United States Department of Agriculture Agricultural Marketing Service | National Organic Program Document Cover Sheet https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Document Type:

□ National List Petition or Petition Update

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

⊠ Technical Report

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

Narrow-Range Oils

Crops

1		erep	-
2	Identification of	f Peti	tioned Substance
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4	Chemical Names:	20	Stylet Oil [®] ; OMNI Oil 6; OMNI Oil Supreme;
5	Mineral oil	21	PureSpray Green Horticultural Oil; Safe-T-Side
6		22	Miticide / Insecticide 800EL; Safe-T-Side
7	Other Names:	23	Paraffinic Oil; SunSpray; Volck Supreme Spray.
8	Aliphatic solvents; Dormant oils; Foliage oils;	24	
9	Foliar oils; Horticultural oils; Insecticidal oils;	25	CAS Numbers (see descriptions in Table 2):
10	Narrow-range oils; Neutral oils; Paraffinic Oils;	26	8012-95-1; 8020-83-5; 8042-47-5; 64741-88-4;
11	Petroleum-derived spray oils; Petroleum distilled	27	64741-89-5; 64742-54-7; 64742-55-8; 64742-56-9
12	spray oils; PDSOs; Petroleum spray oils; PSOs;	28	64742-65-0; 72623-84-8; 72623-86-0; 72623-87-1
13	Refined Petroleum distillates; Spray oils; Summer	29	
14	oils; Superior oils; Supreme oils.		Other Codes:
15			EPA PC Codes: 063502, 063503
16	Selected Trade Names:		EINECS: 232-455-8 (White mineral oil)
17	415 Oil; 440 Oil; Superior (440) Spray Oil; BVA		RTECS: PY8030000
18	Spray 10; BVA Spray 13; Calumet Dormant Spray		SMILES: CCCCCCC
19	Oil; Gavicide Green 415; Gavicide Green 440; JMS		
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31			
32	Summary of Petitioned Use		
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The scope of review is for narrow-range oils used as dormant, suffocating, or summer oils, both as insecticides (including acaricides or mite control) [7 CFR 205.601(e)(7)] and for plant disease control [7 CFR 205.601(i)(7)]. Because the substance is already on the National List ("Oils, horticultural – narrow range oils as dormant, suffocating, and summer oils"), this report requested by the National Organic Standards Board Crops Committee is in support of the sunset review to provide the most current information in scientific literature.

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Because of their complexity and variability, the nomenclature for petroleum and its products is difficult to characterize in detail (Neumann, Paczynska-Lahme, and Severin 1981; Barker et al. 2007). The petroleum

derivatives that are used as spray oils are also complex and variable, and have their own specific

44 nomenclature (Davidson et al. 1991; Agnello 2002; Cranshaw and Baxendale 2005; Buteler and Stadler

45 2011). For these reasons, mineral oils used for pest and disease management are identified by several

46 different names. Mineral oil is generally regarded as an archaic name for petroleum, but the term continues

47 to be used as a descriptor for industrial-, technical-, food-, and pharmaceutical-grade petroleum

derivatives. These names sometimes have specific meanings, depending on the context, and are notentirely synonymous with one another.

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The U.S. Environmental Protection Agency (EPA), in its 2007 review, referred to the collective category as "aliphatic solvents" identified by 12 different Chemical Abstract Services (CAS) numbers, and this term is sometimes used in the context of EPA's regulatory classifications. Literature reviews refer to the collective

category as "petroleum-derived spray oils" or "petroleum distilled spray oils (PDSOs)" (Agnello 2002;
Buteler and Stadler 2011). "Mineral oils" and "PDSOs" are used in this review as the most inclusive generic

56 terms.

5758 PDSOs are often referred to by their specific use or distinguished by their chemical and physical properties.

59 As such, these terms cannot be used interchangeably. Dormant oils are used on deciduous trees between

- 60 leaf-fall and bloom. Foliar or foliage oils are applied to actively growing vegetation, as are summer oils.
- 61 Summer oils are applied during warmer weather when there is a greater risk of plant damage. Suffocating

oils are referred to by their mode of action. Collectively, these applications to live plants are referred to as
 horticultural oils. Insecticidal oils target arthropod pests, and will often include acaricidal uses, such as the
 control of mites.

