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Synthetics GBU considerations on Mineral Oil present in food and food contact materials. Evaluation of polyalphaolefin (PAO) synthetic basestocks.

The rise of concern on Mineral Oil contamination in food contact applications

Increased production of processed foods have sparked rising concerns of chemical contamination in the food chain (Ref 1 & 2). Health risks associated with mineral oil hydrocarbon (MOH) constituents, either due to intentional addition or process-derived contamination, have been a focus of this discussion in recent years, with particular interest in two MOH fractions: MOSH (Mineral Oil Saturated Hydrocarbons) and MOAH (Mineral Oil Aromatic Hydrocarbons). The purpose of this document is to explain MOSH and MOAH-associated health concerns and the misconception around synthetic oils, specifically polyalphaolefins.

What are MOSH and MOAH?

The European Food Safety Authority (EFSA) broadly defines MOHs as hydrocarbons containing approximately 10 to 50 carbon atoms, and consisting of three major classes of compounds: paraffins (linear and branched alkanes), naphthenes (including alkyl-substituted cycloalkanes) and aromatics (Ref 1). MOHs therefore belong to substances of unknown or variable composition, complex reaction products or biological materials (UVCBs). MOSH and MOAH comprise distinct MOH fractions, covering a wide range of molecules with varying chain length. Definitions for these molecules are not currently standardized, do not bear any regulatory relevance, and analytical methods used to detect these molecules are unable to distinguish between hydrocarbons of mineral or non-mineral origin:

- **MOSH** – Mineral Oil Saturated Hydrocarbons – EFSA defines MOSH as linear, branched and cyclic alkanes, i.e. the paraffinic and naphthenic fractions of MOHs (Ref 1). Consistent with the EFSA definition, the German Bundesinstitut für Risikobewertung (BfR) defines MOSH broadly as saturated aliphatic and cyclic hydrocarbons of variable carbon chain length (Ref 2).

- **MOAH** – Mineral Oil Aromatic Hydrocarbons - EFSA defines MOAH as not uniquely identifiable MOH-derived complex substances containing four classes of molecules: non-alkylated aromatic hydrocarbons (including naphthalene and polyaromatic hydrocarbons), alkylated aromatic hydrocarbons, partially hydrogenated hydrocarbons and sulfur-containing aromatic compounds (Ref 1). The BfR defines MOAH

as complex substance consisting of unsubstituted or alkylated, and partially hydrated polycyclic aromatic hydrocarbons. MOAH typically constitutes 15 - 30% of the originating crude oil content (Ref 2).

- It should be noted that existing analytical detection methods cannot distinguish between structurally similar products of natural and synthetic origin, examples include waxes, oligomers, and adhesive resins. These techniques also do not provide a means of identifying the origin of substances identified as MOSH/ MOAH, which may be numerous - pesticides, packaging, printing inks, use of recycled paper, plastics, jute/sisal bags (coffee/cocoa), wax coatings, heating oils, some food additives, de-dusting aids, lubricants used in the processes, environmental contamination, including diesel fumes from harvesting machinery, solvents, cleaning agents, as well as, from natural products such as fish, beeswax etc. MOH-derived PAOs may be present in MOSH and consequently, PAO synthetic basestocks may also be detected as MOSH in existing tests (Ref 2 & 3).

What are the health concerns associated with MOSH and MOAH?

- **MOSH** – Primary health concerns associated with MOSH stem from findings indicating that high molecular weight paraffins may be retained in the liver, lymph nodes, and adipose tissues (Ref 1). Inflammatory responses accompanying hepatic and lymph node microgranuloma formation have been observed in one specific strain of rats exposed to white mineral oils (Ref 4, 5 & 6). However, while saturated hydrocarbons are routinely found in human livers, these findings are not associated with abnormalities of clinical relevance (Ref 2, 7 & 8). Reported non-inflammatory lipogranulomas (i.e. oil droplet deposits) historically found in human livers (i.e. in the 1970s and 1980s) are morphologically and histologically distinct from the granulomas found in rats and have been concluded as adaptive responses without clinical significance by the BfR (Ref 2). More recent evaluations of human tissues indicate that MOSH exposure in the general population has decreased to an extent that lipogranuloma formation is no longer observable and possibly no longer relevant (Ref. 2, 9, 10 & 11).

