Mineral Oil

Livestock

Identification of Petitioned Substance

Chemical Names:
Mineral oil

Other Name:
Paraffin oil
Petroleum distillates
Hydrocarbon oils
White mineral oil
Lubricating oils

Trade Names:
Omni Supreme Spray
Mite-E-Oil®
White NF Food Grade Mineral Oil

CAS Numbers:
8042-47-5 (white mineral oil); 8012-95-1 (mineral oil; oil mist); 72623-87-1 (hydrotreated lubricating oils, C20-50); 72623-86-0 (hydrotreated lubricating oils, C15-30); 72623-84-8 (lubricating oils, hydrotreated, solvent deasphalted, C15-30); 64742-65-0 (solvent-dewaxed heavy paraffinic petroleum distillates); 64742-56-9 (solvent-dewaxed light paraffinic petroleum distillates); 64742-55-8 (hydrotreated light paraffinic petroleum distillates)

Other Codes:
232-455-8 (EINECS No, white mineral oil)

Summary of Petitioned Use

The National Organic Program final rule currently permits the use of mineral oil in organic livestock production for direct topical application and as a lubricant under 7 CFR 205.603(b)(6). Regarding the former use pattern, mineral oil acts as an external parasiticide when applied topically to animals infested with mites, lice and other parasites. Conventional operators orally administer mineral oil to lubricate the intestinal tract and dislodge intestinal obstructions in cattle and other ruminants; however, this medical practice is not approved in organic production. Updated and targeted technical information is provided in this technical evaluation report to augment the 2002 technical advisory panel (TAP) review for uses of mineral oil that are approved and prohibited in organic livestock production. This report supports the National Organic Standards Board's sunset review of mineral oil as an allowed external parasiticide and lubricant in organic livestock production.

Characterization of Petitioned Substance

Composition of the Substance:

Mineral oils used in organic livestock production are hydrocarbon molecules containing 15 to about 50 carbon atoms (US EPA, 2007; EFSA, 2012). Crude, untreated mineral oil mixtures consist of three major classes of compounds: paraffins (linear and branched alkenes), naphthenes (alkyl-substituted cyclo-alkanes) and aromatics (including polynuclear aromatic hydrocarbons (PAHs)), which are generally alkyl-substituted. These untreated mineral oils may also contain small amounts of nitrogen- and sulfur-containing compounds (EFSA, 2012). The composition of mineral oil is dependent upon the crude oil source (e.g., location of procurement) and the processing that occurs in the refinery, such as physical separations and chemical conversions. In the 2007 risk assessment for mineral oils, US EPA indicated that most manufacturers are currently using modified refining and cleanup processes to remove the more toxic components and generate refined minerals largely devoid of PAHs as well as nitrogen and sulfur compounds (US EPA, 2007). Because of their complexity, it is not possible to resolve mineral oil mixtures into individual components for quantification. Indeed, an enormous number of individual components—from compounds of varying carbon chain length to isomers of the same carbon chain length—are constituents of crude and refined mineral oil mixtures (EFSA, 2012).

The linear and branched isomers of the C15 saturated alkanes are displayed below in Figure 1 as representative examples of hydrocarbons contained in commercially available mineral oil products. In addition, a C15 example of the commonly occurring naphthene hydrocarbons (cyclic alkane species) is shown below for comparison.

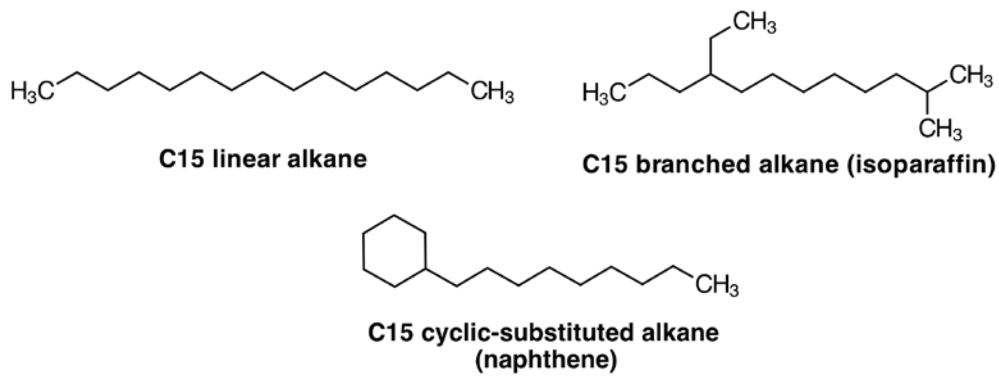

Figure 1. Refined mineral oils are complex mixtures of C15 to C50 hydrocarbons, primarily composed of linear, branched and cyclic alkanes

Source or Origin of the Substance:

Crude petroleum oil is the predominant source of mineral oils used in organic and conventional agriculture, as well as food for human consumption, cosmetic products and drugs. Other fossil fuel sources including coal, natural gas and biomass can produce equivalent mineral oil products, but are used to a lesser extent than liquid petroleum (EFSA, 2012). Refined mineral oils are obtained through physical separation, such as distillation and solvent extraction, and chemical conversion processes, including cracking, hydrogenation, alkylation, isomerization and/or other chemical transformations, from crude petroleum oils (EFSA, 2012). As complex mixtures, refined mineral oils are identified using several CAS numbers depending on the treatment processes utilized and the intended use pattern of the mineral oil product. See the response to Evaluation Question #2 for details regarding the purification and processing steps used in the industrial production of refined mineral oils.

Properties of the Substance:

It is not generally feasible to report specific data for each chemical and physical property due to the diversity of petroleum hydrocarbon mixtures comprising the broad category of mineral oils. Nevertheless, certain patterns are evident despite the inherent complexity of mineral oil mixtures. The melting points for mineral oils are generally below 0 °C. Constituent hydrocarbons of these oils have boiling points ranging from 300 to 800 °C; however, the actual boiling points for the composite substance is dependent upon the types and order of distillation and refining processes employed during refinement. The vapor pressures also exhibit a wide range, from 10^{-3} mm Hg for shorter-chain constituents to 10^{-14} mm Hg for longer-chain constituents. As nonpolar compounds, the octanol-water partition coefficients (K_{ow}) for mineral oil mixtures are typically high. The constituents of mineral oils are also very poorly water soluble, with water solubility estimates ranging from 0.001 to 0.6 mg/L. In general, solubility in water is inversely related to carbon chain length for hydrocarbon compounds. Table 1 below provides pertinent chemical and physical properties for mineral oil.

Table 1. Chemical and Physical Properties for mineral oil.

Property	Description
Appearance	Oily, clear, colorless (highly refined) to light straw, amber (mildly refined)
Physical state	Liquid, viscous liquid
Odor	Odorless (highly refined) to hydrocarbon odor (mildly refined)
Solubility in water	Insoluble or practically insoluble (0.001 – 0.6 mg/L)

Property	Description
Other solubilities	Insoluble in alcohols; soluble in benzene, chloroform, ether, carbon disulfide, petroleum ether and most fixed oils
Boiling point range	300 – 800 °C
Density	0.875 – 0.905 g/mL
Vapor pressure	< 0.5 mm Hg (20 °C); semi-volatile mixture (somewhat volatile for shorter-chain, poorly volatile for longer-chain)
Log K_{ow}	5 – 20
Viscosity	10 – 38 cP

Data sources: US EPA, 2007; HSDB, 2005.
cP = centipoise; unit of measure for viscosity equivalent to millipascals seconds (mPa•s).

<u>Specific Uses of the Substance:</u>

The NOSB sunset review for mineral oil pertains to external applications of the substance for parasitic mite control in sheep, goats, cattle, hogs and other livestock, as well as use as a lubricant.

External parasites such as lice, mange mites and various insects can adversely impact the health of individual animals and lead to economic losses for livestock. These parasites do not generally kill their hosts, but they can weaken the animal and, in some cases, transmit diseases (Pedretti, 2014). Five species of lice—including one species of biting or chewing louse and four species of sucking lice—affect cattle in the U.S. As parasitic organisms, lice puncture the skin of the host animal with their mouthparts and suck the blood of the host (Pedretti, 2014). The major external parasite attacking hogs is the hog louse, which obtains food in an analogous manner to that described for cattle lice. Lice spread from animal to animal through direct contact and/or shared bedding and sleeping/loafing areas (Pedretti, 2014). Livestock infested with lice display increased scratching, rubbing and biting of infested areas, and generally have unthrifty appearance, rough coat and lowered production. In severe infestations, animals may experience loss of hair, bleeding, skin scarring and even anemia if the animal stops feeding (Pedretti, 2014). Lice in cattle and small ruminants tend to congregate around the ears, neck, topline, tailhead, escutcheon and tail switch, while hog lice are generally found in the skin folds of the neck and jowls, behind the ears and on the inside of legs (Pedretti, 2014).

