Mineral oils are safe for human health?

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ENVIRONMENTAL SCIENCE FOR THE EUROPEAN REFINING INDUSTRY

Mineral oils are safe for human health?

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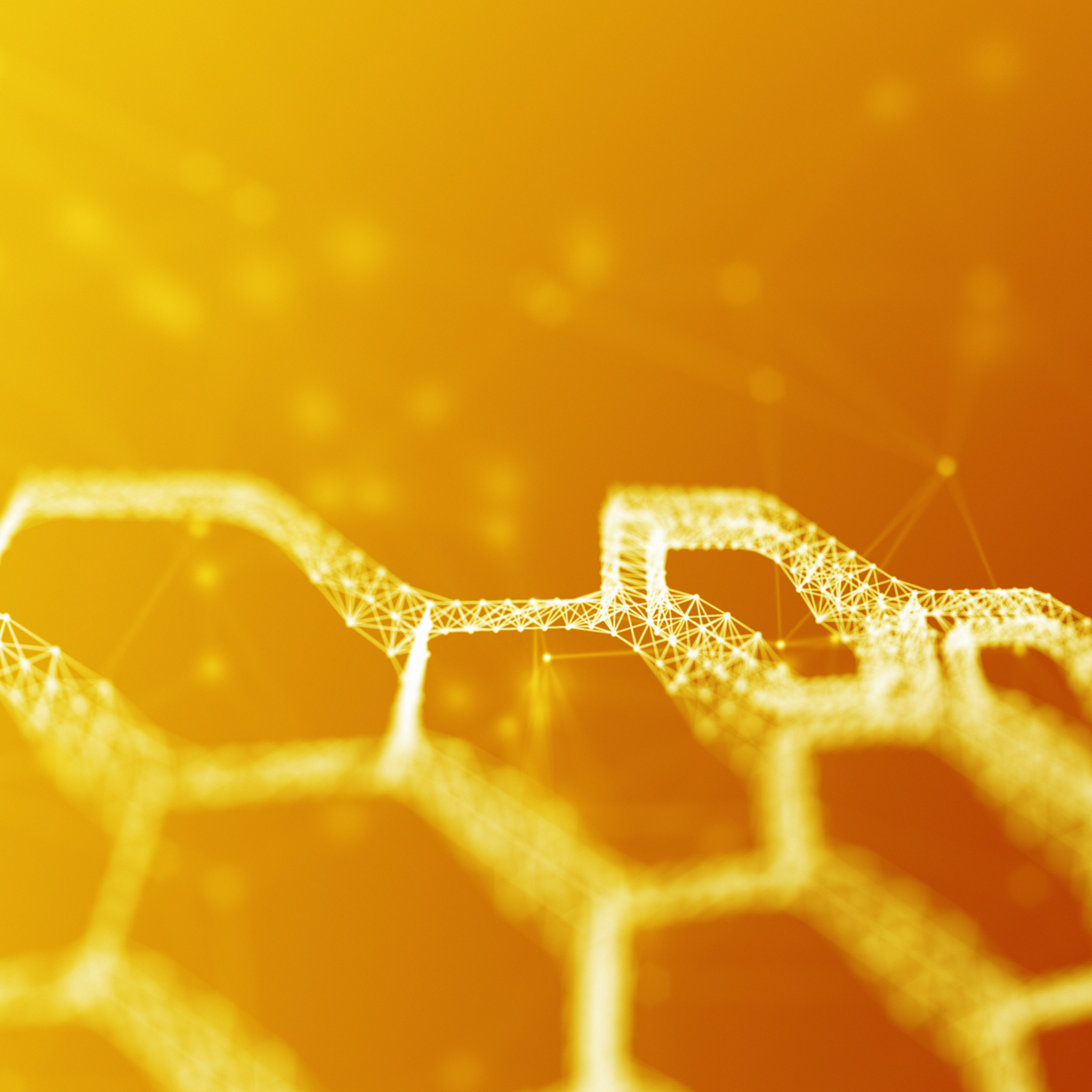

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Executive summary

From petroleum to mineral oils

Mineral oil is a generic term used to group several petroleum derived liquids with "oil-like viscosity" manufactured by atmospheric and vacuum distillation (at temperatures between ~300^{o}C and ~700^{o}C) of crude oil and then further refined. Unrefined crude oil is not used in the formulation of products in contact with the human body or in food related applications.

Mineral oils differ in their physical chemical properties (e.g. viscosity) and chemical composition (e.g. aromatic content) and cannot thus be described with a single chemical formula.

The feedstock used in manufacturing mineral oil contains poly-aromatic hydrocarbons, some of which are classified as hazardous. However, these compounds are either removed using solvent extraction or converted using catalytic hydrotreatment to produce the refined mineral oils. The remaining aromatics found in the refined mineral oils are mainly 1-2 ring highly alkylated structures, which are not carcinogenic.

White oils and waxes are chemically very inert substances. What is thus used for instance, in the cosmetics, pharmaceutical or food contact, are highly refined specialty products derived from petroleum. The use of these highly refined products has a very long history and enjoys an impeccable human safety record. In addition to offering interesting lubricating and moisture barrier properties, they are not allergenic.

Different types of mineral oils

Mineral oils can be roughly divided in two groups; Lubricant Base Oils (LBOs) and Highly Refined Base Oils (HRBOs).

LBOs are petroleum derived mineral oils which have been de-waxed (normal paraffin significantly removed or transformed) to prevent crystallisation at low temperatures which adversely impact LBO performance.

HRBOs, also known as "white oils", are colourless petroleum derived mineral oils from non-carcinogenic LBOs, which are further highly refined to achieve extremely low levels of aromatics to eliminate colour and improve stability. There are two types of HRBOs/white oils:

- Technical white oils, are colourless oils, derived from non-carcinogenic LBOs and further refined by hydrogenation or acid treatment to achieve extremely low levels of aromatics but do not comply with the levels stipulated by pharmacopeia monographs.
- Pharmaceutical white oils, are colourless oils, derived from technical white oils, which are highly refined in a second hydrogenation or acid treatment to achieve extremely low levels of aromatics to ensure they comply with the levels and specifications stipulated by international pharmacopeia monographs.

Multiple uses of mineral oils due to their unique properties

Mineral oils are versatile substances that enable an array of industrial applications due to their physical-chemical properties, which are tailored through manufacturing. One can find mineral oils in the rubber industry, thermoplastic elastomers and polymer applications, adhesives, cosmetics and pharmaceuticals, printing inks, processing aids for leather and textiles and antifoam agents, agriculture in plant protection formulations and binders for fertilisers, and other uses such as coatings, lubricants, cleaning agents, water treatment, and many others.

