

32

Purity is all-important

Cosmetics contain mineral oils. There has been much debate over whether these oils may pose a health risk – above all when lip balm and similar products enter the body not just via the skin but also via the mouth.

In Antiquity, the Egyptian Queen Cleopatra is said to have bathed in donkey's milk to preserve her smooth skin. This level of luxury was the exception rather than the rule; for thousands of years, vegetable oils and beeswax were used as beauty treatments and to care for the skin. Today, however, many cosmetics on the market contain ingredients based on mineral oils. Due to their various positive properties, mineral oils are meanwhile used in creams, lotions, body and facial cleansers, sunscreens, self-tanning lotions, deodorants and antiperspirants, lip balms, make-up, nailcare products, hair gels, Vaseline and baby oil. Depending on the product, the mineral oil content can range from 1 to 99 percent. Vaseline is also used as a base or vehicle in medicinal formulations.

From crude oil to Vaseline

"When they hear mineral oil, some people perhaps think of black crude oil, which contains many harmful substances", says Dr. Bärbel Vieth, who is responsible for the safety of cosmetic products at the BfR. But the mineral oil used in cosmetics has very little in common with the raw material. Unrefined oil, crude oil, is a highly complex mixture containing thousands of constituents. It mainly consists of saturated, unsaturated or aromatic hydrocarbons as well as numerous heterocyclic compounds. It is above all the aromatic compounds that can be carcinogenic. Mineral oils are produced in the various purities required for the different applications by means of fractionated distillation,

02/2018 33

MOSHs, MOAHs, mineral oil

MOSHs is the abbreviation for Mineral Oil Saturated Hydrocarbons, which are contained in all mineral oils. In animal studies, MOSHs were shown to have inflammatory effects on the liver. The European Food Safety Authority (EFSA) has therefore only authorised certain waxes and white oils for use as food additives, and they have to meet the defined criteria. MOAHs stands for Mineral Oil Aromatic Hydrocarbons, which include substances that can have mutagenic and carcinogenic effects such as polycyclic aromatic compounds (PACs).



A contaminant in foods

Not cosmetics but foods are the main source of intake of mineral oils. This is mainly due to packaging made of recycled paper that contains mineral oils. These oils originate from inks used for newsprint. The BfR already pointed to this problem back in 2009. This contamination is undesirable, and this is why barrier solutions such as bags or coatings are used in packaging. As one aspect of the BfR MEAL Study "What's in our food", levels of mineral oil components are determined in foods in order to create a data basis for risk assessment purposes. Data on mineral oil contamination in foods is also being collected on EU level, and Germany is involved in this process. The legal basis for these activities is provided by Recommendation (EU) 2017/84 of the European Commission.

vacuum distillation and subsequent multiple, specific extraction steps. "These are multi-stage physico-chemical and chemical refining methods during which a mixture of substances is separated into individual fractions", chemist Vieth explains.

The more purification stages an oil passes through, the greater the extent to which potentially harmful higher-molecular constituents are filtered out. The necessary purification steps are adapted to the applications for which the mineral oils are used. Mineral oils with a low or medium degree of refining are used for technical applications, for example – in such things as printing inks or as lubricants. Where mineral oils are used in cosmetics, on the other hand, the aromatic compounds are removed to the greatest possible extent in a multistage refining process and via additional hydration steps. This results in highly pure oils and waxes of the kind that have been used in Vaseline for over a century and are today used in many cosmetic products.

How pure are cosmetics?

It is known that mineral oils that are inadequately purified can lead to cancer if they come into contact with the skin, and this is why mineral oils have become a topic of interest to the BfR. "The question that concerns us is whether in their daily routine consumers absorb mineral oil via cosmetics and are therefore potentially exposed to health risks", explains Bärbel Vieth. The BfR has investigated the risk potential of mineral oil in cosmetics and the possible health risks in a whole series of expert discussions and conferences with scientists, consumer organisations, authorities and industry. The BfR has also analysed the occurrence of mineral oil constituents in cosmetics and has developed and validated a suitable analytical method for this purpose.

"Our risk assessment shows that, based on the current state of scientific knowledge, health risks are unlikely due to the use of highly refined mineral oils in cosmetics applied to the skin", says Vieth. "Moreover, mineral oils used in cosmetics meet the purity criteria for medicine." The stipulations of the EU Cosmetics Regulation ensure that only mineral oils that are safe for human health may be used in cosmetic products. According to the regulation, mineral oils may only be used if they are non-carcinogenic, if the refining history is fully known, or when the distillate has been tested using the IP346 method. This method is an input test for those mineral oils that are subsequently subjected to additional purification stages for use in cosmetic products.

"The available data is extremely robust, as the most important data comes from animal studies and all the studies come to the same conclusions", adds Vieth. "Based on current knowledge, therefore, no health risks to consumers are to be expected due to the uptake of mineral oils in cosmetics via the skin."

34 BfR2GO



Lipstick - a special case

As lipstick and lip care products not only remain on the skin but can also be licked and swallowed – thereby entering the body via the mouth – Cosmetics Europe (the European Association of Cosmetics Producers) advises producers to only use mineral oils that are also approved for use in foods. The Joint Expert Committee for Food

Additives (JEFCA) of the WHO and the European Food Safety Authority (EFSA) have derived acceptable daily intakes (ADI values) for these food-approved mineral oils. The BfR risk assessment showed that orally ingested mineral oils from lip care products contribute less than ten percent to the ADI of consumers. In the opinion of the BfR, no health risk is to be expected if producers comply with the recommendations of Cosmetics Europe.

02/2018 35