Mange caused by parasitic mites is highly irritating for animals, and can result in economic losses from wool damage (lamb and sheep) and reduced production of meat products derived from sheep, goat, cattle and hogs (McNeal, 1999). Sheep scab—caused by the parasitic mite *Psoroptes ovis*—is a contagious, highly pruritic (i.e., itching) disease that results in the development of large, yellowish, scaly, crusted lesions, accompanied by damage to wool and hide. Although severe psoroptic mange was documented in one U.S. population of wild bighorn sheep in 1978, reports indicate that sheep scab has been eradicated from the United States, Canada, Australia, New Zealand and Scandinavia (CFSPH, 2009). Chorioptic and psorergatic mange of sheep and goats have also been eradicated in the U.S., while sarcoptic and demodectic mange remain problematic for producers of sheep and goats (Losson, 2011). In U.S. cattle production, sarcoptic mange (scabies), psoroptic mange, chorioptic mange, demodectic mange and psorergatic mange (itch mite) continue to be problematic skin diseases (Losson & Mignon, 2011). Topical treatments of mineral oil are commonly used in organic livestock operations to suffocate lice and mange mites affecting cattle, hogs and other animals (Pedretti, undated; Pedretti, 2014).

In addition to external parasite control, mineral oil was petitioned for use as an internal lubricant in organic livestock production. In the case of “omasal impaction”, the ruminant’s third stomach (omasum) becomes tightly bound and compacted, resulting in severe pain for the affected animal (USDA, 2002). Omasal impaction is related to type II vagal indigestion (failure of omasal transport), which develops as a result of any condition that prevents ingested material from passing through the omasal canal into the abomasum, the fourth and final stomach compartment in cattle (Constable, 2012). In general, impactions in various segments of the gastrointestinal tract may develop in pregnant beef cows during cold winter months when cattle consume less water and are fed lower-quality roughage (Constable, 2014). Mineral oil may be applied as an oral drench at a rate of one to two gallons every 12 hours until the viscous mineral oil treatment lubricates the impaction (USDA, 2002). Abomasal impaction is treated using four liters (approximately one gallon) of mineral oil per day for three days (Constable, 2014). Some livestock producers have indicated that failure to regularly treat for omasal impaction often results in the need for surgery (USDA, 2002). In a related ailment known as "retained mecomium", the baby calf's first manure is blocked, thus rendering the animal unable to excrete normally. Mineral oil serves as an internal lubricant in conjunction with the administration of an enema to unblock the digestive obstruction (USDA, 2002).

Following the technical advisory panel review, the NOSB recommended inclusion of mineral oil for use as a veterinary treatment for omasal impaction in organic livestock production (USDA, 2003). However, based on consultations with the US Food and Drug Administration (FDA), the NOP was informed that mineral oil has not received approval through the FDA drug approval process to be authorized as a medical treatment in cattle, and the substance would not qualify for extra-label use by a licensed veterinarian (USDA, 2006). The US Environmental Protection Agency (US EPA) deferred to FDA as the appropriate regulatory body for use of the substances. Accordingly, the NOP was unable to accept the NOSB recommendation to allow the use of mineral oil as a livestock medication under 7 CFR 205.603 (USDA, 2007). Mineral oil remains prohibited for use in organic livestock production as an orally administered treatment of constipation in cattle and other ruminants.

Mineral oil is commonly used to control bloat in conventional cattle production. Bloat generally occurs in animals after grazing young, lush pasture, particularly if the pasture contains significant amounts of legume species (clover, medics or lucerne). Ruminants such as cattle produce large volumes of gas during the digestive process, and natural foaming agents in legumes and some rapidly growing grasses cause stable foam to form in the rumen. The animal is therefore unable to pass the gas trapped as small bubbles in the foam (Bailey, 2014). In mild cases, animals can be treated orally with an anti-bloat preparation such as mineral oil at 100 mL per cow per day. Severe cases may require insertion of a wide-boar trochar and cannula into the rumen to relieve the pressure followed by direct addition of an anti-bloat preparation (e.g., mineral oil, vegetable oils or dioctyl sodium sulfosuccinate) into the rumen through the cannula (Bailey, 2014; Gay, 2012). Sudden death is commonly observed in cattle that are not closely observed (Gay, 2012). As a preventative measure, veterinary specialists suggest that cattle producers drench each animal twice daily with an anti-bloat preparation or oil when the pasture is considered risky (Bailey, 2014).

There are several other agricultural uses of mineral oil that are not approved for organic production and handling. Conventional livestock producers commonly use mineral oil as a dust control agent in the formulation of vitamin and mineral premixes for supplementation of livestock feed. Mineral oil has been considered irreplaceable in this function because many alternative vegetable oil dust suppressants are known to oxidize the vitamins and minerals used in livestock feed. However, the NOSB recommended that mineral not be added to the National List as an additive in livestock feed due to the availability of alternatives that are not prone to rancidity, including grapeseed, citrus and certain other vegetable oils (USDA, 2002). In addition to livestock uses, mineral oils have insecticide, acaricide and fungicide uses as spray oils on conventional crops as well as residential and municipal property. Mineral oil products also have aquatic uses as mosquito larvicides/pupacides (US EPA, 2007).

<u>Approved Legal Uses of the Substance:</u>

Agricultural uses of mineral oils have existed for over a century, but pesticide products formulated with mineral oil were first registered with the US Environmental Protection Agency (US EPA) in 1990. As of December 2014, there were 117 registered pesticide products containing mineral oil as the active ingredient (US EPA, 2014). These products are generally formulated as liquid concentrates for use as insecticides and/or larvicides on crops, animal premises, commercial/industrial premises, medical premises, aquatic areas, and residential premises. None of the commercially available mineral oil pesticide products are registered for use as external parasiticides; however, technical mineral oil products devoid of pesticidal marketing claims may be topically applied to livestock for parasite control. There are also approved occupational and residential uses of mineral oil products as acaricides, fungicides, herbicides, and virucides (for plant pathogens). Mineral oil products marketed for aquatic applications are designed for usage as mosquito larvicides/pupacides (US EPA, 2007). Mineral oils are exempt from the requirement of a tolerance when applied to growing crops, in accordance with good agricultural practices (40 CFR 180.905). However, US EPA established a tolerance of 200 ppm for residues of mineral oil used as a post-harvest treatment to corn grain and sorghum grain (40 CFR 180.149). Residues of mineral oils are exempt from the requirement of a tolerance when used as an inert ingredient in pesticide formulations applied to growing or harvested crops (40 CFR 180.910) and directly to animals (40 CFR 180.930).

The US Food and Drug Administration (FDA) has approved several uses of mineral oil in food for human consumption and animal feed. FDA has designated mineral oils as Generally Recognized as Safe (GRAS) when used as a release agent sprayed on potato processing equipment, resulting in a presence of mineral oil residue on food of no more than 5 parts per million (FDA, 2001). According to the FDA database for "Everything Added to Food in the United States" (EAFUS), mineral oils are approved for use as direct, secondary direct and indirect food additives in human food and animal feed (FDA, 2014). FDA permits the direct addition of mineral oil to food for human consumption under 21 CFR 172.842 and 172.878. For example, white mineral oil (CAS# 8012-95-1) may be added to release agent, binder and lubricant in capsules or tablets, as well as a defoamer, releasing agent and/or lubricant in various foods. Mineral oils may also be used in the processing of foods as "secondary direct food additives" (21 CFR 173.340) and for various purposes as indirect food additives (e.g., substances used in adhesives) under 21 CFR 175.105, 175.210, 175.230, 175.300, 176.170, 177.1200, 177.2260, 177.2600, 177.2800, 178.2010, 178.3570, 178.3620, 178.3740 and 178.3910). Under 21 CFR 573.680, mineral oils may be used in animal feed for the following purposes, so long as the quantity of mineral oil used in the animal feed does not exceed 3.0 percent in mineral supplements and 0.06 percent of the total ration when present in feed or feed concentrates:

- to reduce dustiness of feeds or mineral supplements;
- to serve as a lubricant in the preparation of pellets, cubes, or blocks and to improve resistance to moisture of such pellets, cubes, or blocks;
- to prevent the segregation of trace minerals in mineralized salt;
- to serve as a diluent carrier in the manufacture of feed grade biuret (nitrogen-based feed additive similar to urea) in accordance with good manufacturing practice;
- for the removal of water from substances intended as ingredients of animal feed.

Mineral oil products are considered unapproved animal drugs according to FDA regulations. Animal drugs containing mineral~~s~~ oils—such as AgriLabs Mineral Oil Light and UNAVET Mineral Oil Light NF—are currently marketed for relief of obstruction or impaction of the intestinal tract in cattle, sheep, goats, swine and horses (AgriLabs, 2014; UNAVET, 2010). Because these animal drugs are not FDA approved, the labels carry the disclaimer: "this drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA." FDA has yet to take regulatory action against these mineral oil products or require safety and efficacy testing for animal drugs containing mineral oil.