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66 "Petroleum distillates" may refer either specifically to those cuts of crude petroleum that are separated by

67 distillation without further refinement or treatment, or may apply more broadly to cracked and treated

68 petroleum products depending on the context (Barker et al. 2007). Narrow-range oils are identified based

69 on the distillation range. Neutral oils are characterized by a relatively high proportion of saturated

hydrocarbons. Paraffinic oils have a relatively high proportion of aliphatic structures. These terms may also appear in the context of the reference cited. Supreme oils are highly refined oils that include many narrow-

range oils but may be distilled at higher temperatures and over a wider range. Superior oils are a category

73 of narrow-range summer oils with low phytotoxicity (Cranshaw and Baxendale 2005).

74

Petroleum distillates can also be used as herbicides (Van Overbeek and Blondeau 1954). These may be called "weed oils," carrot oils, or Stoddard's solvent. Mineral oils that are deliberately applied as herbicides generally have higher levels of polycyclic aromatic hydrocarbons and a lower boiling point than narrowrange oils used as summer, dormant and suffocating oils. As such, they are generally not considered in the same category of horticultural oils and are outside the scope of this review.

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Characterization of Petitioned Substance

84 <u>Composition of the Substance:</u>

PDSOs vary according to the source of petroleum, the refining process, and the treatment method. Crude
petroleum consists primarily of hydrocarbons, with small amounts of nitrogen- and sulfur-containing
compounds, as well as various metals and other non-hydrocarbon impurities. The hydrocarbons in
petroleum may be divided into three or four molecular groups based on weight, volatility, molecular
structure, and distillation or phase-change from liquid and semi-solid to vapor: the aromatic/cyclic group,
the naphthenic/alicyclic group, the aliphatic/paraffinic group (Neumann, Paczynska-Lahme, and Severin)

91 1981; Barker et al. 2007), and – in some cases – the complex hydrocarbons group (Neumann, Paczynska-

- 92 Lahme, and Severin 1981).
- 93

PDSOs are predominately a mixture of long-chain aliphatic (paraffinic) compounds (US EPA 2007) known as alkanes, which belong to the methane series and have the general formula C_nH_{2n+2} . Liquid spray oils are

primarily composed of chain structures with 16 to 32 carbon atoms in the chain (Agnello 2002) that may be

97 linear, branched, or have cyclic structures, such as those shown in Figure 1. Alkanes with fewer than 15

98 carbon atoms are lighter and more volatile; alkanes with 16 or more carbon atoms tend to be more stable at

99 standard temperature and pressure (Neumann, Paczynska-Lahme, and Severin 1981). The EPA recognizes

100 12 different chemical compounds as meeting the specifications for PDSOs registered as pesticides in the

101 United States. These are classified as technical mineral oil (EPA PC 063502) and aliphatic petroleum

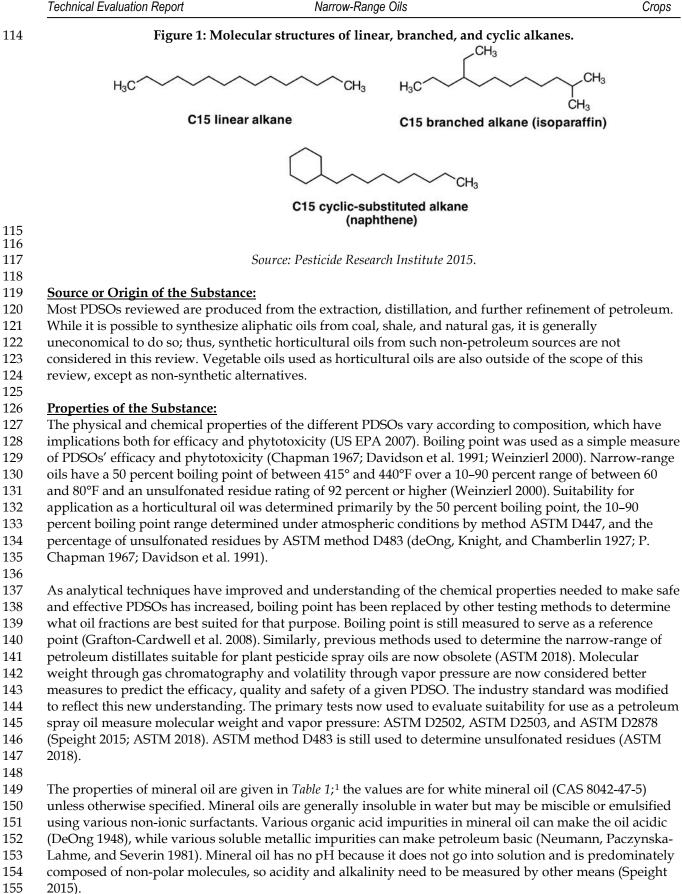
- 102 hydrocarbons (EPA PC 063503).
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Historically, PDSOs have been classified by boiling point and unsulfonated residues; narrow-range oils are
paraffinic petroleum distillates with high boiling points and an unsulfonated residue of at least 92 percent
(Davidson et al. 1991; Grafton-Cardwell et al. 2008). Molecular weight is now the industry standard for
measuring PDSO efficacy and safety for plants because it provides a more accurate representation of a
given PDSO's pesticidal properties than less accurate measurement methods using distillation
temperatures (Agnello 2002). In addition, although boiling point measurement has mostly been replaced

