

Questions and Answers on the Risk Assessment of Cosmetic Products

FAQ from the BfR from 27 January 2014

From shampoos, cremes, toothpastes, lipsticks and suncreams, a fairly large range of cosmetic products belong to the articles of daily use for children and adults.

Repeatedly, there are critical public reports and discussions about several ingredients of cosmetic products, such as preservatives and UV filters, and for this reason, consumers often ask whether cosmetics can pose a fundamental health risk.

In the following paragraphs, the BfR has summarised and answered the most frequently asked questions from consumers regarding the safety of cosmetics:

What are cosmetic products?

Cosmetic products not only comprise decorative cosmetics like lipstick or make-up but also substances and preparations used exclusively or mainly for cosmetic purposes externally on the human body or inside the oral cavity. They include sun lotions, soaps and bodycare products. What they have in common, according to the definition of the EU cosmetics regulation, is that they either serve to clean, to maintain a good condition, to act as a perfume or to alter the appearance - always in relation to the external parts of the body (e.g. skin, hair, fingernails), the teeth or the mucous membranes in the oral cavity.

Do cosmetic products require approval?

Cosmetic products do not have to be licensed but some of their ingredients and additives, such as preservatives, colorants and UV filters, have to be approved. The licensing process is regulated on European level. The risk is assessed by the Scientific Committee on Consumer Safety (SCCS) and the licence issued by the European Commission and, with the involvement of the member states, by the European Parliament and Council.

Who is responsible for the safety of cosmetic products?

The manufacturers of cosmetics must be able to guarantee the safety of their products. By taking random samples, the surveillance authorities of each federal state check that the products comply with legal requirements. It is prohibited to put cosmetic products onto the market which are not safe to human health if used in the intended or reasonably foreseeable manner. Cosmetic products which pose a health risk may not be put onto the market.

Why do cosmetic products have to be notified?

The European Commission operates an internet portal via which cosmetic products have to be notified before they are marketed. Manufacturers are obliged among other things to enter the recipe of their product there so that the poison centres can access them in the course of their consultancy work. Information on nano-sized ingredients must also be entered.

The Federal Office of Consumer Protection and Food Safety provides more information on the notification process at www.bvl.bund.de

What tasks does the Federal Institute for Risk Assessment perform in connection with cosmetics?

The BfR assesses the ingredients of cosmetic products with regard to their health safety, especially when fresh scientific data becomes available. During the assessment process, the Institute is advised by a panel of independent experts, the Committee for Cosmetics.

Are deodorants containing aluminium harmful to health?

The estimated intake of aluminium from antiperspirants could possibly lie within the range determined by the European Food Safety Authority as the tolerable weekly intake. As aluminium is also ingested from other sources, such as food, this level could be exceeded by part of the population. To prevent too high an intake of aluminium, excessive use of antiperspirants containing aluminium should therefore be avoided. In addition to this, deodorants that do not contain aluminium salts should be used after shaving or if the skin in the armpits is damaged.

Can permanent hair dyes cause cancer?

No cancer risks are known from the use of hair dyes. Risk assessment continues to focus on the allergies which could be caused by these products.

Should expectant and nursing mothers stop dyeing their hair?

There are currently no indications of any health risks caused by the use of hair dyes during pregnancy or while nursing.

Why are nanoparticles used in cosmetic products?

Nanoparticles made of titanium dioxide and/or zinc oxide are used as UV filters in suncreams to protect the skin from UV radiation. Materials produced using nanotechnology (so-called biocomposites) in toothpaste are intended to support the natural tooth repair mechanism of saliva.

Cosmetics containing ingredients in the form of nanomaterials must contain a reference to this effect in the list of ingredients in line with the EU cosmetics regulation (EC Reg. No. 1223/2009). The names of these components must be followed by the word “nano” in brackets.

What is known about the health effects of nanoparticles in cosmetic products?

Toxicological tests have already been made for several nanoparticles used in cosmetic products. Accordingly, the behaviour of nanoparticles made of titanium dioxide and zinc oxide on the skin has been well examined. It was confirmed in several experiments that these nanoparticles cannot penetrate healthy human skin cells and remain on the skin surface. They can remain on the skin for longer periods via the hair follicles, but they cannot penetrate it. Hair growth then transports them back to the skin surface.

There are currently many open questions in the assessment of the health risk of nanoparticles. The possible but not yet experimentally proven special potencies of particles in the biological system based on their nanoscale are largely unknown, nor is much data available on the exposure of humans to nanoparticles.

Can sunscreen with nano-sized UV filters be used for babies?

Children aged under two years should not be exposed to direct sunlight because their skin has not yet developed its own protection function against solar radiation. Textile sun protection is also recommended in the shade.

If direct exposure to the sun cannot be avoided, a sunscreen product should be carefully applied to the uncovered areas of the body to prevent sunburn. Although knowledge of the possible risks of nanomaterials is still a bit sketchy in some places, the effects of nanoparticle-sized substances on human skin is comparatively well researched. As the tiny particles cannot penetrate healthy skin, their use in UV filters for sunscreen products does not pose a health risk.

Should consumers avoid cosmetic products containing parabens?

Preservatives, which include parabens, may only be used in cosmetics if they have been assessed as not dangerous to health by the Scientific Committee of the European Union and approved in the EU cosmetics regulation. This committee most recently determined in 2011 that several parabens are safe as long as certain concentration limits are complied with. The BfR does not advocate a general substitution of parabens because these substances are kind to the skin and, unlike other preservatives, pose a low allergy risk.

How dangerous is arbutin in skin bleaching products?

The substance arbutin is used as a skin bleaching agent in cosmetics. Through metabolic processes, arbutin can be split in the skin into D-glucose and hydroquinone. The latter is a suspected carcinogen and is prohibited in Europe in cosmetics such as skin bleaching products. For this reason, the BfR assesses the use of arbutin in cosmetic products as unsafe to health.

What health risks can nail sculpting involve?

Methacrylates, which are contained in several nail sculpting products, have a strong sensitisation potential. Damage to the nail or surrounding skin caused by the sculpting process can remain for years. Risks can be minimised through the professional use of nail sculpting products which in particular guarantees the avoidance of skin contact and the regulated exchange of air in enclosed areas. Self-modelling involves a high risk of sensitisation for every user because unintentional skin contact is difficult to avoid.

What is the “cocktail effect” understood to be in connection with the ingredients of cosmetic products?

The term “cocktail effect” is not scientifically defined. It is commonly used to describe a cumulative effect which could occur if various cosmetic products with ingredients to which a similar effect is attributed were used simultaneously. If these ingredients have a common chemical structure, such as the parabens, this effect is taken into account in the safety assessment with which concentration limits in the product are determined among other things. In addition to this, very large safety margins are calculated into the assessment of the possible health risk.