Paraffin in the Foodstuff and Cosmetic Industry

1. General

Manufacturer / Delivery firm: H&R Wax Company Vertrieb GmbH
Am Sandtorkai 64
D-20457 Hamburg
Tel. 040 / 43218-0
Fax 040 / 43218-400

Raw material class: Microcrystalline wax, Paraffin Wax

2. Information about the manufacturing process

The manufacture of petroleum waxes is characterized by the fact that petroleum waxes are obtained in dependence on and simultaneously to the production of lubricants. In the first stage, the lighter fractions petrol, kerosine, gas oil and paraffinic spindle oil are separated from the crude at atmospheric pressure. In the second stage, the heavier fractions are refined in a vacuum column under mild conditions to give paraffinic neutral oils of increasing viscosities and a vacuum residuum.

Components with a tendency to ageing are then separated off the lubricant fractions by extraction with a selective solvent to obtain a material with non-ageing and light-fast properties. In a complex recycling process, the solvent is recovered to be re-introduced into the refinery process.

In a further stage, the refined paraffin oil is mashed with a special solvent. The charge material is then passed through a vacuum rotary drum equipped with a multi-stage switch and plate filters, with the petroleum waxes are separated by cooling.

The initial filtered material is known as slack wax, which can be further de-oiled by repeated cold precipitation, ‘sweating’ (heating to selectively mobilize the oil), or membrane filtration until the oil content is reduced up to or below 0.5%, and the wax is then known as paraffin or microcrystalline wax. The paraffin waxes are obtained from processing light lubricant base oils while the microcrystalline waxes are obtained from processing vacuum residue, or heavier lubricant base oils.

The undesirable components include aromatics, metals, waxes, and trace components causing unwanted colours or odours (i.e. sulphur). The aromatics include polycyclic aromatic compounds (PACs), some of them are heterocyclics, PACs containing of N, S, and O. An example of a transformation process is hydro treatment, a process in which aromatics are hydrogenated and converted to naphthenics and paraffins by catalytically breaking carbon-carbon bonds under high-pressure hydrogen. Heteroatoms and some aromatics are removed by hydrogenation.

Most paraffinic waxes mainly consist of normal alkanes, with varying amounts of isoalkanes, cycloalkanes (naphthenes), have a melting point in the range of 43°C to 68°C, typically around 55°C and have a translucent white to yellow colour.
Microcrystalline waxes consist of substantial amounts of \textit{iso} - and \textit{cyclo}alkanes, usually with a lesser amount of normal alkanes, melt between 60°C and 95°C and have an opaque appearance with a colour depending on the type and degree of refining applied. Due to the manufacturing process no residues e.g. of solvents or catalysts are to be expected.

3. Description

Pharmaceutical paraffin and microcrystalline waxes are not fluorescent, tasteless and odourless substances, which are used both in the pharmaceutical and cosmetic industry as well as in the food industry. Fundamental technologic characteristics are:

- Stable, resistant against hydrolytic degradation, oxidation processes and rancidness. This feature leads to above-average shelf life and a very small reactivity.
- The thermo stability is given even at high temperatures; therefore paraffins are inert against any substances which are involved in the manufacturing process.
- Free of preservatives, dye stuffs, complexation agents, organic solvents, heavy metals
- Barrier effect against water evaporation or oxygen transfer
- Sterile due to its water content = < 100 ppm
- It acts hydrophobic and inhibits the formation of microbiological organisms.
- No allergenic effects, skin irritation or toxic adverse effects are known.

4. Application

- Food/drug application as coating for packing materials, additives in plastic and paper and board food packing materials, additives to polymeric coating on metal and paper and board substrates in order to control adhesion, gloss and release properties, cheese coatings, chewing gum base, defoamer, glossing agent (the permission is country-specific).
- They may be used in lubricants, wire cables, candles, cosmetics

5. Statutory regulations

5.1 EU

5.1.1. Food additives

According to the EU Directive 95/2/EC on food additives other than colours and sweeteners, as amended, microcrystalline waxes are listed as E 905 and approved for use as a surface treatment on certain fruits at \textit{quantum satis}, as follows:

- Confectionery, excluding chocolate;
- Chewing gum;
- Melons, papaya, mango and avocado.
The use of microcrystalline wax as a glazing agent on confectionery and chewing gum commands only 100 tonnes of product throughout Europe annually, suggesting that this is a minor use. The maximum concentration of wax detected in confectionery was 200 mg/kg and so this figure was used as a conservative default in intake calculations. The peel of melons, papaya, mango and avocado are unlikely to be consumed and so were excluded from intake calculations.

5.1.2. Plastic directive

The Framework Directive 89/109/EC of 1989 determines the requirements to be met by materials intended to come into contact with foodstuffs. The preparation of this documentation is not completed. All products like paper, elastomers, glass, metal, wood (including cork), textiles, adhesives, pigments will be included soon in future EU Directives. Until then the respective national regulations are to be considered as relevant.

The Commission Directive 2002/72/EC of 06.08.2006 relating to plastic materials and articles intended to come into contact with foodstuffs amends the EC Directive 90/128/EC.

This group of hydrocarbon waxes is split in 2 grades by the specifications as laid down in Annex V of the ("Plastic") directive 2002/72/EC.

- Microcrystalline waxes
Waxes (mainly microcrystalline waxes and higher molecular weight synthetic paraffin waxes) fulfilling totally the Annex V specification are listed and accepted as additive with PM Ref no. 95859 (Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstock’s). These specifications concern molecular weight (not less than 500), carbon number (amount < C25 max. 5%) and viscosity (not less than 11 centiStokes at 100 °C).