110 with more analytical methods, gas chromatography is used to measure and clarify the compositions of

spray oils with similar boiling points because products are still branded and marketed based on their

boiling points. Additional information on classification methods can be found in *Properties of the Substance*.



¹ All tables are contained in the Appendix.

- 157 *Table 2* summarizes the characteristics of the different chemicals that the EPA classifies as active ingredients
- in PDSOs. Mineral oil identified as CAS number 8012-95-1 is the broadest category of mineral oil,
- 159 containing within it all the other items on the list. White mineral oil (CAS 8042-47-5) is the most refined and160 most consistent, particularly when sold as pharmaceutical- or food-grade.
- 161

162 **Specific Uses of the Substance:**

- 163 The primary use of PDSOs in organic agriculture is on fruit trees as a dormant oil and as a summer oil for
- the control of soft-bodied insects such as aphids and scales, and to kill the eggs of overwintering insects. It
- 165 is also used to manage various diseases such as powdery mildew and sooty mold on citrus. *Table 3* contains 166 more information on the pest-crop complexes for which PDSOs are used. Mineral oil is also allowed for
- 166 more information on the pest-crop complexes for which PDSOs are used. Mineral oil is als 167 topical use and as a lubricant for organic livestock [7 CFR 205.603(b)(6)].
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169 PDSOs are widely used in conventional agriculture, both as active and non-active ingredients. Outside of

- agriculture, mineral oils have a broad range of industrial, consumer, food, and cosmetic uses.
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172 Approved Legal Uses of the Substance:

173 EPA Approved Uses

- 174 EPA completed its Re-registration Eligibility Decision for aliphatic solvents, which included both mineral
- oils and aliphatic petroleum solvents, in November 2007 (US EPA 2007). As of September 4, 2018, the EPA
- 176 Pesticide Product Labeling System lists 190 registered pesticides that had "Mineral Oil" (PC Code 063502)
- and 34 that had "Aliphatic petroleum solvent" (PC Code 063503) as an active ingredient. *Table 3* lists the
- crops, pests, and diseases that are labeled for the use of EPA-registered pesticides that fall into these twocategories.
- 179 180

181 *Table 3* also summarizes the general timing of application and the legal maximum application rate of

- 182 mineral oils applied to food crops, based either on pounds of active ingredient per acre per year (lb ai/A)
- 183 or pounds of active ingredient concentration per gallon (lb ai/gal). Maximum annual application rates vary
- 184 by the type of equipment used to apply PDSOs, such as airblast, aerial, hand sprayer, or ground boom.
- 185 Ornamentals, shade trees, and other non-food uses are not included, though mineral oils are labeled for a
- 186 considerable number of non-food uses as well as the food uses noted below (US EPA 2007; US EPA PPLS
- 187 2018).
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189 The EPA also approved several aliphatic solvents for use as inert ingredients in registered pesticides.

