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MINERAL HYDROCARBONS IN COSMETIC LIP CARE PRODUCTS

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Recommendation

"Cosmetics Europe recommends only those mineral hydrocarbons for use in cosmetic lip care products which correspond to specifications ensuring a safe use"

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Executive Summary

Mineral hydrocarbons (mineral oils or waxes) are mainly used as food additives, in food contact materials, as well as ingredients of cosmetic lip care products, such as lipsticks, lip gloss or lip balm. The mineral oils/waxes used in cosmetic products are in chemical terms so-called saturated hydrocarbons, also referred to as MOSH (Mineral Oil Saturated Hydrocarbons).

In Europe, mineral hydrocarbons used in cosmetic lip care products are compliant with purity specifications on polycyclic aromatic hydrocarbons as reflected in various pharmacopeia and the safety requirements as given in the EU cosmetic regulation 1223/2009. In addition, the absence of contamination during the supply chain is controlled by robust Quality Assurance and GMP practices.

Against the background of recent discussions on the safety of mineral hydrocarbons in cosmetic lip care products, this recommendation from Cosmetics Europe was updated to confirm the safe use of mineral hydrocarbons in cosmetic lip care products for the consumer.

With respect to potential oral exposure, Cosmetics Europe recommends that only particular mineral hydrocarbon fractions for which an Acceptable Daily Intake (ADI) has been identified, should be used in cosmetic lip products. In 2009 and 2013, the EFSA established an ADI of 12 mg/kg bw/day for high viscosity and medium viscosity white mineral oils on the basis of the NOAEL determined in a chronic toxicity and carcinogenicity study in F344 rats, the most sensitive animal model.

This recommendation applies to all mineral hydrocarbon fractions, i.e. mineral oils and microcrystalline waxes or mixtures thereof, which meet specifications ensuring a safe use in cosmetic lip care products. This recommendation does not apply to synthetic hydrocarbons which are not complex mixtures of various molecules (as mineral oil/wax fractions). For these substances (such as e.g. isododecane, polybutene), a specific safety evaluation needs to be performed on the basis of the available toxicity data.

Background and explanatory notes

1. Background

In the 1980s a change in the refining process prompted a re-evaluation of the toxicity of mineral hydrocarbons (MHC). In the last years, mineral oils used e.g. in cosmetic products are also referred to as MOSH (Mineral Oil Saturated Hydrocarbons). MHC or MOSH in chemical terms are called saturated hydrocarbons.

In 1995, the Joint Expert Committee on Food Additives (JECFA) of WHO and the EU Scientific Committee on Food (SCF) issued a scientific opinion allocating values for the Acceptable Daily Intake (ADI) of some MHC depending on molecular weight, molecular distribution and viscosity.

In 2001, CONCAWE (European Oil Company Organisation for Environment, Health and Safety) submitted further data on the toxicity of medium and low viscosity oils.

In 2002, JECFA issued a new opinion including the allocation of an ADI at 0-10 mg/kg bw for Class I medium and low viscosity oils in addition to an already existing ADI of 0-20 mg/kg bw for high viscosity oils and high melting point microcrystalline wax. For Class II and III medium and low viscosity oils, the existing ADI of 0-0.01 mg/kg bw was expanded [1].

In 2012, JECFA re-evaluated the temporary ADI for medium and low viscosity Class II and Class III oils. Due to lack of data supporting the establishment of full ADIs, JECFA decided to withdraw the temporary ADI for these mineral oil classes [2].

Finally, in 2013, EFSA confirmed the JECFA opinion including the ADIs for high-viscosity mineral oils and Class I medium- and low viscosity mineral oils, renamed medium viscosity mineral oils [3], and concluded that the conservative exposure estimates to microcrystalline wax (E 905) resulted in a sufficient margin of safety compared to the NOAEL established by the Panel for the closely related high viscosity mineral oils [6].