Their availabilities covering a broad range of viscosities* and melting points, allow for their ease of formulation in a very wide spectrum of preparations. In many cases replacement by alternatives offering the same safety-in-use versus performance profile is extremely complex and often impossible.

* Erratum: This sentence has been corrected after the publication of this review.

What are **MOSH** and **MOAH?**

Since 2009, chromatographic peaks seen when analysing coca beans, sunflower oil and packaged food have been characterised as MOSH (Mineral Oil Saturated Hydrocarbons) and MOAH (Mineral Oil Aromatic Hydrocarbons). This MOSH and MOAH terminology, however, is creating confusion at different levels.

From a toxicological point of view, the MOSH and MOAH fractions do not correspond to petroleum derived mineral oils and waxes that are placed on the market. Furthermore, these MOSH and MOAH fractions are also found in products of other than of mineral oil origin, further adding to the difficulty of tracing their origin and the health risk they pose. As an example, n-alkanes have been attributed as MOSH, but are ubiquitously present in nature and are natural components of fruits and vegetables. There are also many other products that would lead to false positives in a "MOSH/MOAH" analysis.

Further adding to the complexity, is the fact that there are a number of lawful uses of petroleum based products in cosmetics and food context, both in the European Union (EU) and in other regions. Their presence should not create a concern of non-compliance or a health risk.

MOSH is a chromatographic measure of the alkane content of an oil. Some MOSH substances have been found to accumulate and cause inflammation of human livers and therefore its presence is undesirable.

The concern around long term toxicity of mineral oil is derived from observations in animal experiments which are extrapolated to the human situation. From all the experiments, it appears that with the exception of the Fischer 344 rat (F-344) model, none of the tested animals (rat strains other than F-344 and dogs) developed adverse effects. The F-344 rat shows unique adverse effects, including liver accumulation of n-alkanes commonly found in natural products such as apples. These adverse effects have been extrapolated to humans and serve as the basis for the health concern to MOSH. From the weight of the available evidence, including decades of safe use, humans do not develop adverse effects to alkanes whether from natural origin or from mineral oils.

MOAH is a chromatographic measure of the aromatic content of an oil, and is considered as an indicator of the presence of unrefined petroleum based products that are not intended to be used in food related, pharmaceutical or cosmetics applications. The concern is based on the possibility that MOAH containing 3-7 membered rings may be potentially carcinogenic. Although aromatics are present in refined petroleum products, the refining processes used to produce mineral oils remove the potentially carcinogenic 3-7 Polycyclic Aromatica Compounds (PAC) The remaining highly alkylated aromatics (mostly 1-2 rings) are harmless making them safe for their intended use.

Food contact

Food is a global commodity, manufactured and traded in many different countries complying with different levels of legislation. There are many different ways by which hydrocarbons of mineral oil origin can end up in food. Whilst the use of white mineral oils in plastics for food contact or as food additive is regulated by EU legislation, other vectors of hydrocarbon transfer such as paper, glass wood or metal may contribute to overall MOSH/MOAH profile of a product.

Thus, whilst there are legally accepted uses of mineral oils that come into contact with food, there are also risks for contamination by products not intended for food related use at all stages of the food supply chain: at the plant and animal production and harvesting stages; during the storage and transportation phase; and finally during the food processing and packaging.

Ensuring consumer safety

The petroleum industry has a long history of safely managing the manufacture, storage, handling and delivery of LBOs, white mineral oils and waxes, to ensure final products loaded and delivered to the manufacturing industry are consistent and safe for the intended final user.

In the case of LBOs, the removal of carcinogenic aromatic hydrocarbons through refining is controlled by the EU legally mandated test IP346. Only LBOs which pass this IP346 test are considered non-carcinogenic.

In the case of wax, the IP346 method and limit is a gatekeeper and applies to the substance from which wax is produced. It gives the “green light” for further processing to meet other regulatory standards.

In the case of white oils involved in food, pharmaceutical or cosmetic industries, the strictest requirements for PAC are in place; in addition to the requirement that the feedstock is non-carcinogenic (controlled by IP346) the removal of PAC is done to a level at which the refined product fulfils international legal specifications.

In conclusion, refined petroleum products, which are used at different stages of food production or as ingredients in pharmaceutical or cosmetic products, are not carcinogenic.

What are mineral oils?

Mineral oils are petroleum derived substances, produced by refining crude oils.

It all starts with crude oil refining which is carried out using two main distillation processes, first atmospheric and then vacuum distillation at temperatures between ~300°C and ~700°C. Vacuum distillation is necessary to prevent hydrocracking at temperatures around 300°C at which the so called "long residue" from atmospheric distillation is processed. The long residue entering the vacuum distillation unit is the starting material used for the manufacturing of "mineral oils". Because the mineral oils' feedstock contains unwanted carcinogenic compounds, these must be eliminated by further, specific refining processes.

There are different refining techniques, used solely or in combinations, designed to eliminate the unwanted compounds from intermediates of mineral oils. These techniques are all based on the principle of removing the 3-7 PAC species.

In the most common processes, solvent extraction or catalytic hydrotreatment is used to remove or convert the aromatic structures found in the vacuum distillates.

The solvent extracted (or hydrotreated) "waxy raffinate" is the primary feedstock for "mineral oil" production. It is comprised of normal, iso- and cyclo-alkanes (normal, iso-paraffins and naphthenics respectively). It also contains aromatics, mostly highly alkylated 1-2 ring aromatics and trace levels of ≥ 3 ring PAC. The latter can be naked or partially alkylated poly-ring systems, and if effectively eliminated the mineral oil will then pass the required carcinogenicity screening tests.

Normal paraffins in an oil are undesirable constituents because they affect technical performance at cold temperature. De-waxing (removing of n-alkanes) of the waxy-raffinate is therefore necessary. This can either be achieved through solvent or catalytic processes.

Solvent de-waxing yields two refinery streams: a "slack-wax" and a "base oil" (LBO). The former consists primarily of n-alkanes with only trace levels of aromatics and is the feedstock used to produce paraffin waxes. Whilst they are of mineral origin, these paraffin waxes are not oils and should not be confused with "mineral oils".

Catalytic de-waxing aims at isomerizing n-paraffins into iso-paraffins and results in increased base oil production. It does however not yield any slack-wax stream.

Lubricating base oils and white oils which can be derived from LBO (e.g. by hydrotreatment) are what are popularly referred to as "mineral oils". Consequently, the generic term "mineral oil" may refer to the intermediate liquid oil fractions obtained at temperatures between ~300°C and ~ 700°C from vacuum distillation, without specific information to refining processes, purity or health hazards.