190 *Table 4* cross-references the status of the various active ingredients classified by EPA as aliphatic solvents

191 under the current regulation at 40 CFR as well as under EPA's now obsolete list system that formed the

192 basis for determining inert ingredients' status under 7 CFR 205.601(m). Substances not included on the

- 193 EPA's list were classified as List 3.
- 194

195 The EPA exempts petroleum oils, or mineral oil, from the requirement of a tolerance when applied to 196 growing crops [40 CFR 180.905]. Mineral oils are also exempt from this requirement of a tolerance when 197 used as inert ingredients in pesticide formulations applied to growing or harvest crops [40 CFR 180.910] 198 and directly to animals [40 CFR 180.930]. Previously published at 40 CFR 180.149 was an EPA tolerance of 199 200 parts per million (ppm) for residues of mineral oil when used "For post-harvest handling on corn grain 200 and sorghum grain;" the EPA last updated the nomenclature for this listing in 2009 [74 FR 46369-46377]. 201 However, because section 108.149 no longer appears in Subpart C of 180–Specific Tolerances – as of 2010, 202 it is unclear whether this specific regulation is still in force. The exemption from the requirement of a 203 tolerance for mineral oil on growing crops at 40 CFR 180.905 does state in paragraph (c) that the pesticide is 204 not exempted when applied to a crop at the time of or after harvest.

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206 U.S. Food and Drug Administration (FDA) Approved Uses

207 Several uses of mineral oil are approved by the FDA for human consumption and in animal feed – food-

- grade white mineral oil, for instance, may be directly added to food [21 CFR 172.340 and 172.878]. FDA-
- 209 approved uses for mineral oil include as a release agent, binder, lubricant, defoamer, floating agent, dust
- 210 control agent, and as a protective coating. These uses are subject to specific limitations. Foods that are
- 211 approved (US FDA 2018) to have white mineral oil as a direct additive include:

- Barley, corn, oats, rice, sorghum, soybeans, wheat
- Dehydrated fruits and vegetables
- Baked goods and confectionaries
 - Wine, vinegar, and pickles
- Egg white solids and frozen meat
 - Yeast
 - Capsules and tablets that contain flavorings, spices, condiments, nutrients, and special dietary supplements

White mineral oil is also approved as an adjuvant with other additives, such as sorbic acid and various polysorbates [21 CFR 172.842]. Synthetic isoparaffinic petroleum hydrocarbons are also permitted as direct food additives [21 CFR 172.882], with permitted uses including froth flotation cleaning of vegetables; as a float on fermentation fluids in making vinegar, wine, and pickles and to prevent contamination with other organisms during fermentation; as a component of coatings on fruits and vegetables; as a coating on egg shells; and as a component of pesticide formulations used on processed foods [21 CFR 172.882(c)]. The FDA

- also permits food-grade mineral oil to be used as a defoaming agent in processing sugar beets and yeasts,
 subject to not more than 150 ppm (measured in hydrocarbons) in yeast [21 CFR 173.340(a)(3)].
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229 Mineral oils are allowed on a wide variety of food contact surfaces subject to technical requirements and

- good manufacturing practices (GMPs) [21 CFR 178.3620] and are widely used in food packaging. Mineral
 oil may be used in food contact adhesives [21 CFR 175.105(c)(5)], acrylate polymer coatings [21 CFR
- 231 off may be used in food contact adhesives [21 CFR 1/5.105(c)(5)], acrylate polymer coatings [21 CFR 232 175.210(b)], hot melt strippable food coatings on frozen meats [21 CFR 175.230(b)(2)], and as a surface
- lubricant on resinous or polymeric coatings [21 CFR 175.300]. White mineral oil is also permitted for use in
- cellophane [21 CFR 177.1200(c)], ethylene-acrylic acid co-polymers [21 CFR 177.1310(b)(2)], oxidized

polyethylene [21 CFR 1620(b)], resin-bonded filters [21 CFR 177.2260(d)], and textiles/textile fibers [21 CFR

236 177.2800(d)(5)] in contact with food. Lubricants used with incidental food contact [21 CFR 178.3570] and in

the manufacture of metallic articles that are in contact with food [21 CFR 178.3910] may contain mineral oil.

Paper and paperboard used in contact with food is permitted to contain mineral oil [21 CFR 176.170(a)(5)],

and paraffin is a major component of waxed cardboard boxes used for produce.

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For the broader category of "mineral oil," the FDA found there was insufficient data to support that
mineral oil was Generally Recognized As Safe (GRAS) (FDA 2000). The FDA affirmed the narrower
category of pharmaceutical (USP)-grade white mineral oil as GRAS when it was subsequently re-submitted
(FDA 2001). The amount in food that is considered GRAS is 5 ppm.

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- 246 Animal feed uses
- 247 Food-grade mineral oils may be used in animal feed for/as:
 - Dust prevention
 - A lubricant in the preparation of pellets, cubes, or blocks
 - Preventing segregation of trace minerals in mineralized salt
 - A diluent or carrier with food-grade biuret in accordance with GMPs
 - Removing water from substances intended as animal feed ingredients [21 CFR 573.680(b)].