For high viscosity and medium viscosity mineral oils (Class I), the EFSA ANS Panel established a group ADI of 12 mg/kg bw/day on the basis of a 2-year feeding study on chronic toxicity and carcinogenicity in F344 rats (considered the most sensitive species and strain). In this pivotal study, the NOAEL was defined at 1200 mg/kg bw/day, the highest dose tested. Based on the results of the study, the EFSA ANS Panel concluded that no carcinogenic effect was observed. Non-neoplastic effects were minor and limited to dose-related infiltration of histiocytes in mesenteric lymph nodes and oil deposition in the liver. These changes were judged to be of no toxicological relevance but indicative of chronic exposure to mineral oils. EFSA concluded a lack of safety concern for humans with respect to systemic toxicity, genotoxicity and carcinogenicity from oral exposure to this kind of mineral oils on the basis of these data from the most sensitive rat strain [3, 4]. Class II and III mineral oils are not supported by this recommendation because an ADI has not yet been established.

Table 1: Classes of mineral waxes and oils with acceptable daily intake (ADI) values as defined by EFSA and JECFA

	ADI	Kinematic viscosity at 100°C (cSt)	Average molecular weight	Carbon number at 5% boiling point
Microcrystalline wax (E 905)	0-20 mg/kg[2]	≥ 11	≥ 500	≥ 25
Mineral oil (high viscosity)	0-12 mg/kg[6]	> 11	≥ 500	≥ 28
Mineral oil (medium and low viscosity) Class I (renamed Mineral oil (medium viscosity) by JECFA)	0-12 mg/ kg[6]	8.5-11	480-500	≥ 25

2. Which raw materials and ingredients are covered by this recommendation?

This recommendation covers all mineral oil hydrocarbons as well as microcrystalline waxes used as raw materials for lip care cosmetic products.

Hydrocarbons originating from plant- or animal-derived lipid/wax materials are not considered within this context since their composition is different from mineral or synthetic hydrocarbons and highly depending on species and geographic location.

This recommendation does not apply to synthetic hydrocarbons which are not complex mixtures of various molecules (as mineral oil/wax fractions). For these substances (such as e.g. isododecane, polybutene), a specific safety evaluation needs to be performed on the basis of the available toxicity data.

The INCI nomenclature used to describe raw materials containing either mineral hydrocarbons or microcrystalline waxes is heterogeneous because the assignment of these INCI names follows different historical developments. Therefore, an exhaustive list of all raw materials potentially covered by this recommendation cannot be provided. But typical raw materials/ingredients consisting of mineral hydrocarbons are presented with their INCI names in Annex 1.

The raw materials/ingredients (being mixtures of various substances) which correspond to specifications as described in section 3 may be preferentially found in the following groups of raw materials. This does, however, not mean that there are – or will be – no other raw materials (compare also Annex 1) which also comply with the specifications described.

- Microcrystalline waxes, isolated from petrolatum (high melting point waxes); INCI name: CERA MICROCRISTALLINA.
- White oils (= highly refined mineral oils = paraffin oils) manufactured by distillation of petroleum and subsequent refinement (hydrogenation or oleum treatment); INCI name: PARAFFINUM LIQUIDUM.

It is not the INCI name but the specific composition which defines whether a raw material complies with the specifications presented in section 3. Only raw materials corresponding to the specification shall be used in lip care products.

The raw materials used in lip care products may be blends of different mineral oil products (e.g. petrolatum) - or blends of a mineral hydrocarbon with a synthetic hydrocarbon component - designed to deliver specific properties depending on their composition. For example, a material from mineral origin (e.g. cera microcristallina) might be combined with a synthetic hydrocarbon wax (e.g. a synthetic paraffin) and a mineral oil (e.g. paraffinum liquidum).
In all such cases, the delivered blends (i.e. mixtures) used as the raw material for the cosmetic lip care product, should comply with the specifications of either mineral oil (medium and low viscosity) Class I, or mineral oil (high viscosity) or microcrystalline wax as described below.

3. Specifications ensuring a safe use of mineral hydrocarbons in cosmetic lip care products

In Europe, mineral hydrocarbons used in cosmetic lip care products shall be compliant with purity specifications on polycyclic aromatic hydrocarbons as reflected in various pharmacopeia or FDA Code of Federal Regulations (CFR) for food additives.