- Paraffin waxes (hard paraffin and synthetic paraffin are listed as synonyms)
The European Food Safety Authority (EFSA) gave a favourable opinion for this group of waxes substances. The 5th amendment of the Plastics Directive, Directive 2008/39/EC came into force on 6 March 2008. This directive permits the trade and use with LMPW as listed under Ref. No.: 95858 from March 2009 and prohibits the trade and use not complying with the new listing from March 2010.

Name of the substance: Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks
Restriction: 0.05 mg/kg food
Not to be used for articles in contact with fatty foods
Specifications:
- Average molecular weight not less than 350
- Viscosity at 100°C min 2.5 cSt
- Content of hydrocarbons with carbon number less than 25, not more than 40% (w/w).

Presumably 2007 the migration directive will be merged with the Plastics Directive 2002/72/EC to an uniform rulebook by the currently discussed amendment of the Framework Directive as well as the amendment of the Plastic Directive through the so-called „SuperRegulation“.
5.1.3. Cellulose

In Directive 93/10/EC the following waxes are listed: natural waxes, paraffin and microcrystalline waxes and montan waxes. The substances may be used as coatings on regenerated cellulose with a maximum amount of 2 mg/dm² of each of the substances.

5.1.4. COE (Council of Europe) inventory coating list

Because the different (natural, montan, hydrocarbon and synthetic) waxes are used as additives to different types of coating they are listed as additive in the COE inventory coating list.

5.1.5. COE (Council of Europe) Paper and Board inventory list

Natural, montan and hydrocarbon waxes are listed. The hydrocarbon waxes are still listed with old references or descriptions. EWF proposed recently to list only the PM ref no. 95859 and the “lower molecular weight” description. With these 2 definitions all mineral and synthetic hydrocarbon waxes are “covered”.

5.1.6. Inventory list Construction materials for drinking water:

For construction materials (including plastic) intended to use for drinking water, separate EC Regulations are in progress. The Plastic Directive is used as starting point.

5.1.7. Compliance with Colipa recommendation No.14 “MINERAL HYDROCARBONS IN ORAL AND LIP CARE” and IKW (German Cosmetic, Toiletry, Perfumery and Detergent Association (RT 75/96 August 1996)

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

"According to present knowledge we advise the producers of cosmetically products to use only
• Mineral waxes with a viscosity of t ≥ 11 cSt (at 100°C, a molecular weight of > 500 and a carbon number of > 25 after distilling off 5% mass and
• Mineral oil with a viscosity of ≥ 8,5 cSt, a molecular weight of > 480 and a carbon number of > 25 after distilling off 5% mass

for lip care. We also advise them to make sure that also in case that the whole quantity applied will be gulped, a possible absorption of mineral oils and waxes is under the “ADI-Values”.

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5.1.8 Compliance with EC Cosmetics Directive
Use of Petrolatum in the cosmetics industry (Colipa recommendation No.15)

We guarantee that the product is produced from substances that are not carcinogenic according to the Dangerous Substances Directive 67/548/EEC and of which the full refining history is known. The Purity our Product complies with Monograph No 1034, Pharmacopoeia Eur (Hard Paraffin/Paraffinum solidum).

We can confirm that our product is not listed as forbidden in compliance with Directive 2004/93/EC Annex II. Please notice, that there are a few PAH listed on Annex II under number 612, 637, 638, 639, 640, 641, 642 and 643, which can be detected in very small concentrations in this material.

This raw material has never been tested on animals either by us or on our behalf. We do not intend to carry out animal tests on this material.

5.2. Germany

Food additives are regulated in the regulation „Verordnung über Zulassung von Zusatzstoffen zu Lebensmitteln zu technologischen Zwecken“ from 29.01.1998. The requirements for these additives are laid down in the „Verordnung über „Anforderungen an Zusatzstoffe und das Inverkehrbringen von Zusatzstoffen für technologische Zwecke“ from 29.01.1998.

For hard paraffin and microcrystalline waxes the specifications are identical with “Mitteilung XXV ” of BfR (German Federal Institute for risk assessment.). In addition, the following substances must not exceed the limits given below:

- Arsenic max. 3 mg/kg
- Lead max. 10 mg/kg
- Zink max. 25 mg/kg
- Copper and zinc together max. 50 mg/kg

Besides specifications to the raw materials used, the regulation EU-Directive 1935/2004 states: food may not be influenced for taste and/or odour and food contact articles containing wax blends may not be used for food where fat is the outer phase.

The purity requirements for hard paraffin and microcrystalline waxes for plastic articles and other articles in contact with food are laid down in the “Mitteilung XXV ”of BfR (German Federal Institute for risk assessment.). These substances are allowed in the plastic manufacturing when the purity criteria are fulfilled and they are listed as permitted for each application ( BfR Empfehlungen)

5.3 USA

The regulations of the American Food and Drug Administration FDA 21 CFR concerning the food additives permitted for direct addition to food for human consumption describes the purity criteria of Petroleum wax under FDA 21 CFR §172.886. The intended uses as additive for food packaging or production aid agent for food manufacturing are assigned as listed:
(d) Petroleum wax is used or intended for use as follows:

<table>
<thead>
<tr>
<th>Use</th>
<th>Limitations</th>
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<tbody>
<tr>
<td>In chewing gum base, as a masticatory substance.</td>
<td>In an amount not to exceed good manufacturing practice.</td>
</tr>
<tr>
<td>On cheese and raw fruits and vegetables as a protective coating.</td>
<td>Do.</td>
</tr>
<tr>
<td>As a defoamer in food</td>
<td>In accordance with Sec. 173.340 of this chapter.</td>
</tr>
<tr>
<td>As a component of microcapsules for spice-substances.</td>
<td>In accordance with Sec. flavouring 72.230 of this chapter.</td>
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Daniela Heber, Product Safety                                      Date: 12.03.2008