FDA set an upper limit of 3.0 percent mineral oil in mineral supplements and 0.06 percent in the total

ration when present in feed or feed concentrates [21 CFR 573.680(c)]. However, veterinary products that

contain mineral oil as an active substance are considered unapproved animal drugs by FDA, and have not

had the necessary safety or efficacy testing completed for FDA approval (Pesticide Research Institute 2015).

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258 Action of the Substance:

- 259 Petroleum oils have been thought to have several different modes of action on insects, mites, and plant
- 260 pathogens. A literature review of the mode of action of PDSOs found that they target multiple sites and do
- 261 not interact with specific receptors (Buteler and Stadler 2011). Thus, horticultural oils do not behave like
- 262 most synthetic insecticides. The toxic effects depend on physical and chemical properties of both the oil
- and the insect. As an ovicide, there is evidence that they prevent atmospheric gas exchange and depress
- respiration to the point of being fatal to the eggs (Smith and Pearce 1948; Smith and Salkeld 1966).
- 265 Petroleum oils soften the cuticle, disrupt cuticle waxes, and have teratogenic effects on the epidermis,
- 266 causing aberrant molts. All of these are fatal to the target organisms (Buteler and Stadler 2011). PDSOs also

appear to have some behavioral effects on insects and mites (Buteler and Stadler 2011). These are covered
in greater detail in *Evaluation Question* #5.

270 <u>Combinations of the Substance:</u>

271 Mineral oil is commonly used as an inert ingredient and adjuvant with other pesticides, as well as a co-

- 272 active or tank mix ingredient. Formulations of petroleum oil with liquid soap, Bordeaux mix, and/or lime-
- sulfur were used as combination insecticides, acaricides, and fungicides in fruit production as early as 1917
- (Jones 1919). Botanical insecticides have long been formulated using various petroleum oils (Pyenson 1951).
 The insecticide spinosad may also be mixed with horticultural mineral oils (Taverner et al. 2011).
- The insecticide spinosad may also be mixed with horticultural mineral oils (Taverner et al. 2011).
 Researchers are experimenting with combinations of PDSOs and biopesticides, including *Isaria fumosorosea*,

a fungal pathogen of Asian citrus psyllid (*Diaphorina citri*) (Kumar et al. 2017).

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Horticultural oils are often formulated with wetting agents or surfactants that allow them to be mixed and diluted with water. Most spray oils in the United States contain a non-ionic surfactant dissolved in the oil concentrate at a concentration of 0.35 percent for citrus use and 0.5 percent for deciduous use (Davidson et al. 1991; Agnello 2002). Dormant oils have more variation in both the emulsifiers used and their concentration, ranging between 2 and 20 percent emulsifier (Davidson 1991). These emulsifiers are

frequently polyoxyethylene (POE) compounds that are made from ethylene oxide. Many are considered

285 confidential business information (CBI).

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Status

289290 Historic Use:

291 Petroleum-derived spray oils were first used as pesticides in the late 1800s, potentially as early as 1868

(Matsumura 1975). By 1880, kerosene had become a standard treatment for the control of aphids, scale, and

293 other soft-bodied insects in deciduous fruit trees (Chapman 1967). Early dormant oil products had highly

variable results as an insecticide and sometimes injured the trees during dormancy (Mason 1928). Citrus
 trees in particular were more susceptible to injury and problems with fruit quality resulting from

296 petroleum oil application (deOng, Knight, and Chamberlin 1927). With dormant oils used on pome and

297 stone fruit, damage was minimal and usually reversible, but for citrus fruit the damage could be severe and

298 permanent. The lightest fractions – composed mainly of aromatic and naphthenic substances – were both

299 toxic to plants and non-toxic to insects. Aliphatic fractions that were non-toxic to plants were also non-toxic

300 to insects, and therefore ineffective. However, above a certain molecular weight, the distillate again became

toxic to plants. Thus, to be both effective against insects and non-toxic to plants, petroleum distillates

needed to be confined within a narrow range that was eventually determined to be between 415–440°F
 (approximately 213–227°C) (P. Chapman 1967; Agnello 2002).