There is no reason for concern on possible carcinogenic activity of mineral oil aromatic hydrocarbons (MOAH) in typical cosmetic ingredient qualities of mineral hydrocarbons. MOAH represent the total amount of all types of aromatics present and cannot be directly used to assess a carcinogenic hazard because its qualitative nature is unspecific in regard to the aromatic type. There are two types of MOAH i.e., 3-7 ring polycyclic aromatic compounds (PAC; which contain polycyclic aromatic hydrocarbons, PAHs) which are potentially carcinogenic, and highly alkylated aromatics (mostly 1-2 ring compounds) which do not show carcinogenic effects in highly refined mineral oils. The 3-7 ring aromatics or PAC content is selectively removed by the refining process, including the removal of toxic PACs, namely those polycyclic aromatic hydrocarbons (PAHs) which are closely monitored and regulated during production. Pharmacopeia standards which measure the PAC/PAH content are followed to ensure the purity of mineral hydrocarbons used for lip care products. Trace levels of PAH (ppb range) may be detected using GC-MS, their safety can be assessed as outlined in Article 17 of the EU Cosmetics Regulation. The quality of Petrolatum is ensured by following Cosmetics Europe recommendation No. 15, which requires the absence of carcinogenic effects proven by the refining process. Thus, mineral oils used in lip care products are safe even if MOAH are present. This is demonstrated by the absence of any carcinogenic potential in several long-term studies in rodents [3] with substances representative for ingredients used in cosmetic formulations (cited in the respective REACH dossiers), and supported by a recent BfR communication [7].

More information can be found in the JECFA documents issued in 2003 and 2012 [2, 5].

Table 2: Specifications and purity criteria for hydrocarbons of mineral origin used in lip care products

	ADI	Kinematic viscosity at 100°C (cSt)	Average molecular weight	Carbon number at 5% boiling point	Purity criteria
Microcrystalline wax	0-20 mg/kg[2,5]	≥ 11	≥ 500	≥ 25	FDA
Mineral oil (high viscosity)	0-12 mg/kg[6]	> 11	≥ 500	≥ 28	Ph. Eur.
Mineral oil (medium and low viscosity) class I	0-12 mg/kg[6]	8.5-11	480-500	≥ 25	Ph. Eur

In case of hard hydrocarbon waxes, it might be technically impossible to determine the kinematic viscosity at 100°C. In such cases, the specification >= 8.0 cSt at 120°C could be used as described for microcrystalline waxes (E 905) in the Commission Regulation EU No. 231/2012 [8].

Overall, the key aspect for the safe use of these raw materials in lip care products is the absence of relevant amounts of low molecular weight (i.e. short chain) hydrocarbons.

4. Which analytical methods can be used to check the specifications of raw materials?

The following are standardised methods for the analysis of waxes and oils. However, other analytical protocols can equally be used for the determination of the raw material specification.

4.1. Standardised methods for the analysis of oils

4.1.1. Viscosity at 100°C

Several standardised methods exist to determine the viscosity of mineral oils (e.g. ASTM D-445, ISO 3104). Other standard protocols use different temperatures, but the results can be converted.

4.1.2. Carbon number

The specification "carbon number ≥ 25 at the 5 % boiling point " means there is not more than 5 % of hydrocarbons with a chain length less than 25. It can be determined by Gas Chromatography. A standard method is e.g. ASTM D 6352 or EN 15199-1.

4.1.3. Molecular weight:

The mean molecular weight can be determined from the kinematic viscosity of the oil. A standard protocol can be found in ASTM D-2502.

4.2. Standard methods for the analysis of waxes

4.2.1. Viscosity at 100°C

The same method as for oils (ASTM D-445) can also be used for waxes. If the material is not totally soluble in the normalised solvent of the method, the viscosity at 100°C may be obtained by extrapolation from measurements performed at 120°C, 130°C and 150°C.

4.2.2. Carbon number

The specification "carbon number $\geq$ 25 at the 5 % boiling point " means there is not more than 5 % of hydrocarbons with a chain length less than 25, which is consistent with food regulations. It can be determined by Gas Chromatography. Standard methods are ASTM D-2887 and ASTM D-5442. The European Wax Federation has developed a method for analysing this parameter in microcrystalline waxes (attached). It should be possible to use this method also for petrolatum.

4.2.3. Molecular weight

The method for oil (ASTM D-2502) is not applicable to waxes. No standard protocols exist, but osmometry in four different concentrations in toluene at 65°C has been proposed as a suitable method.

5. What if not all the required analytical data are available?

In general, all the information should be available from the supplier of the hydrocarbons raw material.

