Questions and Answers on Mineral Oil in Cosmetic Products

BfR FAQ of 26 May 2015

Cosmetic products can contain mineral oils, waxes and white oils from refined and processed crude oils. The proportions of potentially carcinogenic hydrocarbons are reduced and/or eliminated through the processing of the crude oil.

The Federal Institute for Risk Assessment (BfR) has assessed whether the amount of aromatic hydrocarbons in cosmetic products which can conceivably be absorbed through the skin constitute a health hazard. Taking into account all scientific evidence available, health risks for the consumer are unlikely. The BfR answers some frequently asked questions in the following paragraphs.

What are mineral oils?
Mineral oil is produced from crude oil and contains a mixture of thousands of different hydrocarbons. The amount of crude oil components which could possibly impair health can be reduced or even eliminated through various processing stages such as refining, extraction and hydrogenation. These components also include so-called MOAH (mineral oil aromatic hydrocarbons) for which a carcinogenic potential cannot currently be ruled out in all cases. White oils, waxes and distillates, which are also used in cosmetic products, are produced through processing.

From a chemical point of view, mineral oil always contains mineral oil saturated hydrocarbons, or MOSH for short. MOAH can also occur alongside these despite processing. The MOAH fraction consists of a complex mixture of various aromatic hydrocarbons which often have side chains in many positions, which means they are alkylated to a high degree. Scientific data on most of the individual substances and their metabolites regarding their health effects is lacking.

Is it allowed for cosmetic products to contain mineral oil?
According to the EU cosmetics regulation 1223/2009, mineral oils are permitted in cosmetic products if the full refining history is known and either the starting material is free of carcinogens or the distillate was tested for carcinogenic properties using specific methods.

Why are mineral oils used in cosmetics?
Mineral oils have various functions in cosmetic products. They are used as antistatic agents, plasticisers, skin protection products, solvents and viscosity regulators. Because of their many and varied functions, mineral oils are to be found in skin creams and lotions, body and face cleansing products, sun protection products, self-tanning lotions, deodorants and antiperspirants, lip care products, make-up, nail care products, hair gels, skin and eye ointments, denture adhesives, Vaseline and baby oil. The concentration ranges from 1 to 99 %, depending on the product.

How can I recognise whether cosmetic products contain mineral oil?
The ingredients of cosmetic products have to be declared. Examples of the designations of mineral oils on cosmetic products are:

- Paraffinum liquidum
- Paraffin
- Cera Microcristallina
- Petrolatum

What health risks are known regarding the absorption of mineral oils through the skin?
Considering all available lines of evidence it has to be assumed that mineral oil products are absorbed through the skin only in very small quantities, if at all.

Animal toxicity studies with long-term dermal exposure (subchronic toxicity) consistently showed no indications of health-damaging effects for saturated hydrocarbons (MOSH). After treatment with a petrolatum-paraffin wax mixture, slight eye irritations were observed in test animals; in humans slight skin redness occurred in individual cases after treatment. The sensitisation potential of mineral oil products is also low. In a study with 80,000 participants, it was shown that medicinal white oils have no sensitisation potential in human skin, which means they do not trigger allergies.

There are gaps in the data, however, which make a health risk assessment more difficult. These include data on uptake through the skin after contact over a long period, on oral bioavailability and on the relevance of histopathological changes in the liver (microgranules) which occurred in animal studies in a particularly sensitive strain of rats after feeding them the respective preparations. There have also been reports of a similar accumulation of MOSH in the human body associated with uptake through food, but these were non-inflammatory deposits with unclear clinical relevance. Little is currently known about the effects and occurrence of aromatic hydrocarbons (MOAH) in cosmetic products. An overall assessment is further complicated by data gaps regarding the composition of the mineral oil mixtures used by the cosmetics industry.

Does BfR expect health risks through mineral oils in cosmetic products?
From a BfR point of view and in line with the latest level of available knowledge, risks to consumer health through the uptake of mineral oils in cosmetics via the skin are not to be expected.

Mineral oils have been used in cosmetic products for over a hundred years. On the basis of the available data it can therefore be assumed that products with MOAH proportions in the percentage range have been on the market for many years. Despite their widespread use, however, no related health effects have been observed to date through cosmetic products. There are currently no clinical or epidemiological findings to indicate the opposite.

Because of the data gaps mentioned above, however, it must also be pointed out here that especially where possible oral intake is concerned (e.g. via lipstick), a final risk assessment is more difficult.

Should the MOAH proportion in cosmetic products be reduced?
The BfR has conducted random spot checks on various cosmetic products to establish their MOAH content. Analyses of individual cosmetic products with declared mineral oil content show big differences with regard to the amount measured. The maximum levels established lay in the single-digit percentage range in several samples, whereas only traces were detected in other products. A minimisation of the MOAH levels would therefore appear to be technologically feasible and is recommended by the BfR for cosmetic products.

How does the BfR Cosmetics Committee assess the mineral oil findings in cosmetic products?
The question of the health risk assessment of MOSH and MOAH in cosmetic products - in particular regarding the development of skin cancer - was discussed intensively at the 15th meeting of the BfR committee for cosmetic products. The dermatologists in attendance em-

phasised that there are no indications for dermal health-damaging effects which can be attributed to cosmetic products. There is, for example, no data indicating that the use of lipstick would increase the rate of skin cancer in the area around the mouth. Although baby oils and creams, some of which contain high concentrations of mineral oils due in part to the low sensitisation potential, are used in the nappy area, no increase in skin diseases or even skin tumours has been observed in this body area among children or adults. In the treatment of psoriasis, Vaseline, which consists of petroleum jelly, is applied over the entire body and covered with cloths. To date, no increase in the incidence of skin lesions has been reported in connection with this treatment either.

More information at the BfR website on the subject “Cosmetic Products”:

Mineral oils in cosmetics: According to the latest level of available knowledge, no health risks are to be expected through intake via the skin, BfR Opinion No 014/2015 of 26 May 2015
http://www.bfr.bund.de/cm/349/mineral-oils-in-cosmetics-considering-all-available-scientific-evidence-no-health-risks-are-to-be-expected-from-absorption-vie-the-skin.pdf

Questions and answers on the migration of mineral oil from packaging materials to foodstuffs
http://www.bfr.bund.de/cm/349/questions-and-answers-on-the-migration-of-mineral-oil-from-packaging-materials-to-foodstuff.pdf