Sun cream and similar products - are there health risks?

BfR FAQ on sunscreen products dated 19 December 2019

When the sun shines brightly, sunburn is often not far away. To prevent things from getting to that stage, it is recommended to avoid direct sunlight on the skin or to apply sunscreen products to the skin. They can protect the skin by converting the ultraviolet rays of the sun into heat. This occurs with the help of UV filter substances. UV filters which are used in cosmetic products must undergo an assessment procedure in the European Union, which evaluates whether their usage as UV filters in sunscreen products is safe up to a maximum concentration. We have put together some important questions and answers about the possible health risks of UV filters.

How do sun creams work?
Sunscreen products contain filter substances. They do not allow the ultraviolet (UV) rays of the sun to get to the skin. Distinctions must be made between organic chemical and mineral (physical) UV filters. In the case of organic chemical filters, molecules absorb sun radiation and convert it into heat. An example of such a filter is octinoxate, a variant of cinnamic acid. By contrast, mineral sun creams contain titanium dioxide or zinc oxide. These pigments reflect the sunlight like tiny mirrors. Sunscreen products often contain both chemical and mineral UV filters. The sun protection factor indicates how well a product protects from the sun. The higher the value is, the longer you can stay in the sun - depending on skin type.

How dangerous are UV filters in sunscreen products?
According to the current state of science, no impairments to health are to be expected from sunscreen products available in the European Union. The reason: Only products with assessed UV filters may be sold in the EU. An assessment by the Scientific Committee on Consumer Safety (SCCS) must have confirmed safe usage as UV filters in sunscreen products up to a maximum concentration beforehand. At present, 30 filter substances may be used in the EU.

How are sunscreen products assessed?
Cosmetic products, which also include sun creams, do not need to be authorised in the EU. However, a safety assessment must be carried out for each used ingredient and each product. An additional requirement applies to UV filters, along with colourants and preservatives; all three substance groups may only be used in cosmetic products when they have been listed, based on a risk assessment by the SCCS of the EU Commission, in the relevant annex of the EU Regulation on Cosmetic Products (EC) No 1223/2009 (EU CPR) (Annex IV: List of Colorants Allowed in Cosmetic Products; Annex V: List of Preservatives Allowed in Cosmetic Products; Annex VI: List of UV Filters Allowed in Cosmetic Products). As part of the procedure, the SCCS assesses the substances for possible health hazards. The basis for this are scientific data in which all important toxicological information must be described, and information as to whether and in which quantities the substance can enter the body via the skin. If the data situation is insufficient, the SCCS requests further studies. Manufacturers may use only those UV filters for which no risk can be deduced from their usage in the intended concentration. Approved substances are listed in the EU CPR.

A study of the US Food and Drug Administration, presented in the expert journal "JAMA" in May 2019, has come to the conclusion that chemical UV filters in sun creams enter the bloodstream via the skin. How can this result be interpreted?
The FDA investigation must be regarded against the backdrop of American legislation. Sunscreen products are sold as over-the-counter drugs in the USA. Only products complying

with the requisite of limiting the amount of UV filters in the blood are allowed. The concentration in the blood plasma must be less than 0.5 ng/ml. If the value is higher, the manufacturer must provide toxicological studies. As companies have not submitted any studies so far, the FDA has reviewed compliance with the limit value. By contrast, in the European Union, UV filters must be tested (for example, to see whether substances are transferred into the bloodstream) and assessed - including information on maximum blood levels reached. This means: According to the current state of knowledge, no impairments to health are to be expected from sunscreen products available on the European market.

Sunscreen products sometimes contain nanomaterials, such as the UV filter titanium dioxide. How suspicious are these nanomaterials?
Nanoparticles, which are used as UV filters in sunscreen products, must be assessed by the scientific experts' committee of the EU Commission, SCCS. The contact of nanoparticles with the skin has also been well researched. Studies have proven that, for example, nano-titanium dioxide cannot enter the human bloodstream in the form in which it is used in cosmetic products. Based on the available findings, the SCCS reached the conclusion: Health risks are unlikely for nano-titanium dioxide as a UV filter in a concentration of up to 25 per cent in sunscreen products. This applies to healthy, intact and sunburnt skin. People whose skin is damaged due to illness (allergies, acne, neurodermitis) should consult a specialist. The SCCS has limited its conclusion to applications (e.g. creams, lotions) which do not lead to exposure of the lungs through inhalation.

UV filters are also used in lipsticks and lip balms. Is this dangerous?
Lips react more sensitively to UV radiation than the rest of the facial skin. Therefore, many lipsticks and lip balms contain UV filter substances. According to the current state of knowledge, it can be concluded that lipsticks only make a very small contribution to the intake of UV filters. The BfR considers impairments to health to be unlikely, in keeping with the current state of scientific knowledge. For the UV filter 4-methylbenzylidene camphor, the BfR recommends avoiding use in lipsticks and lip balms, as the margin of safety (*MoS*) is not considered to be sufficient for the permitted maximum concentration (4 %) in cosmetic products. The margin of safety is the result of the dose which no longer causes damaging effects in animal experiments, divided by the dose absorbed by the consumer. The margin of safety is needed to take into account the difference between animals and humans, and the differences between individual people. A value greater than 100 is generally considered to be sufficient.

Do UV filters in sunscreen products increase the risk of cancer?
According to the current state of knowledge, UV filters do not increase the risk of cancer. According to information from the German Cancer Research Centre, there is neither proof nor scientific publications in the form of clinical studies which give reason to suspect that there is an increased cancer risk due to UV filters in sunscreen products.

Which sunscreen products and UV filters are recommended?
The BfR does scientific risk assessment. It is not allowed to and will not recommend any individual products. This is also the case for UV filters, which are combined in most sunscreen products anyway. Essentially: According to the current state of knowledge, no impairments to health are to be expected from sunscreen products which are available on the European market.

It should be noted that no sunscreen product provides full protection from UV radiation. The best protection comes from textile sun protection - clothing which covers the skin. Uncovered areas of the body should be covered with sunscreen products. This especially applies to

children. Infants and young children aged up to two years old should not be exposed to direct sunlight.

The Federal Office for Radiation Protection also provides more tips about the correct protection against UV radiation on its website:
https://www.bfs.de/EN/topics/opt/uv/protection/protection_node.html

Further information on the subject from the BfR website:

BfR FAQ on titanium dioxide dated 15 August 2017 (in German)
https://www.bfr.bund.de/de/titandioxid___es_besteht_noch_forschungsbedarf-240812.html

Zinc oxide as a UV filter (BfR Opinion No. 037/2010 of 18 June 2010, in German)
https://www.bfr.bund.de/cm/343/sonnenschutzmittel_zinkoxid_als_uv_filter_ist_nach_derzeitigem_kenntnisstand_gesundheitlich_unbedenklich.pdf

Further information on sunscreen from 17 July 2007 (in German):
http://www.bfr.bund.de/de/presseinformation/2007/13/immer_auf_ausreichenden_sonnenschutz_achten_-9678.html

About the BfR
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