Mineral oil is a generic term used to group several petroleum derived liquids with "oil-like viscosity" manufactured by vacuum distillation of the residue from atmospheric distillation. There are about 40 substances (each with its own identifier or CAS number) which could be regarded as "mineral oil" with boiling points from ~300°C and ~ 700°C. Members of the mineral oil family differ in their physical chemical properties (e.g. viscosity) and chemical composition (e.g. aromatic content). Mineral oil consists of thousands of different types of hydrocarbons and can therefore not be described with a single chemical formula. As with other petroleum substances mineral oils are described as complex substances of Unknown or Variable composition, Complex reaction products or Biological materials, or shortly UVCB. In the EU, by law "mineral oils" are UVCBs and not mixtures. The latter is made of constituents which are intentionally blended to achieve a certain composition. It is rather a matrix in which hydrocarbon constituents follow a physical chemical pattern varying according to crude oil and controlled manufacture, which results in a single entity with its own intrinsic properties behaving as a (complex) substance.

Although mineral oils are UVCBs, its constituents are not entirely unknown. They are indeed hydrocarbons described as PINA: Paraffin, Iso-Paraffin, Naphthenic (also called normal, iso and cycloalkanes respectively) or Aromatic. The variable proportions of the PINA constituents, which can be modulated by manufacturing processes, make mineral oils a versatile enabler of industrial applications. The complex composition of PINA constituents of mineral oils can be managed (e.g. narrowed or expanded) for example by the "width" of the boiling point range, by removal of aromatics, creation of naphthenics, etc. The exact composition is however neither necessary nor possible because physical-chemical parameters and high level descriptors such as carbon range distribution and PINA proportions allow profiling the substance. Hence, the proportion of all hydrocarbon types influence the profile of the mineral oil.

The aromatic content of a mineral oil is one of the key parameters for its selection in a specific application. There are different industry standards to determine that aromatic content, it is therefore imperative to quote the actual method used to avoid misunderstanding and misinterpretation of results. The results obtained from different standards do not correlate and should be contextualised. It must also be noted that the aromatic constituents in a mineral oil have a high molecular weight and high initial boiling point (because they are produced at vacuum distillation). Low boiling solvent (1 bar) type aromatic compounds such as benzene, toluene, or xylenes (BTX) are not constituents of a mineral oil.

Mineral oils can be roughly divided into two main groups:

LBOs are petroleum derived mineral oils which have been de-waxed (normal paraffins significantly removed or transformed) to prevent crystallisation at low temperatures which adversely impacts LBO performance. The LBO composition depends on the crude oil source and the manufacturing processes resulting in deviating LBO properties. The oils are called 'paraffinic', if the paraffinic constituents are in the majority, or 'naphthenic', if mainly determined by the naphthenic hydrocarbons. An exactly specified threshold between a paraffinic and a naphthenic oil does not exist. LBOs contain aromatics mainly 1-2 ring aromatic hydrocarbons which are highly alkylated.

Aromatic levels are determined by the manufacturing process and the intended application. Carcinogenic aromatic hydrocarbons are found in the 340°C and ~ 540°C boiling point range. These carcinogenic compounds are eliminated in the refining process and the mineral oils are tested by the legally mandated test IP346. Only LBOs which pass this IP346 test are considered non-carcinogenic according to the EU-CLP regulation. In conclusion, LBOs contain aromatics but these are safe providing they pass the IP346 test.

HRBOs also known as "white oils" are colourless oils deriving from non-carcinogenic LBOs, which are further highly refined to achieve extremely low levels of aromatics to eliminate colour and improve stability. Hydro-or acid treatment are the most common refining processes to eliminate aromatics. There are different industry standards to measure aromatic content, it is therefore imperative to quote the actual method used to avoid misunderstanding and misinterpretation of results. Depending on the method[1] different results are recorded which do not compare. The results obtained from these different standards do not correlate and should be contextualised.

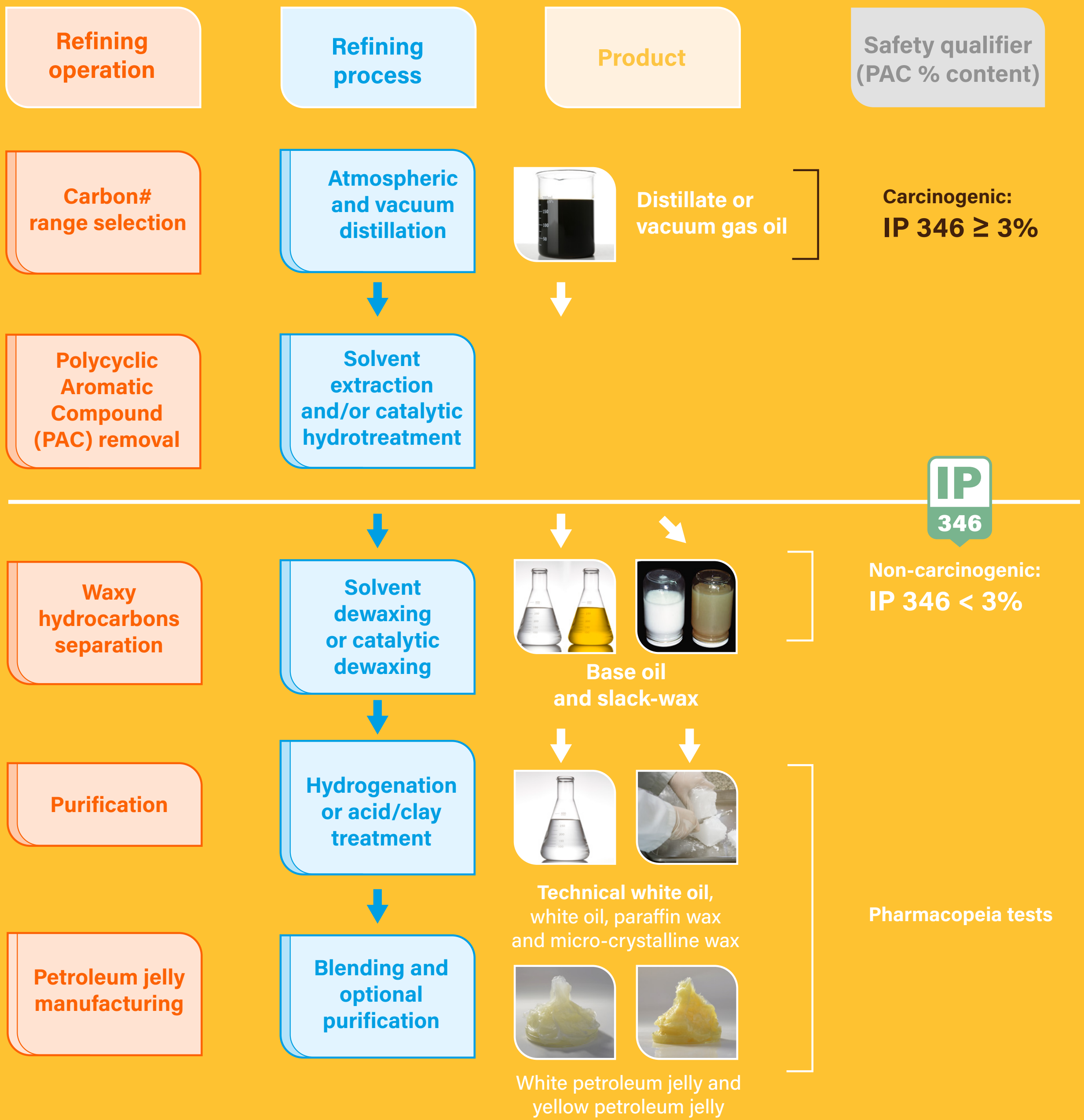
There are two types of HRBOs/white oils, technical white oils and pharmaceutical (medicinal – paraffinum liquidum) white oils.