Action of the Substance:

In addition to lubrication, the viscous nature of mineral oils can be used for the control of external parasites in conventional and organic livestock production. Like other animals, livestock parasites such as mange mites, lice, ticks and various insect species require oxygen to survive. Mineral oils suffocate these pest organisms by clogging the pores that deliver oxygen to cells throughout their bodies (Pedretti, undated; Pedretti, 2014). This mode of action is considered physical rather than chemical control of external parasites.

When used as a medical treatment in conventional production, mineral oils serve as physical lubricants for obstructions of the digestive tracts of livestock animals. Mineral oil is typically administered orally to treat intestinal blockages. The viscous nature of mineral oil lubricates the intestinal tract to provide physical relief for various forms of intestinal impaction in ruminants and other forms of livestock (USDA, 2002). As a constipation treatment, mineral oil softens fecal contents by lubrication and retardation of water absorption (Gal-Ezer & Shaoul, 2006). Mineral oil also lines the gut of treated animals, thereby reducing the re-absorption of toxins and suppressing the excessive fermentation and putrefaction occurring in the duodenum, jejunum and ileum of ruminants ~~during~~ when afflicted with diarrhea (USDA, 2002).

Combinations of the Substance:

As a mixture of compounds, mineral oils can be described as combinations of several different types of hydrocarbon oils. Mineral oil mixtures used as lubricants and external parasiticides are not combined with other substances due to their specific use patterns in organic livestock production. Additionally, mineral oils are rarely combined with other substances when used as the active ingredients in pesticide products for conventional crop production due to their limited water solubility and compatibility issues (USDA, 2002). Of the 117 EPA-registered pesticide products using mineral oil as the active ingredient, only one product—SA-50 Brand Malathion-Oil Citrus & Ornamental Spray insecticide—is co-formulated with another substance. Specifically, this product contains malathion (organophosphate insecticide) and refined mineral oil at five and 75 percent, respectively (US EPA, 2014). Mineral oil larvicides (e.g., Bonide and Kontrol Mosquito Larvicides) are applied directly to water without prior mixing, while mineral oil fungicides for turf grass, such as Civitas One, are mixed with water prior to application (Bonide Products Inc, 2010; Univar USA Inc, 2011; Pedro-Canada, 2012). The label for Civitas One also indicates that, when preparing tank mixes, mineral oil should not be combined with propiconazole, chlorothalonil, DMI fungicides or iron-containing products due to the potential for phytotoxicity in treated vegetation.

Status

Historic Use:

Mineral oils have been used in conventional agriculture for over a century. As an active substance, mineral oils are administered orally to clear obstructions of the digestive tract in livestock animals and applied externally to kill parasites such as lice and mites. Conventional livestock producers using back rubbers commonly mix an insecticide (e.g., coumaphos, permethrin or phosmet) with a "good grade" of mineral oil to allow cattle to treat themselves for pasture flies, hornflies and face flies when loafing and scratching (Townsend, undated). The available information does not indicate how long mineral oils have been used in livestock production for these purposes; however, it is likely that these use patterns began in the early- to mid-twentieth century. Spray oils, including petroleum oils, have been utilized for insect control on crops and trees for over 130 years. Post-harvest uses of mineral oils on corn and sorghum to combat storage insect infestation were included in a tolerance petition in the 1950s (US EPA, 2007).

Organic Foods Production Act, USDA Final Rule:

Synthetically produced livestock parasiticides and drugs are eligible for use in organic production due to their listing in Section 2118 of the Organic Foods Production Act of 1990 (OFPA). Specifically, the OFPA states that the National List may allow the use of substances that would otherwise be prohibited under organic regulations (i.e., synthetics) if the substance contains an active ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps, and seals, insect traps, sticky barriers row covers, and equipment cleaners" (OFPA 2118(c)(B)(i)).

The National Organic Program final rule currently permits the use of mineral oil in organic livestock production for topical use and as a lubricant (7 CFR 205.603(b)(6)). Mineral oil acts as an external parasiticide when topically applied to infested animals. In addition, mineral oil dislodges intestinal obstructions in cattle when administered orally; however, mineral oil is not approved for oral use in organic production. Horticultural oils, including dormant, suffocating and summer oils, are highly refined petroleum oils that are allowed as insecticides (7 CFR 205.601(e)(7)) and plant disease control agents/fungicides (7 CFR 205.601(i)(7)) in organic crop production. Due to its inclusion on EPA List 4A, white mineral oil (CAS# 8042-47-5) is an allowed synthetic inert ingredient for use with nonsynthetic substances or synthetic substances listed in section 205.603 of the National List (7 CFR 205.603(e)(1); US EPA, 2004). White mineral oil (CAS# 8012-95-1) is also an allowed excipient for use in the manufacture of animal drugs since it is FDA approved for addition to food (7 CFR 205.603(f); FDA, 2013).

International

All of the international organizations surveyed have provided guidance on the use of mineral oil in organic production. Among these are regulatory agencies (Canada, EU and Japan) and independent organic standards organizations (Codex and IFOAM). International organic regulations and standards concerning mineral oil are described in the following subsections.

Canadian General Standards Board

Canadian regulations permit numerous uses for mineral oils of varying purity. Mineral oils are allowed for external application only under Section 5.3 (health care products and production aids) of the permitted substances list for livestock production (CAN, 2011). Section 4.3 (crop production aids and materials) of the permitted substances list for crop production includes summer oils for use on foliage as suffocating or stylet oils. In addition, this section of the permitted substances list allows the use of dormant oils as sprays on woody plants only (CAN, 2011). Summer oils and stylet oils are refined to highly refined mineral oils that contain only small amounts of unsaturated hydrocarbons such as PAHs, while dormant oils are only mildly refined and thus have higher unsaturated hydrocarbon content (Bográn, 2006).

Codex Alimentarius Commission

The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (CAC/GL 32-1999) indicate that mineral oil is only permitted for use in traps for organic crop production. Specifically, Section 5 of Table 2 (substances for plant pest and disease control) states that mineral oil may be used in traps when the need is recognized by the certification authority (Codex, 2013).

European Union

According to Annex II of the European Organic Regulation (EC) No 889/2008, mineral oil may be used as an insecticide and/or fungicide only in fruit trees, vines, olive trees and tropical crops (e.g., bananas). Use of substances listed in Annex II is subject to the requirements of Article 5 of the regulation, which states that "where plants cannot be adequately protected from pests and diseases by measures provided for in Article 12 (1)(a), (b), (c) and (g) of Regulation (EC) No 834/2007, only products referred to in Annex II to this Regulation may be used in organic production" (EC, 2008).

Japanese Ministry of Agriculture, Forestry and Fisheries

Japanese regulations for the organic production of livestock only mention the use of "petroleum oil aerosol" and "petroleum oil emulsion" for plant pest and disease control (Table 2). Otherwise, it does not appear that Japanese organic regulations permit the use of mineral oil or related products in organic livestock production (JMAFF, 2012).

International Federation of Organic Agriculture Movements

The IFOAM Norms permit the use of "light mineral oils (paraffin)" under Appendix 3 (crop protectants and growth regulators). There are no approved uses for mineral oils or related substances in organic livestock production under the IFOAM Norms (IFOAM, 2014).

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

<u>Evaluation Question #1: Indicate which category in OFPA that the substance falls under:</u> (A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?

(A) Mineral oil is used in organic livestock production as an externally applied pesticide to combat livestock parasites (e.g., lice and mites). In addition, it may also be used as a medical treatment for intestinal impaction in cattle, sheep and other ruminants.

(B) White mineral oil (CAS# 8042-47-5) is included on US EPA's 4A list of Minimal Risk Inert Ingredients (US EPA, 2004). In addition, residues of mineral oil are exempt from the requirement of a tolerance when used as an inert ingredient in pesticide formulations applied to growing or harvested crops (40 CFR 180.910) and directly to animals (40 CFR 180.930).

<u>Evaluation Question #2:</u> Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Petroleum in the form of crude oil is the primary natural resource used for the production of mineral oil. The constituents of petroleum range from light-colored oils containing mostly small hydrocarbon chains (i.e., C1–C12) commonly observed in gasoline to dark, viscous, asphalt-like substances composed of longer chain hydrocarbons (i.e., ≥ C40). In order to obtain mineral oil from this extremely complex mixture of hydrocarbons, the crude oil must be sent through several processing units comprising modern oil refineries (Wright, 2012). The first stage of crude oil processing occurs in the desalting unit, where water washes salt from the crude oil before it proceeds to the distillation units (Wright, 2012; EFSA, 2012). From this point, the desalted crude oil proceeds through a series of sequential distillations to separate different boiling fractions. The captured mineral oil fractions are subsequently purified using a combination of processing strategies, including solvent extraction, catalytic hydrocracking and/or wax removal (Wright, 2012; EFSA, 2012). Details on the various distillation methods of crude oil and both refinement routes are provided in the following sub-sections.