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305 A breakthrough occurred when research determined that the most effective and least toxic petroleum 306 distillates had a specific gravity of between 0.8917 and 0.8092 and a viscosity of between 50–350 seconds, 307 and that emulsifying the distillates to spray smaller droplets was both more effective as an insecticide and less harmful to the plants (Volck 1929). The product was named "Volck oil" after the inventor. Research 308 continued to find ways to improve the efficacy and reduce phytotoxicity of petroleum-based spray oils 309 310 (DeOng 1948; Davidson et al. 1991; Agnello 2002; US EPA 2007; Buteler and Stadler 2011). A parallel set of 311 research set out to increase the phytoxicity of petroleum distillates to enhance their use as herbicides (Van 312 Overbeek and Blondeau 1954).

313

314 Dormant oil sprays of miscible petroleum distillates have long been used in organic fruit production

programs (Rodale 1961) to control aphids, scale, thrips, and mites (Yepsen 1984). "Dormant" oils were

316 recommended for organic citrus production, but because citrus is non-deciduous and mature trees of most

317 citrus varieties will have fruit at some stage of development throughout the year, the oils are not applied

during dormancy. Organic citrus producers were recommended to use very dilute sprays made with

319 highly refined "white oils" (Rodale 1961).

Narrow-Range Oils

Because of plant damage and quality issues, the use of petroleum oils on foliage during warmer weather was more limited, and the history is not as well documented. Applications to growing foliage were

historically called "summer" oils in the research and extension literature, though the oils could be applied
in any season (particularly for foliage growing in controlled environments or in tropical or subtropical
climates). Therefore, a more accurate description is "foliage" or "foliar" oils (Chapman, Pearce, and Avens

- 326 1943; Agnello 2002; Cranshaw and Baxendale 2005).
- 327

While summer oils were used on foliage in warm weather, early pest management guides recommended
 oils for dormant use only (Mason 1928). Improved refinement techniques in the 1930s helped reduce plant

injury from petroleum distillates applied in warmer weather (Voorhees 1937). Highly refined white

- mineral oils with almost all of the unsaturated hydrocarbons removed and an unsulfonated residue of over
- 90 percent were used both by themselves and with botanical insecticides such as pyrethrum and rotenone(Pyenson 1951). The petroleum distillates were sometimes labeled as co-active ingredients in these
- formulations but were often declared as "inert ingredients." Historic use of petroleum-derived summer oils
- 335 on vegetables and other herbaceous annual crops is less well established. Oil emulsion sprays were
- recommended for aphids that were vectors of beet viruses, but the recommendation referred to corn oil
- 337 (Yepsen 1984). Foliar application of petroleum oils was used in some certified organic vegetable production
- prior to the passage of the Organic Foods Production Act, but that historic use is not as well documented as
- dormant oil or summer oils on citrus and deciduous trees.
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341 Organic Foods Production Act, USDA Final Rule:

- 342 Horticultural oils are explicitly mentioned as eligible for inclusion on the National List of Synthetic
- 343 Substances at 7 U.S.C. 6517(c)(1)(B)(i) and are also included on the National List for use as dormant,
- suffocating, or summer oils, both as insecticides (including acaricides or mite control) [7 CFR 205.601(e)(7)]
- and for plant disease control [7 CFR 205.601(i)(7)].
- 346 347 <u>International</u>
- 348 Canada
- Dormant and summer oils are contained in CAN/CGS- 32.311 Table 4.3. Dormant oils are "[f]or use as a dormant spray on wood plants. Shall not be used as a dust suppressant." Summer oils are limited for use
- dormant spray on wood plants. Shall not be used as a dust supp.
 "[o]n foliage, as suffocating or stylet oils." (CAN/CGSB 2015).
- 352353 CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of
- 354 Organically Produced Foods (GL 32-1999)
- Table 2 of the Codex Alimentarius Commission's Guidelines for the Production, Processing, Labelling and
- 356 Marketing of Organically Produced Foods lists "Paraffin oil" as a substance permitted for plant pest and
- disease control, with the limitation "Need recognized by certification body or authority" (FAO/WHO Joint Standards Programme 1999).
- 359
- 360 European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
- Paraffin oil is permitted as an insecticide and acaricide in Annex II of the European Council Regulation
- 362 governing organic standards (EU Commission 2008).
- 363
- 364 Japan Agricultural Standard (JAS) for Organic Production
- The Japanese Agricultural Standard for Organic Plants, Table 2 allows mixed oil emulsion, petroleum oil aerosol, and petroleum oil emulsion for plant pest and disease control without annotation (Japan MAFF 2000).
- 368
- 369 IFOAM Organics International
- 370 The IFOAM Organics International standards Appendix 3 permits the use of "light mineral oils
- 371 (paraffin)" without annotation for plant pest and disease control (IFOAM 2014).
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Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