Technical white oils are colourless petroleum derived from non-carcinogenic LBOs, which are further highly refined by hydrogenation or acid treatment to achieve extremely low levels of aromatics but do not comply with the levels stipulated by pharmacopeia monographs using a UV-DMSO (ultraviolet - dimethyl sulfoxide) method. They do however meet the requirements of the Food and Drug Agency 21, CFR-178.3620(b).

Carcinogenicity has been eliminated and the aromatics present are mainly 1-2 ring highly alkylated structures. These dewaxed oils can be naphthenic or paraffinic in their composition depending on the predominant alkane type. Viscosity is a key parameter which is closely related to boiling point, molecular weight and carbon range distribution.

Pharmaceutical white oils (paraffinum liquidum) are colourless petroleum derived from technical white oils, which are further refined by hydrogenation or acid treatment to achieve extremely low levels of aromatics which comply with the levels and specifications stipulated by international pharmacopeia monographs using a UV-DMSO method. Carcinogenicity has been eliminated and the aromatics present are mainly 1-2 ring highly alkylated structures. These dewaxed oils can be naphthenic of paraffinic in their composition depending on the predominant alkane type. Viscosity is a key parameter which is closely related to boiling point, molecular weight and carbon range distribution. Kinematic viscosity (at 100°C) is used by World Health Organization (WHO), Food and Agriculture Organization (FAO), and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) set the categories high viscosity (>11 mm2), Class I (8.5 – 11 mm2/s), II (7.0 – 8.5 mm2/s) and III (3.0 – 7.0mm2/s) medicinal white oils. Toxicological evaluation of pharmaceutical white oil is based on the WHO/FAO/JECFA definitions and monographs.

[1] (e.g. NMR, UV, IR, GC-MS, LC-GC-FID, 2D-GC-TOF MS)



Refining operation
Refining process
Product
Safety qualifier (PAC % content)
Carbon# range selection
Atmospheric and vacuum distillation
Distillate or vacuum gas oil
Carcinogenic:
IP 346 ≥ 3%
Polycyclic Aromatic Compound (PAC) removal
Solvent extraction and/or catalytic hydrotreatment
IP 346
Waxy hydrocarbons separation
Solvent dewaxing or catalytic dewaxing
Base oil and slack-wax
Non-carcinogenic:
IP 346 < 3%
Purification
Hydrogenation or acid/clay treatment
Technical white oil, white oil, paraffin wax and micro-crystalline wax
Pharmacopeia tests
Petroleum jelly manufacturing
Blending and optional purification
White petroleum jelly and yellow petroleum jelly

What are mineral oils used for?

Mineral oils are versatile substances that enable an array of industrial applications due to their physical-chemical properties tailored through manufacturing. The oil application fit often requires supplier and end user discussions to select the suited oil properties for a specific process. The following industries use mineral oils:

- **Rubber industry:**

Mineral oils can be used as plasticisers and processing aids during the manufacture of the elastomer compound. The requirements of mineral oil in the rubber industry can be very different depending on the type of polymer used. For instance, Styrene-Butadiene-Rubber (SBR) used in passenger car tyres requires high aromatic content to improve rolling resistance, wet grip and abrasion. On the other hand, non-polar rubbers like Ethylene-Propylene-Diene-Monomer (EPDM) require the use of mineral oils with a low aromatic content.

- **Thermoplastic elastomers and Polymer applications:**

Two important types of thermoplastic elastomer are using mineral oil in high quantity, namely, styrene block-polymers (TPE-S) and poly-olefins (TPE-O). These applications require mineral oil with a very low aromatic carbon content to be used as plasticiser for TPE-S and TPE-O. If the aromatic content is higher, the styrene domain is affected by the oil, resulting in a decrease of mechanical properties, especially at higher temperatures. For very demanding requirements such as UV stability and/or for food contact applications, pharmaceutical white oils should be selected. Mineral oils are also used to produce molding aids for plastic parts.