It is difficult to predict the general hydrocarbon composition and degree of purification for commercially available mineral oil mixtures without an associated CAS number. According to US EPA, "some of these CAS Numbers have very similar components, because different CAS Numbers may represent petroleum distillates which are very closely related to each other, since the assigning of CAS Numbers for petroleum distillation products…is based on the last step in the refining process" (US EPA, 2007). As a result, nearly identical mineral oil mixtures—conceivably produced via alternative refining pathways—will have different CAS numbers despite being essentially identical in composition and/or level of purity. US EPA (2007) also noted the following based on discussions with manufacturers of mineral oil products:

> *Discussions…indicated that many registrants have converted their processes to produce [Technical Grade Active Ingredients] and to formulate end-use products which have lower amounts of undesirable components (i.e., with lower amounts of sulfur- and nitrogen-containing groups [as measured by higher Unsulfonated Residues (UR)], and with fewer side-chains containing polynuclear aromatic hydrocarbons (PAHs)). These sulfur- and nitrogen-groups and the PAHs have been found to produce phytotoxicity, formerly a cause for concern among growers using these spray oil products.*

Distillation

Crude oil is separated into high value products (e.g., gasoline, diesel and kerosene), mineral oils/lubricating oils, and asphalt materials through a series of distillation steps. The first distillation step takes place in the atmospheric distillation unit, where crude oil is distilled at atmospheric pressure into several fractions, the final of which has boiling points as high as 370 ºC (EFSA, 2012). Lower boiling fractions from the atmospheric distillation are further processed for the production of gasoline and other fuel oils. Higher boiling fractions, which contain higher molecular weight hydrocarbon compounds, are then taken to the vacuum distillation unit for additional separation. Operating at a reduced pressure of 0.1 bar, the vacuum distillation unit separates the high boiling fraction—commonly known as "residual bottoms"—into several different fractions, including the volatile hydrocarbons, light vacuum distillate and heavy vacuum distillate (EFSA, 2012). The heavy residue containing the asphaltic material does not distill under these conditions and is left behind. In some refineries, desalted crude oil is taken directly to a distillation unit operating slightly above atmospheric pressure for separation of the hydrocarbons based on boiling point (and therefore molecular weight). Fractions containing C11–C13 hydrocarbons are processed into kerosene and jet fuel, while diesel and gas oils are derived from C14–C25 fractions. Higher boiling fractions consisting primarily of C26–C40 hydrocarbons are used in the production of mineral oils and lubricating oils for a variety of applications (Wright, 2012).

The distillate fractions relevant to mineral production consist of paraffins (normal, linear alkanes), naphthenes (cyclic-substituted alkanes) and various aromatic hydrocarbons. Paraffin and naphthene are the preferred compound classes for mineral oil uses (Mackerer, 2003). In contrast, aromatic hydrocarbons are considered undesirable components because these species are oxidatively unstable and cause sludge formation; alter the viscosity index; and contain nitrogen, sulfur and metallic impurities. Further, the aromatics with three to seven fused rings are known to be carcinogenic agents (Mackerer, 2003). Processing of the distilled oil fractions is required to reduce the content of these undesired aromatic compounds.

Refinement

Following distillation, the higher boiling fractions corresponding to crude mineral oils require further processing and refinement prior to use. Two refinement routes are used in modern refineries: extraction and refinement. The first involves a separation process forming the desired mineral oil as well as undesired byproducts consisting largely of aromatic hydrocarbon compounds. Alternatively, the conversion process chemically transforms the undesirable aromatic structures into desirable structures with the use of molecular hydrogen, heat and pressure in the presence of a catalyst (Wright, 2012). Both of these refinement processes typically include a subsequent dewaxing step to produce mineral oils with desired low temperature properties such as fluidity.

Solvent Extraction. Mineral refinement has traditionally involved solvent extraction, while more recently developed techniques utilize catalytic conversion of the undesired aromatic hydrocarbons. The solvent extraction unit physically separates the aromatic hydrocarbons as well as other compounds of higher polarity from the crude mineral oil mixture. Solvents used for the extraction step are completely or mostly immiscible with saturated hydrocarbons, and commonly consist of phenol, furfural and sulfur dioxide, sulfolane and/or N-methylpyrrolidone (Wright, 2012; EFSA, 2012). In general, about one-third of the original aromatic content and only a few percent of the initial polynuclear aromatic hydrocarbon (PAH) content remain in the solvent extracted mineral oil.

Dearomatization. Subsequent dearomatization processes can be used to further process the solvent extracted oils (EFSA, 2012). In this higher-level refinement, the feedstock obtained from the first solvent extraction is treated with sulfur trioxide or fuming sulfuric acid in a stirring reactor. These reagents react with the aromatic hydrocarbons to yield arylsulfonic acids and any remaining S-, N-, and O-containing molecules are decomposed, oxidized or neutralized. Following the reaction, the mixture separates into a hydrocarbon layer and a sulfuric sludge layer containing most of the water-soluble sulfonic acids and by-products (EFSA, 2012). The layers are separated, and the oily layer containing oil-soluble sulfonic acids neutralized with an aqueous alkaline reagent (e.g., sodium hydroxide or potassium hydroxide) and subsequently extracted with alcohol (ethanol or propanol). Dearomatization must be repeated several times to quantitatively remove the aromatic hydrocarbon content (EFSA, 2012).

Hydrocracking. Catalytic hydrocracking is an alternative refinement strategy utilized as part of the conversion process. Here, crude mineral oil is subjected to a chemical reaction with molecular hydrogen (H_2) in the presence of a catalyst at high temperatures and pressures (420 ºC and 3,000 psi). The aromatic and naphthene rings are broken, opened and chemically combined with other carbon fragments using hydrogen to form an isoparaffin (branched alkane) structure. Additionally, processing/purifying the resulting crude reaction mixture aids in the removal of water, ammonia and hydrogen sulfide from the desired mineral oils (Wright, 2012).

Wax Removal

Mineral oil refinement may also include a dewaxing step. In the tradition solvent dewaxing process, the warm mineral oil mixture is diluted with an anti-solvent of waxes, blended and progressively cooled (EFSA, 2012). This process induces the selective crystallization of waxes, thereby removing these undesired chemical components from the mineral oil mixture. The slurry of wax crystals in liquid mineral oil is then filtered to facilitate separation. Typical dewaxing solvents include light ketones, LPG, toluene, and/or a blend of these solvents (EFSA, 2012). Alternatively, the catalytic hydrodewaxing process removes waxes through selective hydrocracking of linear molecules over a micro-porous, shape-selective catalyst at high temperature (300 to 360 ºC) and under moderate to high hydrogen pressures. Commonly employed catalysts include aluminosilicates (e.g., mordenite) or zeolites designed with controlled pore sizes, sometimes in combination with promoters such as platinum metal (EFSA, 2012).

Evaluation Question #3: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

According to USDA organic regulations, the NOP defines synthetic as "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources" (7 CFR 205.2). The industrial production of highly refined, food-grade mineral oils involves chemical processing and refinement using various chemical reagents and/or catalysts. Specifically, crude oil is desalted, distilled and subjected to solvent extraction, dearomatization with fuming sulfuric acid or sulfur trioxide, and/or catalytic hydrocracking treatments to reduce the concentration of polar constituents containing heteroatoms (nitrogen, oxygen and sulfur atoms) as well as polynuclear aromatic hydrocarbons (PAHs) and other aromatic compounds (EFSA, 2012; Wright, 2012). Crude oil is considered an economically significant natural resource throughout the world, and would likely be classified as a naturally derived, non-synthetic substance according to NOP definitions. To produce mineral oil, the chemical composition of natural crude oil is altered through physical separation (distillation) followed by reactions/combination with synthetic substances and reagents (aromatic solvents, strong acids and/or catalysts). Mineral oil is therefore considered a synthetic material. As such, the NOSB classified mineral oil as "synthetic" since initially recommending addition of the substance to the National List (USDA, 2002).

<u>Evaluation Question #4:</u> Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

A wide range of carbon chain lengths, molecular weights and chemical/physical properties define the constituent compounds comprising mineral oil mixtures. As a result, descriptions concerning the environmental fate and transport characteristics for mineral oil require some degree of generalization. Vapor pressures for mineral oils exhibit a very wide range—from somewhat volatile to very poorly volatile (10^{-3} to 10^{-14} mm Hg)—due to spread of molecular weight components in these oily mixtures. In general, the octanol-water partition coefficients (K_{ow}) are high, with log K_{ow} values ranging from about 5 to 20, for smaller- to larger- chain length (i.e., lower to higher molecular weight) hydrocarbon molecules (US EPA, 2007). These components are therefore also likely to have high organic carbon normalized soil-water partition coefficients (K_{oc}), indicating a high degree of sorption to the organic matter in soils and foliar surfaces onto which they are sprayed. The constituents are also very poorly soluble in water, with water solubility values ranging from 0.001 to 0.6 mg/L (practically insoluble to minimal solubility). When combined, these sorption and solubility characteristics suggest very modest migration of mineral oils in the dissolved phase of water. This conclusion has been confirmed through modeling, which showed that most mineral oil components would partition to the terrestrial phase and remain sorbed to soil or foliar surfaces (US EPA, 2007). Based on the available bioconcentration data, the hydrocarbon components of mineral oils demonstrate little tendency for bioaccumulation in fish and other animals (ATSDR, 1997).

