a risk to their health.

The BfR has compiled answers to some frequently asked questions in order to clarify the current knowledge regarding the safety of cosmetic products.

What are cosmetic products?

Cosmetic products include not only decorative cosmetics such as lipstick or makeup but all substances and mixtures that are intended to be applied to external parts of the human body or in the oral cavity for cosmetic purposes. This also includes toothpaste, sunscreen, soaps, bath additives and body care products. All these products have in common that they are used to cleanse, maintain a good condition, perfume or change the appearance - always in relation to the exterior of the body (e.g. skin, hair, fingernails), the teeth or the mucous membranes of the oral cavity. The relevant definitions and legal provisions can be found in the EU Cosmetics Regulation and, for a few specific items, in the German Cosmetic Products Regulation.

Information on [the legal regulations for cosmetics](#) is available from the Federal Office of Consumer Protection and Food Safety (BVL).

Who is responsible for the safety of cosmetic products?

Manufacturers of cosmetic products must guarantee the safety of their products. The regional authorities of the German federal states ("Länder") conduct surveillance of random samples to verify whether the products meet the legal requirements. Cosmetic products that pose a health risk may not be sold or distributed. Anyone who manufactures cosmetic products or imports them into Germany must also notify the competent authorities of the federal states ("Länder") in advance.

Do cosmetic products or their ingredients have to be authorised?

Cosmetic products are not subject to authorisation. However, certain ingredients such as colourants, preservatives, and UV filters are assessed by the EU Commission's Scientific Committee on Consumer Safety (SCCS) before they are included in so-called positive lists. Once these ingredients have been included in the positive lists, they may be used for the stated purpose. In addition, there is a list of ingredients prohibited for use in cosmetics, as well as another list that stipulates use restrictions, maximum concentrations or warning notices for selected substances.

Why do cosmetic products have to be notified - and what does this mean?

Cosmetic products do not require authorisation in the EU. However, they must be notified to the EU Commission before being placed on the market.

For this purpose, information on the formulation (the so-called "frame formulation") and various other details must be stored in the access-protected internet portal CPNP ("Cosmetic Product Notification Portal"). The information stored there allows, among other things, the poison centres to assess the health risk in the event of misuse of cosmetic products and to provide appropriate medical advice.

Which tasks does the German Federal Institute for Risk Assessment perform in connection with cosmetic products?

The BfR assesses the health risk associated with ingredients in cosmetic products, especially when new scientific data is available. During the assessment process, the Institute may seek advice from a panel of external experts, the BfR Committee for Cosmetics. However, the actual assessment itself is conducted exclusively by BfR employees.

Are aluminium-containing deodorants (antiperspirants) harmful to health?

Aluminium salts are commonly used as an ingredient in deodorants, or more precisely: in so-called antiperspirants, as they reduce sweating under the armpits and subsequently the formation of malodours caused by bacteria. According to the current state of knowledge, health impairments due to the use of these antiperspirants are unlikely, even with regular use of such products.

In this context, there was a level of uncertainty in risk assessment for some time due to a lack of data. At the beginning of 2014, the BfR therefore recommended that aluminium-containing deodorants should not be applied directly after shaving or on injured skin to

reduce personal exposure to aluminium. However, this recommendation has since been revised based on new research findings showing that the contribution of aluminium-containing antiperspirants to overall aluminium exposure is significantly lower than previously assumed.

Can permanent hair colourants cause cancer?

As part of an EU Commission initiative, hair dyes have been subject to toxicological assessment by the Scientific Committee on Consumer Safety (SCCS) for several years. Only hair dyes that do not pose a health risk in the concentrations used may be utilised. According to current knowledge, there is no cancer risk associated with the use of hair dyes. However, some of the ingredients in hair dyes can cause allergic reactions. Respective products must therefore be labelled with a warning that allows people who suffer from allergies to avoid the products.

Should hair colouring be avoided during pregnancy and breastfeeding?

From a scientific point of view, it is not necessary to refrain from hair colouring during pregnancy and while breastfeeding as a precautionary measure. The risk assessment by the Scientific Committee on Consumer Safety (SCCS) also includes particularly sensitive individuals.

