Cosmetics Europe
the personal care association

COSMETICS EUROPE

N° 14: MINERAL HYDRO CARBONS

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CE RECOMMENDATION N°14

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MINERAL HYDROCARBONS IN ORAL AND LIP CARE

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Recommendation

"Cosmetics Europe recommends to use only those mineral hydrocarbons in oral and lip care products, for which an Acceptable Daily Intake (ADI) has been identified."

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Background and explanatory notes

1. Background

1987: A re-evaluation of the toxicity of mineral hydrocarbons (MHC) was prompted by a change in the refining process of white oils. Short and long term studies in rats revealed accumulation related effects by oral administration of some mineral hydrocarbon oils and waxes of low viscosity and short chain length.

1995: A scientific opinion was issued by the Joint Expert Committee on Food Additives (JECFA) of WHO, followed by an opinion of the E.U. Scientific Committee on Food (SCF). Values for the Acceptable Daily Intake (ADI) were allocated to some MHC depending on the molecular weight, molecular distribution and viscosity. JECFA requested further data on the toxicity of medium and low viscosity oils, which were submitted by Concawe in 2001.

2002: JECFA issued a new opinion in summer of this year allocating a permanent ADI also for medium high viscosity oils (class I).

2012: JECFA re-evaluated the temporary ADI for mineral oils medium and low viscosity class II and class III established in 1995. As data supporting the establishment of full ADIs was not made available, the committee decided to withdrawn the temporary ADI for these classes of mineral oil.

2013: EFSA confirmed JECFA findings and supported the temporary ADIs established by JECFA for microcrystalline waxes, high-viscosity mineral oils and medium-and low-viscosity class I mineral oils.

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

This recommendation concerns only mineral hydrocarbons as raw materials for cosmetic products, which are likely to be ingested in a significant manner (oral and lip care products).

Mineral hydrocarbons concerned by the recommendation include:

- White oils (= mineral oils = paraffin oils) by distillation of petroleum and refinement (hydrogenation or oleum treatment)
  INCI name: PARAFFINUM LIQUIDUM

- Petrolatum. INCI name: PETROLATUM

- Microcristalline waxes, isolated from petrolatum (hard, high melting point waxes) INCI name: CERA MICROCRISTALLINA

- Ozokerites, formerly fossil waxes (semi-cristalline waxes)
  INCI name: OZOKERITE

- Ceresines, formerly refined fossil ozokerites. Nowadays, name identical to ozokerite. INCI name: CERESINE

- Paraffins (= paraffin waxes), isolated from petrolatum (soft, low melting point waxes). INCI name: PARAFFINS

Mineral Hydrocarbons are physically derived from petroleum, but do not include gases (methane, ethane...) and solvents (light isoparaffins, white spirit...). Very hard waxes (melting up to 150°C) obtained by Fischer-Tropsch synthesis are not considered as petrolatum-derived waxes.

3. How are the MHC specified, for which an ADI has been determined?

The Joint Expert Committee on Food Additives (JECFA) of WHO allocated in its opinions ADIs for the following materials:

Waxes with the following specifications:

- Viscosity ≥ 11 cSt at 100°C
- Carbon number ≥ 25 at the 5% boiling point
- Average molecular weight ≥ 500

High and medium and low viscosity oils class I with the following specifications:

- Viscosity ≥ 8.5 cSt at 100°C
- Carbon number ≥ 25 at the 5% boiling point
- Average molecular weight ≥ 480

More information can be found in the attached JECFA document, or in the JECFA monograph.

http://www.inchem.org/documents/jecfa/jecmono/v50je04.htm

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 this list is not exclusive, as other analytical protocols exist which 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). 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 equal or less than 25. It can be determined by Gas Chromatography. A standard method is e.g. ASTM D-2887.

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 ≥ 25 at the 5 % boiling point " means there is not more than 5 % of hydrocarbons with a chain length equal or less than 25. 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 petrolatums.

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 can be done if not all the required analytical data is available ?

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

If a blender is not able to provide the information, he should be encouraged to go one step upstream to his supplier to get at least the specifications of the components he is using in the blends.

Should the supplier be unwilling to disclose the composition of the product, he should at least be able to indicate the carbon chain length distribution and if low molecular weight material is present in his product. He should also be able to guarantee that all batches meet the specifications within acceptable statistical limits.

The necessary analyses could also be performed in contract laboratories, which have the necessary expertise.

The following rough guidelines can help with a first estimation whether or not a material falls within the specification expressed in the opinion of JECFA:

If the carbon number distribution and the **carbon number at the 5% boiling point** have not been determined according to one of the standard methods, the latter can nevertheless be

roughly estimated if the carbon number range is known. Assuming a linear relationship between the distillation point and the molecular weight of the distillate, the following calculation applies:

5 % of Carbon number range=

$$Carbonnumber_{low} + \frac{5*(Carbonnumber_{high} - Carbonnumber_{low})}{100}$$

If unknown, the carbon number range itself can be obtained from the distillation range by plotting:

Boiling point °C	*250*	*300*	*350*	*400*	*450*	*500*	*550*
Carbon number	*14*	*17*	*20*	*24*	*30*	*36*	*44*

For an estimate and as a rule of thumb, the **average molecular weight** is roughly given by the same figure as the boiling point in °C at the 50 % distillation point.