Photodegradation and hydrolysis are not expected to be important degradation pathways for mineral oils. Aliphatic oils do not contain functional groups that are sensitive to radiation in the ultraviolet or visible light ranges. Alternatively, aromatic components—such as polynuclear aromatic hydrocarbons (PAHs) and hydrocarbons with aromatic side chains—have photosensitive groups that undergo direct photolysis (US EPA, 2007). Most mineral oil manufacturers now produce products with substantially reduced amounts of aromatic components (US EPA, 2007), which suggests that photodegradation is not the predominant breakdown pathway for mineral oils used in organic livestock production as external parasiticides and lubricants. In addition to being poorly soluble in water, mineral oils do not contain functional groups that are susceptible to hydrolysis in aqueous suspension (US EPA, 2007).

Microbial degradation is generally considered the primary breakdown pathway for the hydrocarbons in mineral oil mixtures released to soils. Most of the oils used in pesticide formulations—including petroleum-based mineral oil mixtures used in organic livestock production—are substantially degraded in laboratory tests, but the rate of degradation in the terrestrial and aquatic environment is dictated by metabolic capacity of microorganisms at the release site (Cornish, 1993). The biodegradation rates of paraffins (linear alkanes) are significantly higher than those of naphthenic (cyclic substituted alkanes) and aromatic hydrocarbons (Haus, 2001). As a result, mineral oils containing significant amounts of aromatic and naphthenic components degrade more slowly compared to mineral oils of higher paraffinic composition. Highly refined mineral oils that were catalytically hydrocracked and/or solvent dewaxed and solvent extracted to remove aromatics and polar compounds are generally degraded by approximately 75% of the original amount within 21 days under pseudo environmental conditions (Haus, 2001). Refined mineral oils are therefore considered moderately persistent in soil and water with active microbial populations. Although the environmental impacts are less severe for refined mineral oils, large volume spills of these substances may require bioremediation, especially in areas with less active microbial populations (Aluyor & Ori-jesu, 2009).

Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

Mineral oils may be classified as highly refined or mildly treated/untreated. The white mineral oils that are likely to be used for lubrication and external parasite control in organic livestock production are highly refined oils that contain negligible quantities of toxic contaminants compared to untreated and mildly treated oils. This section provides summaries of the available toxicology literature on mineral oils for terrestrial and aquatic taxa, with an emphasis on the potential toxicity of highly refined mineral mixtures.

Testing in laboratory animals has demonstrated that mineral oils are slightly to practically non-toxic to mammals on an acute exposure basis. Mineral oils are mild irritants, classified as Toxicity Category IV (lowest toxicity) for skin irritation and Category III for eye irritation (US EPA, 2007). Highly refined "white" mineral oils produced no sensitization reactions in guinea pigs repeatedly exposed to the substance as part of oil company research (Mahagaokar, 1996) and pesticide registrant-submitted studies (US EPA, 2007). Therefore, US EPA has not classified mineral oils as dermal sensitizers. According to laboratory studies in rats and rabbits, mineral oils are practically non-toxic (Toxicity Category IV) via the oral route of exposure, with an oral LD_{50} value (dose lethal to 50% of test subjects) of greater than 28,000 mg/kg in rats (US EPA, 2007). Air concentrations of mineral oil mist at 3.9 mg/L resulted in death for 50% of rats (LC_{50}) in an inhalation toxicity study. US EPA (2007) noted that the slight inhalation toxicity (Toxicity Category III) observed in the latter study is likely related to physical irritation from exposure to foreign material and not necessarily due to systemic chemical toxicity. Lastly, mineral oils have low acute systemic toxicity and are classified as Toxicity Category IV for dermal exposure, with an LD_{50} value of greater than 5,000 mg/kg in rats (US EPA, 2007).

Despite the low level of acute toxicity associated with mineral oil exposure, these substances may exert more significant toxic effects following repeated exposure events. In a developmental toxicity study, a sample of white mineral oil was administered to female Sprague-Dawley rats at doses of 0 or 5,000 mg/kg body weight per day for days 6 through 19 of gestation (EFSA, 2012). No reproductive or developmental toxicity was observed during the course of this study. A related reproductive/developmental toxicity study in which males (30 day exposure) and females (39 day exposure) were administered refined mineral oil by oral gavage (1,000 mg/kg-day) showed no treatment-related effects on pup body weights, sex ratios, live litter sizes, viability indices, and general physical conditions (EFSA, 2012). In a chronic exposure study, paraffinic and naphthenic mineral oils and waxes were observed to accumulate in a dose-related fashion in the liver and mesenteric lymph note (MLN) following 90-day (sub-chronic) exposure via gavage (force feeding) in Fischer 344 rats (EFSA, 2012). In some cases, mineral oil accumulation in the liver led to histopathological changes classified as granulomas or microgranulomas, which consisted of focal aggregations of macrophages surrounded by inflammatory cells and occasionally necrotic cells and fibrosis. The available literature suggests that the MLN histocytosis is a non-specific, adaptive effect observed with higher molecular weight and poorly absorbed materials, and will not likely progress to more severe pathological effects following long-term exposure. Further, the effects in Fischer 344 rats dosed with white mineral oil mixtures have not been observed in other species or rat strains, such as Sprague-Dawley rats (EFSA, 2012).

The carcinogenicity and genotoxicity potential for mineral oils is generally dependent upon the degree of refinement and presence of PAHs in the mixture. White mineral oils—which have undergone the most severe acid, solvent or hydrocracking treatment—showed no activity in a series of skin-tumor bioassays (IARC, 2012). In addition, single injections of the substance under the skin of mice induced no treatment-related tumors during the following 18 months. Direct injection of highly refined food-grade mineral oils into the body cavities of certain strains of mice induced plasma-cell neoplasms and reticulum-cell sarcomas (IARC, 2012). In contrast, repeated exposure to untreated/mildly treated mineral oil mixtures is associated with the occurrence of skin, stomach, bladder and scrotal cancer in animals and humans (IARC, 2012). Less refined mineral oil preparations containing PAH constituents with greater than three aromatic rings were carcinogenic when applied to the shaved skin of mice (EFSA, 2012). For example, such treatments have resulted in the appearance of cutaneous epithelial tumors (e.g., papillomas, squamous cell carcinomas or sebaceous adenomas). Untreated/mildly treated mineral oils are also capable of changing the structure of DNA; in fact, results from a series of *Salmonella typhimurium* assays (AMES tests) indicate that unrefined mineral oils are weakly mutagenic (EFSA, 2012). In general, experts have identified the alkylated and non-alkylated aromatics of three to seven fused rings as the causes of genotoxicity and mutagenicity of mineral oil mixtures (EFSA, 2012).

Much like the mammalian studies, the results of avian and honey bee studies suggest that refined mineral oils are practically non-toxic to birds and honey bees via acute oral and contact exposure, respectively. No mortality was observed at the highest dose tested for mallard ducks and bobwhite quail (LD_{50} greater than 2,250 mg/kg); however, subacute studies in birds have shown effects, including reduced reaction to external stimuli and increased incidence of toe picking at high concentrations (1,000 ppm) of refined mineral oil in food (US EPA, 2007). In addition, pesticide registrant submitted data reports indicate that certain types of oils have caused smothering when tested on bird eggs. Based on the approved use pattern for mineral oil in livestock production, it is highly unlikely that the substance will impact bird eggs in the local environment. Honey bee acute contact toxicity studies using three mineral oil formulations revealed no treatment-related effects, providing LD_{50} values ranging from greater than 25 to greater than 1,830 µg/bee (US EPA, 2007). With regards to invertebrates, mineral oils are toxic to insects through contact exposure, disrupting gas exchange (respiration) as well as their ability to fly and feed on plant surfaces covered with oil (Bográn, 2006). Only targeted mites and lice (i.e., external parasites) should be subject to the toxic effects of mineral oil based on the approved use pattern in organic livestock production.

Refined mineral oils are generally characterized as minimally toxic to aquatic organisms on an acute exposure basis. These oils are non-toxic to fish, with essentially no mortality observed in any of the nine fish species exposed to mineral oils in laboratory studies. Statistically significant reduction of shell deposition was observed in 50% of test organisms at 5.57 mg/L in a 96-hour oyster toxicity study. US EPA (2007) proposed that this effect is potentially due to the formation of mineral oil coatings on algal materials, which renders the oysters less able to break down and utilize these important food sources. No lethal effects were observed in the aquatic invertebrate *Daphnia magna* (freshwater water flea) exposed to mineral oil pesticide formulations (LC_{50} greater than 14 mg/L), but other effects such as floating and immobilized organisms were noted (US EPA, 2007). In sufficiently high concentrations, petroleum oils block oxygen diffusion and suffocate aquatic life.