- **MOAH** – Among the various types of molecules present in MOAH, the primary health concerns, mutagenicity and carcinogenicity, are specifically associated with the 3-7 ring polycyclic aromatic hydrocarbon (PAH) fraction (Ref 1, 2, 11 & 12).

What is being done about the concern of MOSH and MOAH?

In order to make informed decisions, the European Commission has recommended that during 2017-18 Member states review and monitor MOH content levels in various food substances, and where appropriate investigate the source of the mineral oil hydrocarbon contamination (Ref 13). Considering it's PAH content, the MOAH concentration typically recommended in consumer products depends on its intended end use, as well as specific characteristics of the MOAH fraction (Ref 2). ExxonMobil takes an active interest in these issues and supports industry and trade associations, technical studies and publications on the safe use of synthetic and petroleum substances in food and food contact applications and supports the European Commission's development of technical facts and data to help make informed decisions.

How do MOSH and MOAH mineral oils differ from polyalphaolefin synthetic oils?

Despite being saturated hydrocarbons and thus fitting the definition of the alkane fraction of MOSH, PAO synthetic oils and MOSH are fundamentally different. As opposed to MOSH, PAO oils are not derived from mineral feedstock, but are polymerized from high purity synthesized alpha olefins. Choices of catalysts allow synthesis of PAOs with various degrees of branching, including highly organized and structurally defined molecules (Figure 1). Pure monomers used as building blocks for the manufacturing of PAOs typically include 1-hexene, 1-octene, 1-decene, 1-dodecene and 1-tetradecene. Consequently, PAOs lack the chemical complexity, diversity, and analytical uncertainty associated with MOSH (Ref 14 & 15). In addition, PAOs are structurally distinct from MOAH due to a lack of aromatic constituents and therefore do not share adverse biological properties associated specifically with the 3-7 ring aromatic hydrocarbon constituents in MOAH.

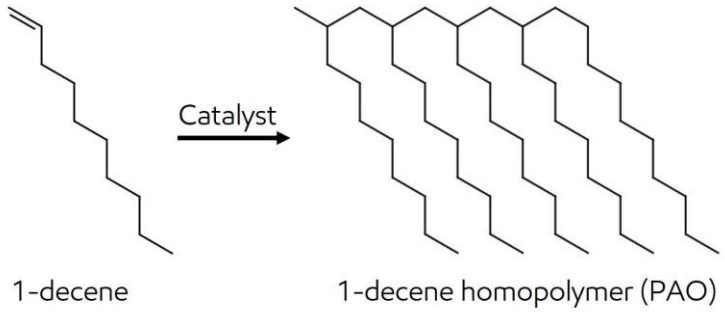

***Figure 1**: Generalized representation of the synthesis of a polyalphaolefin (PAO) from 1-decene*

- **Absorption, Distribution, Metabolism, and Excretion (ADME)**: The differences in physico-chemical properties between MOSH, MOAH, and PAO synthetic oils are reflected in distinct ADME characteristics. MOSH and MOAH are differentially absorbed based on physico-chemical properties following ingestion (Ref 1). Following absorption, certain MOSH tend to be oxidized in the liver. However, depending on the natural branching and carbon number, these oxidation reactions may occur slowly, resulting in tissue accumulation of certain MOSH constituents over time (Ref 11, 16, 17). By contrast, unalkylated MOAH tends to be an easily accessible substrate for enzymatic oxidation which prevents tissue accumulation but may lead to the formation of mutagenic intermediates (Ref 11, 12). Polar metabolites of MOSH and MOAH constituents may be excreted via urine or feces (Ref 1). Existing toxicokinetic analyses with radiolabelled PAOs indicated that these substances are not extensively absorbed from the gastrointestinal tract of rats following oral administration. The predominant route of excretion is via the feces and any material that is absorbed is likely to be cleared rapidly from the blood. Experimental findings are concordant with a predicted low degree of oral absorption of PAOs with large molecular weights and low associated water solubility (< 0.1 mg/L) and large partition coefficient (log Kow > 6.5).