- **Adhesives:**

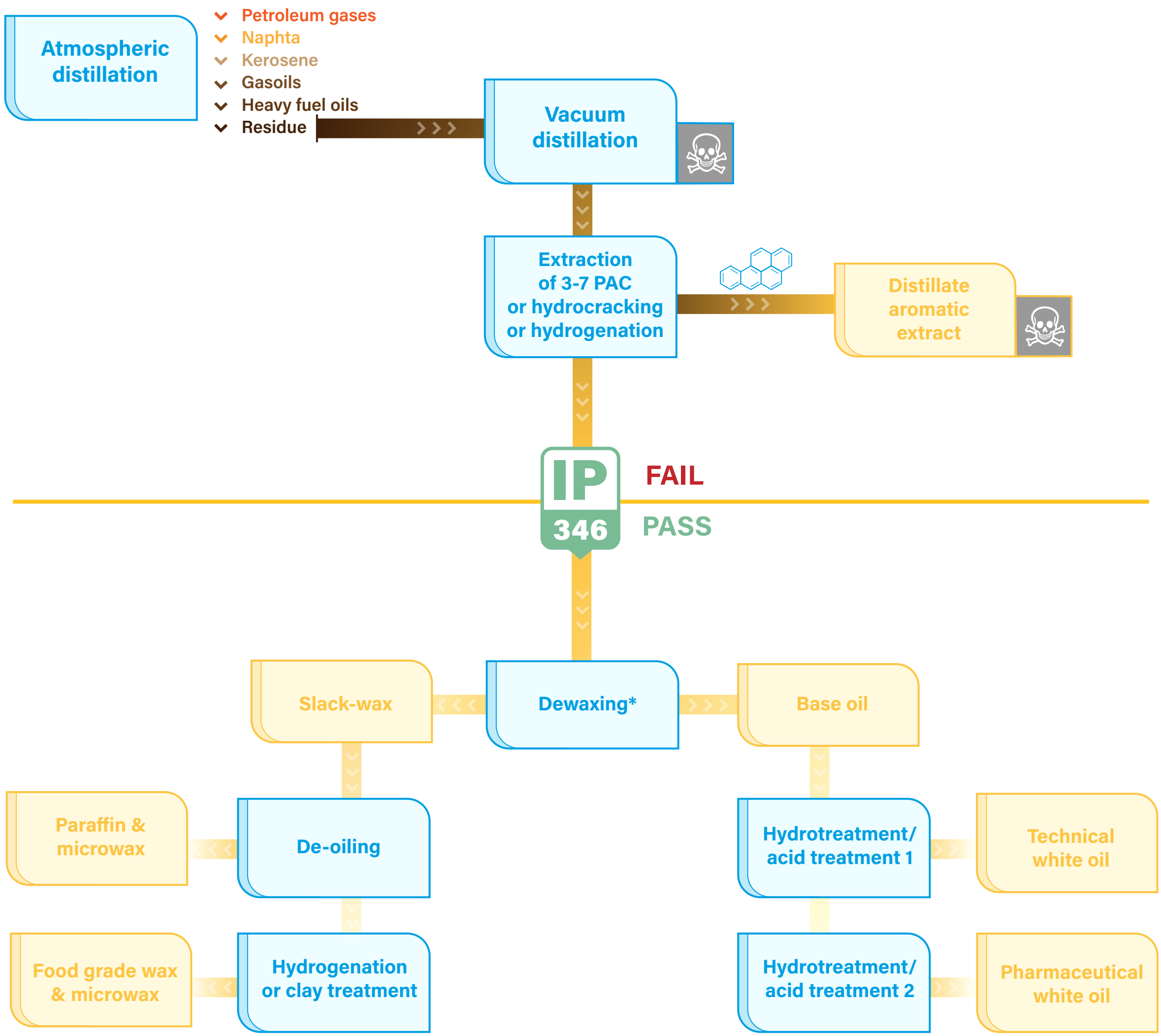
Most pressure sensitive hotmelt adhesives (HMPSA) are based on Styrene-Butadiene-Rubber and contain significant amounts of highly refined mineral oil. The right choice of the oil and the correct use of the adhesive prevents undesired migration from the adhesive through the packaging material into the food.

- **Cosmetics and Pharmaceuticals:**

For these applications only highly refined, products are used; those are specified with special additional criteria described in the monographs of international pharmacopeias[2] and related regulations as the FDA specifications.

To maintain the highest safety standard, the purity criteria defined by those regulations are always applied.

[2] (Ph. Eur., USPa, JP)



*Dewaxing not necessary for naphthenic base oils and white oils manufacture

- **Pharmaceuticals and medical devices:**

Usage in pharmaceuticals requires the full compliance of a product in relation to all tests of a particular pharmacopeia monograph (i.e. Paraffin Liquidum in Ph. Eur.).

Petroleum jelly (Vaseline, reg. trade mark), pharmaceutical white oils, micro- and paraffin waxes are used in many different applications like sticks, pastes, ointments, fatty creams, lotions and liquids, covering in principle every part of the human body from feet to scalp and hair including mucosal-, eye- and lip-applications.

The range of concentration can vary from very small percentage such as 1% up to 100%, depending on the formulation and targeted application. For example refatting bath oil for dry skin or baby oil can consist of 100% pharmaceutical white oil. Paraffin wax products for thermal therapy and anti-rheumatic therapy can consist of 100% paraffin wax. Other applications such as lotions and ointments will consist also water varying from small to significantly high quantities (i.e. up to 70%) and build emulsions, suspensions or other forms of non-miscible blends with the help of suitable emulsifier systems and/or other functional additives.

The function of the oil and wax products in pharmaceutical products is highly diverse. Depending on the physical form they are used as excipient and base materials for drug delivery, as viscosity modifier, refatting agent, emulsion stabiliser and moisturiser. The last function is mainly based on the strong occlusive effect, which the products demonstrates. The list of applications is only a selection and is in reality more comprehensive.

- **Cosmetics:**

The usage in cosmetic products is similar to that of pharmaceuticals. To guarantee the safe usage, the products are also specified against the above (same) mentioned monographs of the international pharmacopeias and related regulations. It is important to know that in cosmetics the purity requirements (PCA tests) of the monographs are the main focus, whereas the other physical data might show a deviation to the specification of the monographs (i.e. drop point, melting range or viscosity). This is well established and serves special needs like high temperature resistance of cosmetic goods in tropical regions or i.e. for sun protection products.

Moreover, the product range for the raw materials and cosmetic end products is very similar to pharmaceuticals. This is also valid for the concentration range. A typical example is the global Vaseline (reg. trademark) application, in which petroleum jelly is used up to 100% (in some cases with very small amounts of dyestuffs and perfume) for dry skin and skin protection. Again, other applications such as lotions and ointments will consist also water varying from small to significantly high quantities.

In cosmetics blends of the described oil and wax products are in use and the portfolio of applications is even more comprehensive as personal hygiene products. Soaps, shaving foams, and make-up remover, hair care, and – styling formulations, baby care, lip care and the complete range of beauty products like mascara, lipsticks and many more applications are known.

For all those applications often special properties are necessary to guarantee the performance of the end products. Therefore, the high number of varieties of the oil and wax products, combined with their different ways of manufacturing is needed and required by the cosmetic industry.

All cosmetics uses are accompanied with a labelling of the so called INCI[3] names, which are available for every single. product.

[3] Internationally used Cosmetic Ingredient names

Printing inks generally consist of at least three components – the colour pigment, a binder , and a solvent. Mineral oils are used as solvents. For applications such as newspaper black inks, the mineral oil usually acts as a binder; the oil must have a dark colour, a polar character and provide good dispersion of carbon black. Aromatic oils are used here, but they must be non-carcinogenic.

- **Processing aids and antifoam agents:**

Processing aids for leather and textiles:

For the production and processing of textile yarn it is necessary to apply a layer of a processing aid, mainly to prevent tearing at very high processing speeds. Mineral oils are also used for the formulation of re-fatting agents for leather production. In this application the emulsifying properties and light stability of the oil are important.

Antifoam agents:

The formation of foam can seriously disturb processes. Typical sectors where anti-foams are used are textile processing, paper production, production of inks and lacquers, polymerisation processes and lubricants. Mineral oils fulfil the requirements for antifoam agents: chemically inert, not soluble, easily dispersed, and a lower surface tension than the foaming material.