<u>Evaluation Question #6:</u> Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

As stated in the response to Evaluation Question #4, the hydrocarbon constituents of mineral oils do not degrade via hydrolysis or photolysis, and are generally slow to biodegrade in the environment (US EPA, 2007; Haus, 2001). As a result, mineral oil residues from large volume spills may persist in the environment for significant periods of time following an accident. On the other hand, large-scale environmental exposure and contamination is unlikely for normal use of mineral oil in organic livestock production as an external parasiticide and lubricant. Mineral oil contaminants are not generally detected in plant materials; however, mineral oil hydrocarbons at concentrations of 20 to 800 mg/kg have been detected in the fat of marine and freshwater fish, even in areas that have not recently experienced an oil spill (EFSA, 2012). Interestingly, laboratory bioconcentration studies in fish suggest the potential for only limited bioaccumulation in aquatic animals (ATSDR, 1997).

Large volume spills of oils are also responsible for the formation of hypoxic (oxygen deficient) dead zones in the receiving waterways. Specifically, oil slicks on the surfaces of waters are capable of restricting the natural processes of mixing atmospheric oxygen into the water column as a means of replenishment. In addition, aquatic microorganisms that degrade mineral oil hydrocarbons consume oxygen, thus leading to further oxygen depletion from the water body (NOAA, 2010). Large volume spills of mineral oil to the soil could also result in long-term contamination of local groundwater sources based on laboratory studies (Duffy, 1980). Mineral oils are likely to be more persistent in this context since biodegradation processes are significantly lower in the anaerobic zone of the soil. The degree of environmental contamination discussed here for surface and groundwater would not be possible based on the volumes used in organic livestock production. These forms of environmental contamination are generally related to large-volume spills or ruptures of oil pipelines, which lead to the release of crude oil to the terrestrial and aquatic environments and generally require extensive bioremediation (USGS, 2014). As such, the only conceivable routes to large-scale environmental contamination with mineral oil hydrocarbons is through the procurement, transport and processing of the petroleum-based feedstock materials.

Aside from accidental releases of crude oil and processed mineral oils, the release of certain manufacturing reagents could be hazardous to the environment. Specifically, the use of highly reactive substances—including strong acids (e.g., fuming sulfuric acid) and sulfur trioxide—during the dearomatization of crude mineral oil mixtures could lead to environmental impairment if improperly handled and/or released to the environmental untreated in waste streams (EFSA, 2012). Both of these substances are primary contributors to the formation of corrosive acid rains that result in degradation of urban and rural environments (ATSDR, 1998). Additionally, sulfur trioxide is a strong oxidizer, which enhances the combustion of other substances, and inhalation exposure may result in the development of lung and larynx cancer due to the formation of sulfuric acid (ATSDR, 1998; NJDH, 2008). Despite these concerns, IARC (2012) noted that "in recent decades, acid treatment has largely been replaced by extensive refining with solvent extraction and/or hydro-treatment, which has further reduced the level of PAHs and other contaminants." This suggests that few manufacturers currently utilize sulfuric acid and sulfur trioxide for mineral oil finishing.

<u>Evaluation Question #7:</u> Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

A small number of chemical interactions have been identified for mineral oils. Of specific relevance to livestock production, research has indicated that ingested mineral oils may interfere with the absorption of fat-soluble vitamins (USDA, 2002). Indeed, FDA (21 CFR 201.302) consider the consumption of drugs containing mineral oils to be potentially problematic for maintaining levels of these essential nutrients:

> *Studies have indicated that when mineral oil is used orally near mealtime it interferes with absorption from the digestive tract of provitamin A and the fat-soluble vitamins A, D, and K, and consequently interferes with the utilization of calcium and phosphorus, with the result that the user is left liable to deficiency diseases. When so used in pregnancy it predisposes to hemorrhagic disease of the newborn.*

However, an examination of human case studies suggests that even massive overdoses of mineral oil for a period of approximately five months do not have a significant impact of vitamin A, D, E and K levels in treated subjects. It is therefore possible that the reduction in serum concentrations of fat-soluble vitamins observed in other studies is only a temporary effect associated with beginning a mineral oil treatment regimen. In addition to decreasing the absorption of vitamin K, which promotes the synthesis of proteins that help control bleeding (i.e., clotting factors), mineral oil ingestion may also interfere with the absorption of oral anticoagulant drugs (HSDB, 2005; Johnson, 2014). Lastly, the MSDS for a commercially available livestock impaction treatment indicates that the mineral oil active ingredient has the potential to react with chlorine, fluorine and other strong oxidizing agents (Avatar Corporation, 2010).

<u>Evaluation Question #8:</u> Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).

When released to the agro-ecosystem, mineral oil hydrocarbons can have a variety of effects on non-target soil organisms. Mineral oil sprays are effective insecticidal treatments for soft-bodied insects, including those with and without exoskeletons (Bográn, 2006). Specifically, mineral oils (and other oily substances) suffocate insects, mites and other related organisms by clogging the pores that deliver oxygen to cells throughout their bodies (Pedretti, 2014). This insecticidal mode of action suggests that large releases of mineral oils to soils would be problematic for non-target soil organisms, such as earthworm, grubs and nematodes. Indeed, one laboratory study demonstrated that treatment of lagoon sediment with either mineral oil or a synthetic lubricant resulted in significantly decreased nematode abundance, species richness and number of species present (Beyrem, 2010). Alternatively, a variety of soil microorganisms—such as the bacterial strains *Bacillus subtilis* and *Bacillus cereus* —are capable of enzymatically biodegrading mineral oils in soils, utilizing these substances as sources of carbon and hydrogen for biosynthesis (Aluyor & Ori-jesu, 2009). The white rot fungus *Polyporus* sp. S133 and fungal species isolated from cow dung and poultry droppings are also capable of breaking down and utilizing crude oil (Hadibarata & Tachibana, 2009; Obire, 2008). Information is not readily available regarding the impacts of mineral oil exposure on bacterial and fungal species unable to metabolize these substances.

Some of the reagents used to manufacture refined mineral oil mixtures may also adversely impact the composition and properties of soils if accidentally released to ecosystems. Of particular concern are highly acidic and alkaline waste streams resulting from the use of sulfuric acid, sulfur trioxide and alkaline substances (e.g., sodium hydroxide and potassium hydroxide) in the dearomatization process (EFSA, 2012). Introduction of highly acidic or alkaline solutions to the agro-ecosystem could drastically alter soil pH, thereby adversely impacting the ability of affected soils to support plant life and other soils organisms. Although such releases are possible, producers of hazardous substances (e.g., manufacturers and laboratory facilities) are required to neutralize and ensure proper disposal of production wastes according to applicable local, state and/or federal laws. Risks associated with highly acidic or alkaline waste streams are also minimized due to the increased adoption of catalytic hydrocracking over acidic dearomatization methods for mineral oil processing and refinement (IARC, 2012).

Little information is available regarding the potential or actual impacts of mineral oil contamination upon endangered species, population, viability or reproduction of non-target organisms and the potential for measurable reductions in genetic, species or eco-system biodiversity. However, the report discussed above concerning nematode exposure in microcosm experiments indicates that contamination of natural nematode ecosystems with mineral oil may lead to contracted populations as well as loss of species diversity and richness (Beyrem, 2010).

Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

The natural feedstock for mineral oil is petroleum, primarily in the form of crude oil. To produce commercial mineral oils, the crude oil is first desalted and distilled to generate distillate fractions based primarily on molecular weight. Mineral oils are obtained through processing and refining the higher boiling fractions consisting primarily of C26–C40 hydrocarbons (EFSA, 2012). Solvent extraction, dearomatization with fuming sulfuric acid or sulfur trioxide, and catalytic hydrotreatment methods are used to remove polar compounds containing heteroatoms (nitrogen, oxygen and sulfur atoms) and aromatics, including toxic polynuclear aromatic hydrocarbons (PAHs). Of these methods, only the dearomatization process presents the potential for environmental impairment. Sulfuric acid and sulfur trioxide are primary contributors to the formation of corrosive acid rain that result in degradation of urban and rural environments (ATSDR, 1998). In addition, sulfur trioxide is an oxidizing agent that enhances the combustion of other substances, and repeated inhalation exposure may result in the development of lung and larynx cancer due to the formation of sulfuric acid (ATSDR, 1998; NJDH, 2008). Manufacturers are increasingly replacing acidic dearomatization with solvent extraction and/or hydrotreatment to refine crude mineral oils (IARC, 2012), thereby reducing the environmental contamination potential for the production process.

When released to the environment, mineral oil hydrocarbons are moderately persistent and generally partition to soils and suspended solids. As highly non-polar substances, the hydrocarbons in mineral oil mixtures are very poorly soluble in water. The octanol-water partition coefficients are high (log K_{ow} = 5–20), further suggesting that mineral oil hydrocarbons will adsorb to the organic matter in soils and exhibit limited mobility in water (US EPA, 2007). The available bioconcentration data points to minimal bioaccumulation of mineral oils in fish and other animals (ATSDR, 1997). Photodegradation and hydrolysis are not expected to be important environmental fate pathways for mineral oils due to the absence of reactive functional groups in the chemical structures of hydrocarbons (US EPA, 2007). Instead, microbial degradation is recognized as the primary break down pathway for hydrocarbons in mineral oil mixtures. Mineral oils containing significant amounts of aromatic and naphthenic components (e.g., mildly treated and untreated mineral oils) biodegrade more slowly than more highly refined paraffin-based mineral oils, which were 75% degraded within 21 days in laboratory analyses (Haus, 2001).