Why are nanomaterials used in cosmetic products?

In accordance with the EU Cosmetics Regulation, cosmetic products containing nanomaterials must include a corresponding statement in the list of ingredients on the packaging. In this case, the name of the respective ingredient must be followed by the word "nano" in brackets.

Nanoparticles are used as UV filters in sunscreen to protect the skin from UV radiation (e.g., titanium dioxide, zinc oxide). Nanotechnologically produced materials (so-called biocomposites) in toothpaste are intended to support the natural tooth repair mechanism of saliva. In addition, numerous pigments are used in cosmetic products. Some of these are in nano form, such as carbon black. Other pigments have a broad particle size distribution and contain a nanoscale proportion, such as titanium dioxide. In skin care products, nanocapsules are intended to protect and transport active ingredients and improve the skin care effect. However, according to the EU Cosmetics Regulation, only those nanocapsules that are biologically stable and that do not dissolve are to be considered nanomaterials. Research is being conducted into the refinement of the physical properties (e.g. transparency) of finished cosmetic products using nanomaterials.

Are sunscreens that may contain phthalate plasticisers as an unavoidable contamination harmful to health?

The State Agency for Nature, Environment and Consumer Protection of North Rhine-Westphalia and the Federal Environment Agency have detected the substance mono-n-hexyl phthalate (MnHexP) in urine samples from children and adults. This substance can be produced in the body as a metabolic degradation product of various phthalates.

Sunscreens containing a certain UV filter were discussed as one of the possible sources. Traces of one of the possible source substances for MnHexP, namely DnHexP, were detected in some cosmetic products during investigations by the monitoring authorities of the German federal states ("Länder"). DnHexP itself is prohibited as an ingredient in cosmetic products, but it could be introduced into such products as an impurity of the raw material, i.e. the UV filter.

However, the concentrations of DnHexP detected in some sunscreens are comparatively low. According to a preliminary risk assessment by the BfR, it is highly unlikely that the use of such products will cause any impairment to health.

Can sunscreens with nano-sized UV filters be used on small children and infants?

Children under the age of two should not be exposed to direct sunlight, as their skin has not yet developed its own protective function against solar radiation. Textile sun protection is also recommended in the shade. If direct sun exposure cannot be avoided, the uncovered parts of the body should be carefully moisturised with a sunscreen with a high sun protection factor to avoid sunburn. Some of these sunscreens contain nano-sized titanium dioxide or zinc oxide particles as UV filters.

The effect of these nanoparticle-sized substances on human skin has been comparatively well researched. The tiny particles cannot penetrate healthy skin, which means that, according to current knowledge, their use in UV filters for sunscreens is also harmless to the health of small children and infants.

Should consumers avoid cosmetic products that contain parabens?

Preservatives, including parabens, may only be used in cosmetics if they have been assessed as safe for health by the Scientific Committee on Consumer Safety (SCCS). The SCCS is currently reassessing some parabens as they were suspected of disrupting the body's hormone balance (as so-called "endocrine disruptors"). The reassessment has confirmed that no health impairment is expected if the maximum concentrations of methylparaben, propylparaben and butylparaben as previously permitted for cosmetics within the EU, are complied with.

The BfR does not advocate for a general replacement of parabens with other substances because parabens are well-tolerated by the skin and, unlike some other preservatives, have a low allergy risk. This also applies to ethyl paraben, which is commonly used in cosmetic products.

How hazardous is arbutin in skin lightening products?

Arbutin is a substance used as a skin lightening agent in cosmetics. Arbutin can be degraded to D-glucose and hydroquinone through metabolic processes in the skin. Hydroquinone is suspected of being carcinogenic and is banned in cosmetic products like those for skin bleaching in Europe. Deoxyarbutin is also banned in cosmetic products. In its 2023 opinion, the SCCS assessed alpha-arbutin and arbutin (beta-arbutin) in certain cosmetic products as safe up to a maximum concentration. Hydroquinone in this context may only occur in technically unavoidable traces.

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.

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