- **Agriculture:**

Plant protection formulations often contain mineral oils as a carrier, mostly in an oil-in water emulsion.

They are also used as dust binders for fertilisers.

- **Other uses:**

Other uses are coatings, cleaning agents, metal working fluids, release agents or binders, road and construction, lubricants, fuel, mining operations, water treatment, etc.

Why is "petroleum" used for products in contact with the human body such as cosmetics, personal care, or pharmaceutical products?

Unrefined crude oil is not used in the formulation of products in contact with the human body or in food related applications. What is used, however, are highly refined specialty products derived from petroleum. The use of these highly refined products in, for instance a cosmetics or food context has very long history and enjoys a perfect human safety record. White oils and waxes are chemically very inert substances which, in addition to offering interesting lubricating and moisture barrier properties, are not allergenic. Further important properties are:

- No reactions with the other formulation components or the packaging material
- Virtually no aging due to oxidation
- No impurities such as aflatoxins, pesticides or other pollutants
- No risk from BSE/STE[4] or other pathogens
- No allergenic potential, dermatologically very well tolerated
- Does not contain any of the known risk substances such as dioxane, ethylene oxide, nitrosamine formers, NO_x, etc.
- Genetically modified organisms are neither contained nor used in the production
- Makes very stable and long-lasting emulsions
- Colour, odour, and flavour neutral

In addition, white oils and waxes do not contain neither palm oil, nor coconut oil or animal raw material.

Their availibilities in both liquid and solid form, and covering a broad range of viscosities and melting points, allow for their ease of formulation in a very wide spectrum of preparations.

In many cases replacement by alternatives offering the same safety-in-use versus performance profile is extremely complex and often impossible.

[4] BSE (Bovine spongiform encephalopathy)/TSE (Transmissible Spongiforme Encephalitis) are commonly known as animal diseases with risk of transmission to humans. Cosmetic products with animal origin may be affected, a BSE/TSE certificate is a requirement in this case.

What are **MOSH** and **MOAH?**

The MOSH and MOAH terminology was introduced in 2009[5] to describe chromatographic peaks seen when analysing cocoa beans, sunflower oil and packaged food in general. Also today, in the strict sense, the concept is described in strictly chromatographic terms as substances eluting with certain retention time in not yet fully standardised analytical methods.

For background, chromatography is a laboratory technique allowing the separation of products in their (individual) components and measuring the relative proportions of these substances in a mixture.

This MOSH and MOAH terminology, however, is creating confusion at different levels:

MOSH and MOAH fractions do not correspond to petroleum products that are placed on the market. These fractions may contain constituents of products of different degrees of refining and purity. Furthermore, these fractions can also be found in products of other origin than mineral oil, further adding to the impossibility of tracing their origin and the health risk they pose. For example, n-alkanes are ubiquitous in nature and are found in fruits and vegetables, e.g. edible oils contain up to 100 mg/kg natural n-alkanes C 23-C33. But there are also many other products that would lead to false positives in a “MOSH/MOAH” analysis.

Further adding to the complexity, is the fact that there are a number petroleum based products lawfully used in cosmetics and food contact, both in the EU or in other regions, and their presence of MOSH and MOAH fractions is not only practically unavoidable but there is also no reason for suspecting non-compliance or a health risk.

[5] Biedermann, Maurus, Katell Fiselier, and Koni Grob. "Aromatic hydrocarbons of mineral oil origin in foods: method for determining the total concentration and first results." Journal of agricultural and food chemistry 57.19 (2009): 8711-8721

Is **MOAH** a hazardous substance for human health?

MOAH has been considered as an indicator of the presence of crude oil based products that are not intended to be used in food related, pharmaceutical or cosmetics applications. The concern is based on the possibility that MOAH containing 3-7 membered rings may be potentially carcinogenic.

MOAH is a chromatographic[6] measure of the aromatic content of an oil. MOAH does not exist in isolation and is not equal to a manufactured mineral oil substance. MOAH gives the total amount of all types of aromatics present and cannot be directly used to assess the hazard because its quantitative nature is unspecific in regards to the aromatic type.

There are two types of MOAH; the 3-7 PAC which are potentially carcinogenic, and the highly alkylated aromatics (mostly 1-2 rings) which are harmless. Refining is necessary to remove the 3-7 PAC, thus effectively eliminating the carcinogenicity of an oil. There are established international standards to measure the 3-7 PAC and the highly alkylated aromatics. Therefore, a simple MOAH measurement cannot distinguish between the hazardous 3-7 rings PAC which are removed by refining from the non-hazardous highly alkylated aromatics which are typical constituents of refined oils.

The interpretation of a MOAH chromatogram is thus highly contextual because a refined oil with a certain MOAH content could be of no concern compared to unrefined oil with lower MOAH content that could be potentially carcinogenic. What really matters is the level of refining, the MOAH content is not important to determine the carcinogenicity of an oil.

The classification as a carcinogen does not apply if it can be shown that the substance contains less than 3% (DMSO) extract (as measured by IP 346). This criteria has been set according to the CLP regulation (Classification, Labelling and Packaging) in EU and is legally binding.

[6] chromatography is a laboratory technique allowing the separation of products in their (individual) components and measuring the relative proportions of these substances in a mixture

Is MOSH a hazardous substance for human health?

MOSH has been considered as a concern because these fractions have been found to accumulate and cause inflammation in human livers. Its presence is therefore considered as undesirable. MOSH is a chromatographic measure of the alkane content of an oil. MOSH does not exist in isolation and is not equal to a manufactured mineral oil substance. While mineral oil can be found as MOSH by chromatography, MOSH is not mineral oil because the interpretation of MOSH will vary subject to the situation.

While MOSH found in human and animal tissues may originate from a mineral oil product, its composition in the body does not reflect the composition of the originally manufactured product. This mainly occurs because once in the body different toxicokinetic/dynamic processes will influence the composition of the mineral oils that humans are exposed to. The concern around the long term toxicity of mineral oil is derived from observations in animal experiments. These experiments are however only models which results are extrapolated to the human condition. These animal experiments include dogs and mostly rats, and their results show that, at the exception of the "F-344 rat" model, none of the tested animals (other rat strains and dogs) developed any adverse effect and certainly not humans. The mere retention of MOSH in human tissues has thus not been shown to be pathologic.

The F-344 rat is an exception as it is the only experiment which has shown adverse responses to some type of alkanes, typical constituents of mineral oils. A specific MOSH fraction of n-alkanes, commonly found in olive oil and apple peel, make the F-344 rat ill. These unique adverse effects (including what is observed in the liver) have however been extrapolated to humans and serve currently as the basis for the health concern to MOSH.