Highly refined, food-grade mineral oils are slightly toxic to practically non-toxic to mammals, birds, honey bees and several aquatic organisms. Insects, mites and worms are particularly sensitive to treatment with mineral oils. Indeed, oily substances suffocate these organisms by clogging the pores that deliver oxygen to cells throughout their bodies (Pedretti, 2014). A recent study also demonstrated that the introduction of mineral oil to lagoon sediment reduced nematode abundance, species richness and number of nematode species in the local environment (Beyrem, 2010). In addition to the proposed mode of action, the latter result suggests that large releases of mineral oil to soils could adversely impact populations of non-target soil organisms, such as earthworms, grubs and beneficial nematodes. In addition, large volume spills of oils are responsible for the formation of hypoxic (oxygen deficient) water bodies incapable of supporting fish and other aquatic life. Oil slicks on the surfaces of waters generate these dead zones by restricting the natural processes of mixing atmospheric oxygen into the water column and acting as energy sources for aquatic microorganisms that further deplete the supply of dissolved oxygen (NOAA, 2010). Large-volume spills of petroleum products to soil are also capable of contaminating local groundwater sources and aquifers (Duffy, 1980).

<u>Evaluation Question #10:</u> Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Mineral oils are mildly irritating to the skin and eyes of humans and other mammalian species. Materials Safety Data Sheets (MSDS) for mineral oil products therefore recommend the use of safety glasses and protective clothing when using the substance. The MSDS also states that users should avoid breathing mineral oil mists (Avatar Corporation, 2010), presumably due to the potential for aspiration of the substance into the lungs and subsequent chemical inflammation of the lung tissues (US EPA, 2007). Repeated inhalation of oil mists may also result in irritation to the nose and throat (Avator Corporation, 2010). Refined mineral oils are considered slightly toxic to practically non-toxic to humans via the oral, inhalation and dermal exposure routes based on comparisons to laboratory studies conducted using experimental animals. Because refined mineral oils exhibited no lethal or other adverse effects in animal studies, US EPA did not determine an acute human Reference Dose (RfD) for the substance (US EPA, 2007). Likewise, the available data suggests that repeated oral and dermal exposure to relatively high doses of mineral oil is not correlated with reproductive and developmental effects in mammals (US EPA, 2007).

The International Agency for Research on Cancer (IARC) has evaluated the carcinogenic potential for various mineral oil mixtures. Mineral oils are most problematic to human health in situations where oil mists are generated, potentially leading to substantial dermal and inhalation exposure. At-risk occupations include metalworking, printing-press operating and cotton- and jute-spinning (IARC, 2012). Experimental evidence indicates that mineral oils vary in their potential to cause cancer with the degree of treatment or processing. Solvent extraction and/or catalytic hydrocracking treatments reduce the PAH content, and thus the carcinogenicity of the refined mineral oils. Untreated/mildly treated mineral oils were implicated as human carcinogens based on evidence from a large number of case reports for skin cancer, particularly of the scrotum, in mule-spinners (i.e., operators of a machine used to spin cotton and other fibers), metal workers and other populations of industrial workers (IARC, 2012). Studies have also pointed to a correlation between mineral oil and a range of other cancers, including those of the larynx and pancreas, based on data for metal workers and related manufacturing occupations; however, similar studies showed no associations. There is also sporadic and inconsistent support for an association of mineral oil exposure with the incidence of bladder, stomach, rectal and lung cancer, among other tumor sites (IARC, 2012).

Untreated and mildly treated oils are carcinogenic to humans (Group 1), while highly refined mineral oils are not classifiable as to their carcinogenicity to humans (Group 3) (IARC, 2014). The latter phrase is used for highly refined mineral oils since the associated carcinogenicity data is insufficient to draw definitive conclusions due to the limitations in assessing exposure to these mineral oils as well as the lack of consistency in study findings by cancer site. IARC (2012) provided the following conclusion regarding the potential carcinogenicity of less refined mineral oils:

> *There is sufficient evidence in humans for the carcinogenicity of untreated or mildly treated mineral oils. Untreated or mildly treated mineral oils cause cancer of the skin (observed in the scrotum). There is sufficient evidence in experimental animals for the carcinogenicity of untreated vacuum distillates, acid-treated oils,*

> *and aromatic oils, including extracts from solvent treatment of distillates and the high-boiling fraction of catalytically cracked oils. There is sufficient evidence in experimental animals for the carcinogenicity of mildly hydrotreated oils. Untreated and mildly treated mineral oils are carcinogenic to humans (Group 1).*

According to the MSDS provided for a livestock AgriLabs mineral oil-based impaction treatment, "no component of this product present at greater than 0.1% is identified as a carcinogen by the U.S. National Toxicology Program, the U.S. Occupational Safety and Health Administration, or the International Agency for Research on Cancer (IARC)" (Avatar Corporation, 2010). Other mineral oil products used in organic livestock production are presumably of similar composition and carcinogenicity status. Based on the body of available scientific evidence and allowed use patterns, it is highly unlikely that human exposure to food-grade mineral oil mixtures used in organic livestock production would result in adverse health effects.

Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

A variety of naturally occurring (nonsynthetic) and synthetic substances are available for the treatment of intestinal impaction and external parasite infestations. The only ruminotorics (agents and mixtures that promote forestomach function) recommended for promoting the passage of fibrous materials through the omasal or abomasal compartments of ruminal digestive tracts are mineral oil, vegetable oils and dioctyl sodium sulfosuccinate (DSS). Intragastric administration of soybean oil, peanut oil and/or sunflower oil have been suggested as alternatives to mineral oil for lubrication of the omasum and treatment of bloat in ruminants (Dowling & Coetzee, 2012; Animal Welfare, 2014). DSS, on the other hand, is not approved for use in organic production and can adversely affect beneficial rumen protozoa populations (Dowling & Coetzee, 2012). The remainder of this section provides a summary of alternative substances for mineral oil external parasiticides in organic livestock production. See Evaluation Question #12 for a discussion of cultural practices that may preclude the use of mineral oils and other substances to treat external parasites and impaction in livestock.

A variety of control strategies are used to treat mange and mite infestations in sheep, goats, cattle and other forms of livestock. Most of the available treatments are performed through spray dipping or vat dipping, topical application of nonsystemic (no uptake and circulation in the body) acaricides, as well as oral, topical or injectable formulations of systemic drugs (Losson & Mignon, 2011). Although spray dipping is time consuming, the treatment method can be useful for small herds. Vat dipping, on the other hand, is time efficient, but fairly expensive and difficult to manage due to the large volumes of water used and the disposal requirement for waste wash solutions (Losson & Mignon, 2011). The following treatment regimens are commonly used for conventionally produced cattle in the United States: two dippings in 0.3% coumaphos (synthetic miticide) with no withdrawal time, two dippings in 0.2–0.25% phosmet (synthetic organophosphate insecticide/miticide) with a 21-day withdrawal time, and/or three dippings in 2% lime-sulfur (calcium polysulfides; formed through combination of hydrated lime and elemental sulfur) with no withdrawal time (Losson & Mignon, 2011). Only hot lime-sulfur is registered for use on lactating dairy cows. Injectible formulation of systemic parasiticides, including avermectins (i.e., ivermectin and doramectin) and milbemycins (moxidectin), are approved for control of psoroptic and sarcoptic mange at 200 μg/kg in non-lactating dairy cattle (Losson & Mignon, 2011). Likewise, sheep scab associated with various parasites can be treated with injections of ivermectin, doramectin or moxidectin, as well as acaricides administered as dips or sprays (CFSPH, 2009). The following paragraphs provide specific information for natural and synthetic materials used as external parasiticides in organic production.

Numerous natural, non-synthetic materials are used as mite repellents and/or miticides to control infestations of burrowing mites in organic livestock production. Vegetable oils may be applied to the skin of affected livestock to suffocate pests, including mites and insects. With the exception of mineral oil, petroleum based products such as kerosene and diesel are not allowed for use as external parasiticides (Macey, 2009). Mixtures of vegetable oils and essential oils (e.g., neem, anise, camphor, eucalyptus, pennyroyal, pine, rosemary and sassafras) are also used to control mites and lice on infested livestock (Macey, 2009; Pedretti, undated). Diatomaceous earth—a naturally occurring material composed of the fossilized remains of tiny, aquatic organisms called diatoms—is commonly used as an insecticidal and miticidal agent. The substance is not poisonous; rather, it absorbs the oils and fats from the cuticles of insect exoskeletons, causing the exposed insects to dry out and die (NPIC, 2013). Diatomaceous earth also has sharp, abrasive edges that pierce the exoskeletons of exposed insects, thereby accelerating the insecticidal process (Macey, 2009; NPIC, 2013). Topical treatments of garlic powder and addition of garlic tinctures (infusion of garlic in grain alcohol or water) to feed are also used to control mites. For small spots of mange, it is recommended that producers saturate the areas with garlic tincture and rub the substance into the skin (Macey, 2009). Botanical insecticides containing the natural substance pyrethrum (extracted from the flower head of the Chrysanthemum plant) without the synthetic synergist piperonyl butoxide may also provide effective parasite control in organically produced cattle (Macey, 2009).