- **Repeat-Dose Toxicity**: As discussed above, repeat-dose toxicity evaluations revealed inflammation-associated microgranuloma formation in a specific strain of rats that are not relevant in humans (Ref 1, 2, 4-11). There is no evidence for microgranuloma formation in PAO exposed rats (Ref 14 & 15). Subchronic exposures to certain MOAH has the potential to result in haematological abnormalities based

on repeat-dose exposures of heavy paraffinic distillate aromatic extract in mice (Ref 19). No significant or enduring toxicological effects were reported in repeat-dose toxicity assessment studies in rats exposed to representative PAOs, i.e. 1-decene, homopolymer (hydrogenated), 1-dodecene dimer with 1-decene (hydrogenated), and 1-dodecene trimer (hydrogenated). These results are indicative of PAO synthetic oils not producing significant systemic toxicity following repeated exposure.

- **Developmental & Reproductive Toxicity**: A number of studies have addressed developmental and reproductive toxicity of MOSH and MOAH constituents. Studies evaluating pre-natal exposure to white mineral oil (Ref 18) and heavy paraffinic distillate aromatic extract (Ref 19) indicated low potential for developmental and reproductive effects in MOSH-exposed rats. By contrast, exposure to heavy paraffinic distillate solvent, and therefore containing MOAH, has been associated with both fetal (i.e. decreased fetal body weight, delayed and/or reduced ossification) and maternal toxicities (i.e. decreased weight gain, low thymus weight, and red vaginal discharge) (Ref 20). Developmental and reproductive toxicity studies of PAOs (i.e. 1-decene, homopolymer, hydrogenated and structural analogues related to 1 dodecene polymer with 1-decene, hydrogenated) revealed no effects in rats up to the highest tested concentration (1000 mg/kg/d) (Ref 14 & 15).

- **Mutagenicity and Carcinogenicity**: PAO synthetic basestocks consist of saturated hydrocarbons and therefore do not share the genotoxic and carcinogenic characteristics associated with the 3-7 ring PAH fraction of MOAH. 3-7 ring aromatic molecules can be structurally accessible to biotransformation reactions yielding reactive, genotoxic metabolites (Ref 1, 11 & 12). The lack of aromatic constituents in PAO synthetic basestocks precludes the formation of reactive (mutagenic) intermediates. *In vitro* genotoxicity and cytogenicity studies on representative PAOs (1-decene 1-dodecene homopolymer, hydrogenated and 1-dodecene trimer, hydrogenated) supported this hypothesis by providing evidence of non-mutagenicity and non-clastogenicity of PAOs. *In vivo* mutagenicity study in mice exposed to 1-decene, 1-dodecene homopolymer resulted in a negative outcome, thereby providing further evidence that PAOs are not genotoxic (Ref 14 & 15).

Polyalphaolefins are safe for use in food contact application:

PAO synthetic oils have been determined to be safe for use in food contact applications. PAOs have been reviewed by the European Food Safety Authority (EFSA) and the resulting opinion concluded that "there is no safety concern for the consumer if the substance complies with the given specifications and its migration does not exceed 60 mg/kg food" (Ref 21). This scientific opinion enabled the listing of PAOs complying with given specifications in EU Regulation 10/2011, without specific migration limit restriction (EU Ref No. 60027) (Ref 22). SpectraSyn synthetic basestocks are compliant with U.S. FDA 21 CFR 178.3570 for lubricants with incidental food contact and are H1 National Sanitation Foundation (NSF) registered, signifying that ExxonMobil SpectraSyn™ PAO basestocks (including SpectraSyn Plus™, SpectraSyn Ultra™, and SpectraSyn Elite™) grades meet requirement for white mineral oils and are thus acceptable as ingredients for use in lubricants with incidental food contact.

In summary

- MOSH and MOAH are complex, MOH-derived fractions associated with unique hazard profiles
- As a result of the manufacturing process, PAO synthetic oils do not contain aromatic molecules and are thus per definition chemically and biologically distinct from MOAH.
- PAO synthetic oils may be detected as MOSH in existing laboratory tests. However, being synthetically-engineered chemicals, PAOs do not share the chemical complexity of MOSH and should not be considered as mineral oil of concern due to their low hazard profile.
- There can be a multitude of sources of mineral oils. In the event of high levels of mineral oil hydrocarbon being detected in food applications, detectable hydrocarbons need to be traced back to their potential sources in a step by step process considering each stage of the supply chain.
- ExxonMobil has a broad range of PAO synthetic oils fulfilling the requirements of EU 10/2011 Regulation. Food contact statements are readily available from customer service.

ExxonMobil continues to work with the relevant industry and regulatory bodies to develop robust scientific data and risk-based analysis to help assure the continued safety of products by customers and end consumers

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