Both in the EU and the US mineral oil substances find legal use in cosmetic and pharmaceutical formulations and as biocides (active substances and carriers). In the US, also their use as lubricants and as release and anti-dusting agents is legally accepted.

Can mineral oil end up in food?

The use of mineral oil is regulated differently, depending on the national regulation in place:

- **European Union**

White mineral oils are permitted to be used in plastics for food contact applications according to Regulation 10/2011/EU on plastic materials and articles intended to come into contact with food, when specifications fulfil the criteria set in FCM 95 (PM Ref.: 95883).

Most food contact materials or substances - other than plastics - like paper, elastomers, glass, metal, wood (including cork), textiles, adhesives, pigments are not yet covered by binding EU regulations (directive and legislation). Therefore other non-binding EU resolutions, national standards such as the German BFR recommendations for food contact materials (plastics, paper, rubbers, etc.) or other relevant industry standards, e.g. guidelines on printing inks, paper etc. may be considered.

- **United States**

The regulations of the American Food and Drug Administration FDA 21 CFR §178.3620 concerning the purity criteria a), b) or c) apply for uses in the range of indirect food contact. The intended uses as additive for food packaging or production aid agent for food manufacturing are assigned through cross-reference to further paragraphs.

Lubricants with incidental food contact are subject to the paragraph FDA 21 CFR §178.3570. Mineral oil is listed with a maximal concentration of 10 ppm in foods.

The approval according to FDA 21 CFR §172.878 for direct food contact is given if the white oil is used as additive, as e.g. preservative for eggs (max. 0,1 %) and dried fruits (max. 0,02 %), anti-dusting agent for wheat, maize and other cereals (max. 0,02 %), mould releasing agents (max. 0,3 %) or bakeries (max. 0,15 %), etc.

Food is a global commodity, manufactured and traded in many different countries, and complying with different levels of legislation. There are many different ways by which hydrocarbons of mineral oil origin can end up in food.

In fact, there are legally accepted uses and risks for contamination by products not intended for food related use at all stages of the food supply chain:

- During the vegetal and animal production and harvesting stages, petroleum based products can be used as active substance of formulation aid in plant protection. Alongside, there is the obvious risk for both environmental contamination by petroleum based products as well as spot contamination of fuel and lubricant spills of agricultural and harvesting equipment.

- During the storage and transportation phase there is a combination of regulated and accepted uses of mineral oil (anti-dusting agents) as well as inappropriate sources of contamination (use of unsuited jute batching and machine oils).
- Finally, during the food processing and packaging stage, on the one hand highly refined petroleum based products can be used as food additives and release agents, and, on the other hand, the migration from recycled paper as well as from adhesives and sealants may contribute to the presence of mineral oils in food.

Do hydrocarbon solvents contain MOSH?

According to the European Food Safety Authority (EFSA) definition, MOSH is a fraction of mineral oil hydrocarbons (MOH), comprising straight, branched and largely alkylated cyclic alkanes and containing 10 to about 50 carbon atoms. However, based on our current understanding the best way to describe the MOSH analytical fraction is by starting at mineral oils with a carbon chain greater than C20 (see definition of MOSH).

Hydrocarbon solvents have a different manufacturing process which distinguishes them from mineral oil, with their chain lengths up to C20.

Because of this the MOSH terminology does not apply to hydrocarbon solvents.

How can industry ensure that mineral oils are safe?

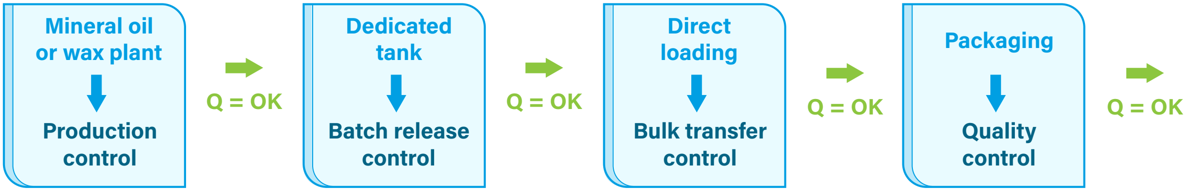
The petroleum industry has a long history of safely managing the manufacturing, storage, handling and delivery of LBOs, white mineral oils, and waxes, to ensure that the end products loaded and delivered to industry are consistent and safe for the intended final user.

All of the products are defined and controlled by sales and manufacturing specifications which are either defined at industry or company levels, and have been carefully designed to control their chemical composition.

In addition to these specifications, the absence of contamination during the supply chain is generally ascertained by robust Quality Assurance procedures and certifications, such as ISO 9001 or ISO 14001. Furthermore, Good Manufacturing Practices (GMP) procedures and certifications, such as Pharmaceutical GMP certifications for some white mineral oils, waxes, and petroleum jellies used as active pharmaceutical ingredients, and FDA GMPs for products used as food additives (USA) will serve the same purpose.

In the case of LBOs, the removal of carcinogenic aromatic hydrocarbons through refining is controlled by the legally mandated test IP346. Only LBOs which pass this IP346 test are considered non-carcinogenic and can be sold in the market. In conclusion, as supported by numerous carcinogenicity studies, whilst LBOs contain aromatics due to their origin they are safe if the oil passes the IP346 test.

Mineral oil / wax handling
Quality control from manufacture to shipment



There are dedicated pipes and tanks for each step in the process.
Procedures are in place for manufacturing, storing, handling, packaging as part of the Quality Assurance process.
Q = Quality

For wax, the IP346 method and 3% threshold is not applied to the wax itself but to the substance from which it originates (called raffinate). The test demonstrates that this raw material is not a carcinogen, and gives the “green light” for further processing to meet other regulatory standards (e.g. pharmacopeia), and it may only be used for informational purposes about initial refining stages.