Commercially available products formulated naturally occurring, non-synthetic active insecticidal and/or miticidal substances are included on the Organic Materials Review Institute (OMRI) product list. OMRI-approved products formulated with the active ingredient pyrethrum include Clarke Merus™ and Merus™ 2.0, Evergreen® Pyrethrum Concentrate, Evergreen® Pyrethrum Dust, PyGanic® Crop Protection EC 1.4 II and EC 5.0 II, PyGanic® Livestock and Poultry Insecticide (OMRI, 2014). For example, the PyGanic® EC 1.4 II product—which contains pyrethrins as 1.4% of the formulation—is approved for use as a livestock and poultry spray to kill and repel flies, mosquitoes and gnats; for effective control of biting and sucking lice on cattle, horses, sheep, goats and hogs; to control poultry lice; to control bed bugs and mites on poultry and in poultry houses; to control sheep tick/sheep ked; to kill fleas and ticks on livestock and pets and to obtain protection against re-infestation; and to control adult darkling beetle (lesser meal worm) in poultry houses (MGK, 2006). In addition to pyrethrum products, Tickless™, Zig-Zag, Bijoux Natural Oils Insect Repellent, and Whiz Natural Oils Insect Repellent are also commercially available and may be applied to animals and around livestock housing areas to repel pest insects and mites (OMRI, 2014).

A limited number of synthetically derived miticides are permitted for use in organic livestock production. Iodine scrubs have been used to control infestations (Macey, 2009). As discussed in this report, mineral oil is approved for use as an external parasiticide in the United States (7 CFR 205.603(b)(6)), and should provide similar control of insects and mites by smothering exposed insects in a manner similar to vegetable oils and essential oils. Light treatments of mineral oil (or vegetable oils described above) should be applied regularly to effectively control mites, ticks, lice and other parasites (Pedretti, undated). Because soap removes the waxy cuticle that protects insects and mites from dehydrating, repeated soaping treatments will kill lice and mites on affected livestock (Macey, 2009; Pedretti, undated). Selected systemic parasiticides—including (i) fenbendazole, (ii) ivermectin and (iii) moxidectin—are allowed as emergency treatments for organically managed “dairy and breeder stock when organic system plan-approved preventative management does not prevent infestation” (7 CFR 205.603(a)(18)). Milk products from treated animals cannot be labeled as “organic” for at least 90 days following treatment with any of these animal drugs. Additionally, treatment cannot occur during the last third of gestation in breeder stock intended for sale as organic, and must not be used during the lactation period for breeding stock. These substances are always prohibited for use in slaughter stock (7 CFR 205.603(a)(18)).

Other substances included in 7 CFR 205.603(b) are not intended for use in the same manner as mineral oil, which is typically used to control external parasites (e.g., mites and lice) and used as a lubricant. Sucrose octanoate esters are approved as external parasiticides in organic livestock production specifically for *Varroa* mite control on honey bees (USDA, 2005). Copper sulfate is approved for use in footbaths to kill bacteria and fungi responsible for foot rot in large animals, and is therefore a viable alternative to hydrated lime for that use pattern in organic livestock production. The following is a full list of substances approved under 7 CFR 205.603(b) as topical treatments, external parasiticides and/or local anesthetics as applicable:

- Copper sulfate – Topical treatment, bactericide/fungicide in foot baths for treating foot rot.
- Formic acid (CAS number: 64-18-6) – For use as a pesticide solely within honeybee hives.
- Iodine – Antimicrobial substance used as a topical treatment.
- Lidocaine – As a local anesthetic; use requires a withdrawal period of 90 days after administration to livestock intended for slaughter and 7 days after administration to dairy animals.
- Lime, hydrated – As an external pest control; not permitted to cauterize physical alterations or deodorize animal wastes.
- Mineral oil – For topical use and as a lubricant.

- Procaine – As a local anesthetic; use requires a withdrawal period of 90 days after administration to livestock intended for slaughter and 7 days after administration to dairy animals.
- Sucrose octanoate esters (CAS numbers: 42922-74-7 and 58064-47-4) – In accordance with approved labeling; it may be used for *Varroa* mite control on honey bees.

<u>Evaluation Question #12:</u> Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Best management practices may prevent the development of omasal impaction and parasite infestation in cattle, sheep and other livestock under certain conditions. This section summarizes the available information regarding cultural practices that may decrease the use of natural and/or synthetic substances for internal lubrication and external parasite control in organic livestock production.

Omasal impaction generally occurs when the feed provided to cattle is tough and fibrous, particularly alfalfa stalks and cuttings from fodder trees, or under drought feeding conditions in sheep that are fed on the ground. The latter form of impaction in sheep is typically due to the accumulation of soil in the omasum (Tuskegee University, undated). Beyond treatment using oral drenches of mineral oil, little targeted information for the prevention of omasal impaction was found in the available literature; however, recommended practices for preventing related ailments—including impaction of the abomasum (fourth stomach compartment in ruminants) and bloat in cattle and sheep—are available for comparison. In healthy animal stock, providing the necessary nutritional requirement for wintering pregnant beef cattle can prevent abomasal impaction (Constable, 2014). Producers using low-quality roughage should augment the ration with grain to meet energy and protein requirements, especially if laboratory analyses indicate these key nutrient parameters are low in the roughage alone. Adequate drinking water should be supplied at all times for animal welfare, and to encourage proper digestion of feed and pasture materials (Constable, 2014). Like bloat, omasal impaction may be prevented through provision of rations containing 10–15% cut or chopped roughage mixed into the complete feed to ease the digestion of fibrous materials. The roughage should be a cereal, grain straw, grass hay, or equivalent, and grains should be rolled or cracked as opposed to finely ground (Gay, 2012).

Preventative measures and cultural control practices are commonly employed in organic livestock operations to reduce the risk of parasite infestation in large animals. Whenever possible, it is highly recommended that livestock producers exercise preventative measures to minimize the risk of mite and lice infestations in herds of cattle and other livestock. Livestock operators should always separate new arrivals for at least three weeks before introduction to the herd. During this time, it is important to check these animals closely for any signs of infestation and to treat when necessary (Pedretti, undated). Likewise, it is essential that livestock managers promptly separate animals displaying early signs of infestation. Providing high quality feed and reducing stress levels in the herd can also minimize the occurrence of widespread mite infestations (Pedretti, undated). The following is a summary of best practices for minimizing the occurrence of parasite infestation in large animal herds (Macey, 2009):

- keep animals outdoors as much as possible to ensure ample exposure to sunlight;
- avoid close confinement of animals;
- provide good quality feed to animals and “free choice” minerals and kelp to young stock during the winter months;
- maintain a stress free environment with ample space to allow for natural behavioral patterns in production animals;
- quarantine any affected animals, and check replacement animals brought into the herd (isolate from the herd and observe for three weeks before introduction);
- maintain a closed herd policy;
- minimize communal grazing with other herds to avoid transmission of lice and mites;
- provide a cattle back scratcher (without an insecticide reservoir) to help control chewing lice populations;
- select for resistance in the herd, and cull animals that are chronically infested with parasites.

Infestations of burrowing mites and lice are readily spread through direct contact between cattle or when straw bedding and other objects become contaminated with burrowing mites (Macey, 2009). Therefore, in addition to avoiding close confinement of animals, it may be necessary to clean livestock housing areas and frequently change bedding materials during times of intense pest pressure. Mite populations generally surge in fall and winter, with the heaviest infestations occurring in late winter and early spring (Macey, 2009). Likewise, operators should clean and disinfect pens, sheds and other infested areas before moving in animals that are free of mite infestations (Weinzierl & Jones, 2000). As with mite and lice prevention in cattle, the primary means of preventing the occurrence of sheep scab, mange and other mite infestations is for sheep producers to avoid exposing sheep to infected animals (McNeal, 1999). When mange is detected, the affected animals should be quarantined to prevent the spread of mites throughout the herd (CFSPH, 2009). In cases of severe infestation, it may be necessary to kill and destroy severely infested animals or market for slaughter the animals that are severely attacked (Weinzierl & Jones, 2000).

Research and technical recommendations regarding non-chemical control methods are lacking in the peer-reviewed and agricultural extension literature. Therefore, it is unlikely that existing infestations can be controlled without the use of natural (non-synthetic) or approved synthetic substances described in Evaluation Question #11.

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