If a blender (supplier who prepares hydrocarbon raw materials by blending various materials with different properties) is not able to provide sufficient information, he should contact his supplier to get at least the specifications of the components he is using in the blends. The supplier should at least be able to indicate the carbon chain length distribution and to what extent low molecular weight material is present in the raw material. Viscosity at 100°C, carbon number and molecular weight parameters are recommended to be provided, but compliance to purity criteria for the ingredients in the mixture/blend or the blend itself is a must.

The blender should also be able to guarantee that all batches meet the specifications within acceptable statistical limits.

The necessary analyses can also be performed in contract laboratories with adequate expertise.

6. References

1) JECFA (2002). Evaluation of certain food additives-fifty-ninth report of the Joint FAO-WHO Expert Committee on Food Additives. WHO Technical Report Series 913
2) JECFA (2012). Evaluation of certain food additives - Seventy-sixth report of the Joint FAO-WHO Expert Committee on Food Additives. WHO Technical Report Series 974

3) EFSA (2013). Scientific opinion on the safety assessment of medium viscosity white mineral oils with a kinematic viscosity between 8.5 – 11 mm^2/s at 100 °C for the proposed uses as a food additive. EFSA Journal 11(1): 3073
4) EFSA (2009) Scientific Opinion on the use of high viscosity white mineral oils as a food additive on request from the European Commission. EFSA Journal 7(11):1387
5) JECFA (2003). Mineral oils (medium- and low-viscosity) and paraffin waxes. First draft by E. Vasavour and J. Chen. WHO Food Additives Series 50
6) EFSA (2013). Scientific Opinion on the re-evaluation of microcrystalline wax (E905) as a food additive. EFSA Journal 11(4):3146
7) BfR (2018). Highly refined mineral oils in cosmetics: No evidence of a health risk on the basis of available data. Updated BfR opinion No. 008/2018 (Feb 19, 2018)
8) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council Text with EEA relevance

Annex 1:
Mineral oil-derived hydrocarbons used in cosmetic products

The following substance classes, characterised by their INCI name (International Nomenclature of Cosmetic Ingredients), are covered in this recommendation. The European Cosmetic Ingredient databases (CosIng, 2015) and/or the International Cosmetic Ingredient Dictionary & Handbook (INCI, 2016) provide the following description:

- *Paraffinum liquidum* (CAS No. 8012-95-1 or 8042-47-5) is a highly refined petroleum mineral oil consisting of a complex combination of hydrocarbons obtained from the intensive treatment of a petroleum fraction with sulfuric acid and oleum, or by hydrogenation, or by a combination of hydrogenation and acid treatment. Additional washing and treating steps may be included in the processing operation. It consists of saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C50.
- '*Paraffin'* (CAS No. 8002-74-2) is a solid mixture of hydrocarbons obtained from petroleum characterized by relatively large crystals.
- '*Synthetic wax*' (CAS No. 8002-74-2) can be either paraffin or hydrocarbon wax. Paraffin wax is a complex combination of hydrocarbons obtained from petroleum fractions by solvent crystallization (solvent de-oiling) or by the sweating process. It consists predominantly of straight chain hydrocarbons having carbon numbers predominantly greater than C20.
- *'Microcrystalline wax'* (CAS No. 63231-60-7) is a wax derived from petroleum and characterized by the fineness of its crystals in contrast to the larger crystals of paraffin wax. It consists of high molecular weight saturated aliphatic hydrocarbons. '*Hydrogenated microcrystalline wax'* (CAS No. 64742-60-5 or 92045-76-6) is a microcrystalline wax that has been hydrogenated.
- *'Cera microcrystallina'* (CAS No. 63231-60-7 or 64742-42-3) is a complex combination of long, branched chain hydrocarbons obtained from residual oils by solvent crystallization. It consists predominantly of saturated straight and branched chain hydrocarbons.
- '*Petrolatum'* (CAS No. 8009-03-8) is a complex combination of hydrocarbons obtained as a semi-solid from dewaxing paraffinic residual oil. It consists predominantly of saturated crystalline and liquid hydrocarbons (CosIng, 2015).
- *'Ozokerite'* (CAS No. 64742-33-2) is a chemically neutralised hydrocarbon wax (petroleum). It is a complex combination of hydrocarbons produced by a treating process to remove acidic materials. It consists primarily of saturated straight chain hydrocarbons.
- '*Ceresin*' (CAS No. 8001-75-0) is a complex combination of hydrocarbons produced by the purification of ozokerite with sulphuric acid and filtration through bone black to form waxy cakes.