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RE: The EU must act on problematic mineral oils in lip care products, evidence from consumer tests shows

Dear Commissioner Bieńkowska,

Lip balms are every day cosmetic products intended to relieve signs and symptoms of skin dryness and chapping. New evidence from laboratory testing sponsored by EU consumer organisations now demonstrates the widespread presence in lip balms of certain problematic mineral oils. **In a recent test, none of the tested products comply with safety recommendations based e.g. on the scientific opinion of EFSA. The tested lip care products therefore represent a potential concern for consumer health, including for children and other vulnerable groups.** Please find enclosed further information about the research.

The European Food Safety Agency [considers](#) that current dietary exposure to certain mineral oils in the European population is of potential concern. As the Scientific Committee on Consumer Safety moreover [expects](#) that through daily use consumers 'eat' up to four lip balms per year, the new evidence underscores the need for a swift EU response to reduce the amount of problematic mineral oils in lip care products.

On behalf of BEUC, The European Consumer Organisation, **I encourage the European Commission to urgently explore how official EU health-based guidance values for mineral oil hydrocarbons (MOSH and MOAH) in lip care products can be established.** Concentrations of problematic mineral oils should in particular be kept at a level low enough to avoid a substantial contribution to total consumer exposure.

A majority of the tested lip balms were also found to contain impurities suspected to present a carcinogenic risk. **We strongly urge the European Commission in cooperation with Member State Competent Authorities to ensure that the content of carcinogenic impurities in lip care products is strictly monitored and reduced to the trace amounts which are unavoidable.**

We would in this context be interested to present our survey in further detail and to discuss with you how to ensure the safety of consumers.

Yours sincerely,

Monique Goyens
Director General

Encl.: EU consumer organisations call for action on mineral oils in lip balms.

Annex – EU consumer organisations call for action on mineral oils in lip balms

Lip balms are every day cosmetic products intended to relieve signs and symptoms of skin dryness and chapping. A 2013 [study](#) performed in the Netherlands for example found that one in three consumers use lip balms. The EU's Scientific Committee on Consumer Safety (SCCS) [expects](#) that through daily use consumers 'eat' up to 20 grams of lip balm per year – or the equivalent of four typical lip balms. This unavoidable consumption makes substances of concern in lip balms particularly problematic.

Some of the most widely used ingredients in lip balms and other lip care products are based on mineral oils. This includes ingredients such as for example petrolatum, paraffinum and microcrystalline wax.

In 2012, the European Food Safety Agency (EFSA) [concluded](#) that exposure to certain mineral oil hydrocarbons ('mineral oils' for short) is of potential concern: whereas some mineral oils may accumulate in the body's organs others are suspected of causing cancer.

Adding to mounting concern about their impact on health, new evidence by EU consumer organisations now demonstrate that certain problematic mineral oils are widely found in lip balms. In a recent test, none of the tested products thus comply with safety guidelines based on *e.g.* EFSA or Cosmetics Europe recommendations. These results underscore the need for a swift EU response to reduce the amount of problematic mineral oils in lip care products.

Consumer exposure to certain mineral oils is of concern

Consumers come in contact with mineral oils from many sources, including through contaminated foods, packaging materials, other environmental sources and cosmetic products. Mineral oils are complex mixtures of thousands of different hydrocarbons that are derived mainly from petroleum but also produced synthetically from liquefaction of coal, natural gas or biomass. Mineral oils mainly consist of mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH). Synthetic hydrocarbons, such as polyolefin oligomeric saturated hydrocarbons (POSH), are structurally similar to MOSH.

In 2012, the European Food Safety Authority (EFSA) published an [opinion](#) on mineral oils in food. According to the agency, some long-chained¹ MOSH may accumulate and cause microgranulomas (*i.e.* microscopic aggregation of cells) in *e.g.* lymph nodes, spleen and liver, while many MOAH may act as genotoxic or non-threshold carcinogens.

Based on an extensive review of all publicly available data on toxicity and exposure, EFSA concluded that current dietary exposure to mineral oils in the European population is of potential concern. As a result of insufficient data, the agency was however unable to derive a tolerable daily intake (TDI) or related health-based guidance values for MOSH.

Mineral oils in lip care products

Mineral oil based ingredients are used in various cosmetic products, from skin creams and lotions, to sun protection products and hair gels.

Lipsticks and lip balms may contain both petroleum derived mineral oils (MOSH) as well as synthetic hydrocarbons (POSH), such as polybutene or polyethylene waxes. At present, little is known about the occurrence of MOAH in cosmetic products, and [data gaps](#)

¹ Specifically, MOSH with a chain-length of 16 to 35 carbon atoms (C₁₆-C₃₅).

regarding the mineral oil mixtures used by the cosmetics industry complicates further assessment.

The Cosmetics Regulation (Regulation (EC) No 1223/2009) **permits** use of mineral oil based ingredients in cosmetic products *provided* the manufacturer knows the full refining history of the material. Possible carcinogenic impurities must be analysed and removed.

According to the German Federal Institute for Risk Assessment (BfR), **dermal exposure** to mineral oil based ingredients do not present a health concern as the absorption of problematic oils through the skin is considered to be low.