For white oils involved in food, pharmaceutical or cosmetic industries, the strictest requirements for PAC are in place; apart from the requirement that the feedstock is non-carcinogenic (by IP346) the removal of PAC is done to a level at which the refined product fulfils the international legal specifications which determine it is non-carcinogenic. These specifications are based on:

- UV tests after DMSO extraction
- Readily Carbonisable Substances (test for reaction with sulfuric acid)

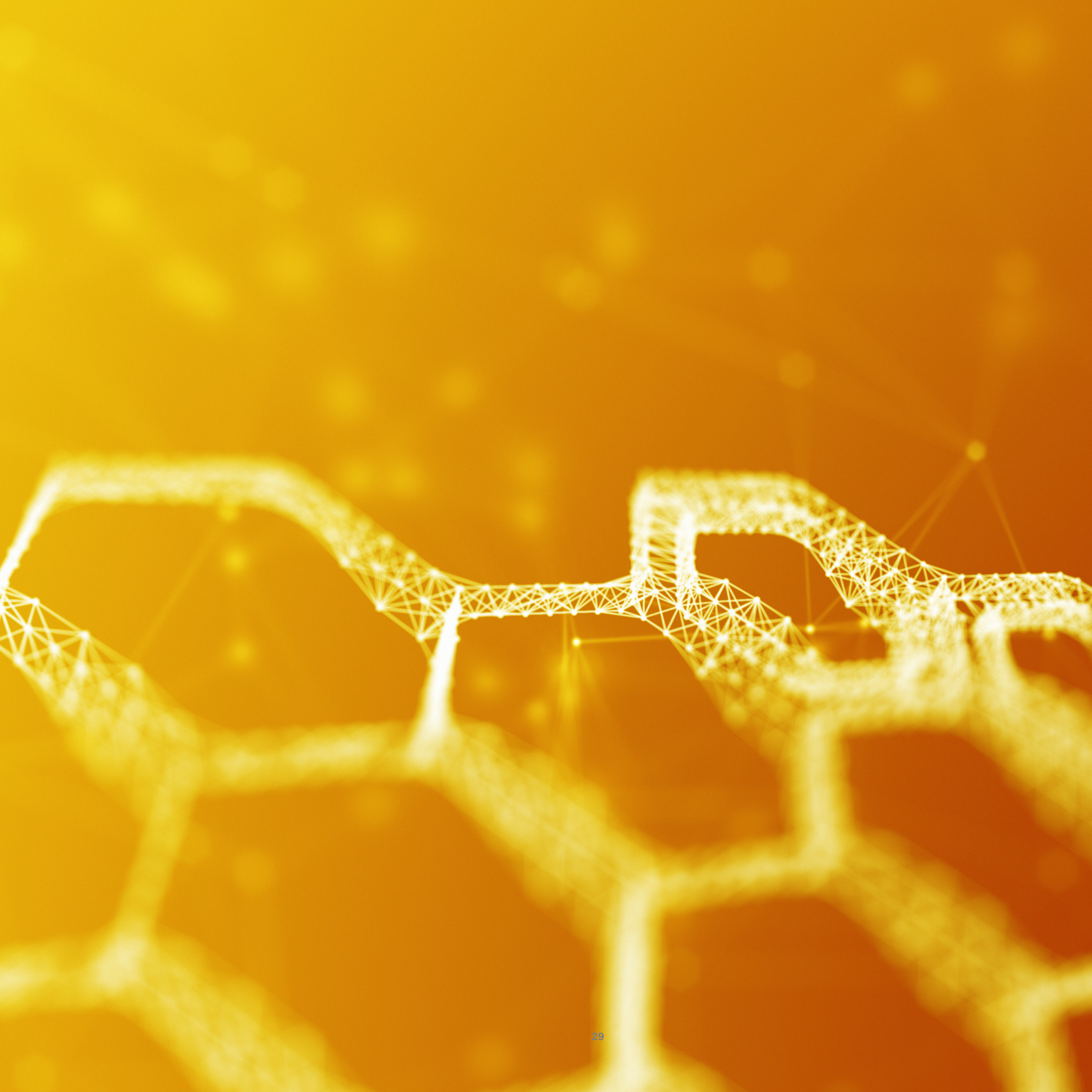
Consequently, refined petroleum products used at different stages of food production or as ingredients in pharmaceutical or cosmetic products are not carcinogenic.

Whilst the refining of mineral oil products decreases aromatic hydrocarbon levels, the refining process is primarily designed to remove a specific family of aromatic substances (the 3-7 ring PAC), which are the potentially carcinogenic species. The presence of MOAH (an unspecific term which may encompass all types of aromatics and will include predominantly highly alkylated 1-2 rings) is therefore not indicative of carcinogenic potential and toxicologists thus focus on PAC.

Unlike the 3-7 ring PAC, some of which are known to be carcinogenic, highly alkylated 1-2 ring systems in the refined product are not genotoxic and are not considered to be a concern for carcinogenicity. Hence, although these species are likely to contribute more to the “MOAH” identified in refined products, they do not pose a carcinogenic risk in these products. Additionally MOAH levels correlate with molecular weight. The longer the aliphatic side chains of the aromatic ring, the heavier the MOAH molecule which results in higher MOAH results.

In summary, mineral oils are safe because:

- Refining sets chemical composition of products at targeted level. In particular, 3-7 ring PAC are eliminated.
- Chemical composition of products is controlled by product specifications and legally mandated tests.
- Absence of contamination during the supply chain is controlled by robust Quality Assurance and GMP practices.
- Petroleum products have been intensively tested for decades for carcinogenicity (mainly using the Mouse Skin painting model) and for accumulation in tissues. A robust correlation has been developed between carcinogenicity from Mouse Skin painting test and IP 346 limit of 3%.
- Manufacturing processes have essentially not changed over last 40 years. Mineral oils and waxes currently on the market are similar to products that have been toxicologically tested over all that period.
- The presence of MOAH in itself is not indicative of carcinogenic potential.
- The mere retention of MOSH in human tissues has not been shown to be pathologic.
- Refined petroleum products used in food industry, in pharmaceutical or cosmetic products, are safe and not carcinogenic.
- High levels of PACs (3-7 rings) in food would generally be indicative of some contamination by components which are not from petroleum origin or from an unrefined petroleum product.



Abbreviations:

BTX:	Benzene, Toluene, or Xylenes
CLP:	Classification, Labelling and Packaging
DMSO:	Dimethyl Sulfoxide
EFSA:	European Food Safety Authority
EPDM:	Ethylene-Propylene-Diene-Monomer
EU:	European Union
FAO:	Food and Agriculture Organization
FDA:	Food and Drug Agency
HRBOs:	Highly Refined Base Oils
GMP:	Good Manufacturing Practices
JECFA:	Joint FAO/WHO Expert Committee on Food Additives
LBOs:	Lubricant Base Oils
MOH:	Mineral Oil Hydrocarbons
MOSH:	Mineral Oil Saturated Hydrocarbons
MOAH:	Mineral Oil Aromatic Hydrocarbons
PAC:	Polycyclic Aromatic Compounds, encompass PAH and poly ring systems with N or S heteroatoms
PAH:	Polycyclic Aromatic Hydrcarbons
PINA:	Paraffin, Iso-Parafffin, Naphthenic or Aromatic
PSA:	Pressure Sensitive Adhesives
SBR:	Styrene-Butadiene-Rubber
TPE-O:	Poly-Olefins
TPE-S:	Styrene Block-Polymers
UVCB:	Unknown or Variable composition, Complex reaction products or Biological materials.

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ENVIRONMENTAL SCIENCE FOR THE EUROPEAN REFINING INDUSTRY

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