Oral absorption may by contrast be a significant source of consumer exposure to MOSH. In its 2012 opinion, EFSA considered that the estimated daily dietary intake of 1.8–18 mg MOSH per person is of potential concern. The Scientific Committee on Consumer Safety (SCCS) meanwhile **estimates** that the daily application of lip care products is 0.057 g per person with a 100 per cent oral uptake. According to Niederer *et al.*,² if lip care products therefore contain, for example five per cent MOSH and POSH, they contribute 2.85 mg to daily dietary exposure – a major contribution to overall consumer exposure.

Regular application of lipsticks or lip care products may consequently result in substantial increases in exposure to mineral and synthetic saturated hydrocarbons (MOSH+POSH). Cosmetics Europe **recommends** that only those mineral hydrocarbons for which an Acceptable Daily Intake (ADI) has been identified are used in oral and lip care products.

A European Consumer Survey: Mineral Oils in Lip Balms

Adding to these concern, mounting evidence by EU consumer organisations demonstrate that problematic mineral oils are widely found in lip balms. Recently, eight consumer organisations, DECO (Portugal), Test-Achats (Belgium), Altroconsumo (Italy), OCU (Spain), UFC-Que Choisir (France), Kuluttajaliitto (Finland), D-test (Czech Republic) and ZPS (Slovenia) cooperated to investigate mineral oils in lip care products.

In total 58 lip balms, representing the main national and international brands, were investigated. Out of these 58 products, 32 contained mineral oil based ingredients or similar synthetic ingredients. All 58 products were sent to a laboratory for further analysis.³

Given the complexity of the mineral oil mixtures, the test was unable to determine individual compounds or substances. Instead, the analysis investigated the concentration of total MOSH, POSH and MOAH fractions, as well as certain MOAH sub-classes, using methods based on gas chromatography.⁴

Results: none of the mineral oil based lip balms pass the safety recommendations

All 32 products with either mineral oil based ingredients or similar synthetic substances contained either MOSH or POSH. In 28 of these products, the presence of MOAH was also detected. MOAH was not detected in products based on synthetic hydrocarbons.

In the absence of official EU health-based guidance values, the results were assessed against three different sets of safety recommendations. Accordingly, the safety 'threshold' was established as:

² M. Niederer, T. Stebler and K. Grob. 2016. Mineral oil and synthetic hydrocarbons in cosmetic lip products. *International Journal of Cosmetic Science* 38: 194-200.

³ The full list of tested products are available with the authors.

⁴ Further details on data and methods are available with the authors.

- Concentration of MOSH+POSH below five per cent (based on Niederer *et al.*⁵);
- Concentration of long-chained MOSH (C₁₆-C₃₅) below ten per cent (partly⁶ based on Cosmetics Europe [recommendations](#)); and,
- Concentration of MOAH below the limit of detection (based on the 2012 EFSA opinion).

None of the tested products with mineral oil based ingredients or similar synthetic ingredients comply with all of these recommendations. The tested products therefore represent a potential concern for consumer health.

Specifically, whereas none of the tested products respect the five per cent MOSH+POSH concentration limit recommended by Niederer *et al.*,⁷ 18 products did follow the adapted recommendations of Cosmetics Europe: that is, they contained no more than ten per cent MOSH with a chain-length of 25 or less. When applied to long-chained MOSH (C₁₆-C₃₅) where accumulation in organs has been demonstrated, however, only four products comply with the Cosmetic Europe recommendation. Yet, these four products were among the 28 products where the test detected MOAH.

These results thus corroborate previous [findings](#) by Forbrugerrådet Tænk KEMI and Stiftung Warentest; in this test, 14 out of 20 tested lip balms on the Danish and German markets contained MOSH+POSH in concentrations between 2 and 77 per cent, while in 12 products MOAH was detected in concentrations ranging from 0.04 to 4.3 per cent.

The EU must act on problematic mineral oils in lip care products

In view of the concern expressed in the 2012 EFSA opinion, this new evidence underscores the need for a swift EU response to reduce the amount of problematic mineral oil hydrocarbons in lip care products. Considering that material applied to the lips is largely ingested, MOSH and POSH levels should be reduced in the majority of lip care products, while MOAH levels must remain below the limit of detection.

BEUC invites the European Commission to explore whether and how official EU health-based guidance values can be established for mineral oil based ingredients in lip care products. In particular, MOSH+POSH concentrations in lip balms and other lip care products should be kept at a level low enough to avoid a substantial contribution to total consumer exposure to these hydrocarbons.

MOAH is a suspected carcinogen for which no safe levels has been established. According to the Cosmetics Regulation, manufacturers are required to analyse and remove possible carcinogenic impurities in their products. Based on evidence from these test, we strongly encourage the European Commission to work with Member State Competent Authorities to ensure that in future the MOAH content in lip care products is strictly monitored and reduced to the trace amounts which are unavoidable.

ENDS

⁵ M. Niederer, T. Stebler and K. Grob. 2016. Mineral oil and synthetic hydrocarbons in cosmetic lip products. *International Journal of Cosmetic Science* 38: 194-200.

⁶ Specifically, given analytical variability, as well as the fact that higher molecular weight waxes (>C₃₅) are more difficult to extract from the matrix, 10 per cent was considered instead of the five per cent recommended by Cosmetics Europe.

⁷ M. Niederer, T. Stebler and K. Grob. 2016. Mineral oil and synthetic hydrocarbons in cosmetic lip products. *International Journal of Cosmetic Science* 38: 194-200.