376 Evaluation Question #1: Indicate which category in OFPA that the substance falls under: (A) Does the 377 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, 378 379 vitamins and minerals; livestock parasiticides and medicines and production aids including netting, 380 tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the 381 substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological concern 382 (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which 383 is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180? 384 385 (A) The substance is the category of horticultural oils. (B) See Table 4. 386 387 Evaluation Ouestion #2: Describe the most prevalent processes used to manufacture or formulate the 388 petitioned substance. Further, describe any chemical change that may occur during manufacture or 389 formulation of the petitioned substance when this substance is extracted from naturally occurring plant, 390 animal, or mineral sources (7 U.S.C. § 6502 (21)). 391 392 The product is manufactured from petroleum. The NOSB previously reviewed petroleum refining in the 393 sunset review for mineral oils used in livestock production (Pesticide Research Institute 2015). Crude oil is 394 extracted from the earth either by drilling or from the mining of tar sands. 395 396 The crude is washed or steamed with water to remove salt and other water-soluble impurities in the brine 397 that accompanies petroleum (Fahim, Al-Sahhaf, and Elkilani 2009). Demulsifying agents and electricity are 398 used to precipitate the salts. Depending on its weight and viscosity, and the available infrastructure in the 399 oilfield, the crude oil may be transported by pipeline, railcar, truck, or ship. Once the crude oil has had the brine and salts taken out, there are three general steps: 1) crude oil distillation, 2) refinement, and 3) 400 401 treatment. Each of these steps may have many different processes involved. 402 403 Distillation 404 The crude is distilled as the temperature is slowly raised to separate the fractions that have different evaporation points. The most volatile compounds – generally the simplest (C1-C4) hydrocarbons of 405 methane, ethane, propane, and butane – are separated first. These have the lowest molecular weights and 406 407 boiling points below 32°F (0°C) (Neumann and Rahimian 1984) and need to be condensed as gases or 408 liquified under pressure. Aromatic ring structures such as benzene, toluene, and xylene are distilled at the 409 next highest temperatures. Naphthenic structures are distilled after aromatics. In this range, the fractions 410 used as naphtha, kerosene, gasoline, and diesel are removed. At higher temperatures, the larger aliphatic 411 structures are removed, including the fractions that are used to make petroleum spray oils. 412 413 After separating fractions at atmospheric conditions up to a temperature of approximately 800°F (427°C), 414 the residuum is then introduced into a tower under vacuum pressure of 50mm of mercury (Hg) (Fahim, Al-415 Sahhaf, and Elkilani 2009). The vacuum further extracts the heaviest fractions. The byproducts throughout 416 the process include methane (natural gas), carbon dioxide, ethylene, sulfur dioxide, and hydrogen sulfide. Vacuums are used to increase the efficiency of extraction and to separate fractions of similar boiling points 417 418 by molecular weight. The heaviest fractions include asphalt and dark, viscous sludges that have a high ash 419 content. 420 421 Refinement 422 The distilled fractions or cuts usually need additional processing to further refine them for use in specific 423 purposes. Certain impurities may be flashed off by high heat or separated by molecular weight or specific 424 gravity. Polar structures such as acids may be removed by ion exchange (Cooper 1977). Immiscible and 425 saturated hydrocarbons, such as phenol and furfural, may also be removed by solvent extraction. Solvents 426 used include furfural, nitrobenzol, dichlor-diethylether, N-methyl pyrrolidone (NMP), and methyl ethyl 427 ketone (MEK) (Neumann and Rahimian 1984; Fahim, Al-Sahhaf, and Elkilani 2009). Further refinement is

428 accomplished through dearomatization, cracking, and wax removal.

- 430 Dearomatization
- 431 Aromatic hydrocarbons, such as benzene, toluene, and xylene, may be removed by solvent extraction or
- 432 catalytic conversion. One chemical used to strip aromatics is sulfur dioxide, which is used in the Edeleanu
- 433 process (Neumann and Rahimian 1984). The pesticide industry has improved techniques for removing the
- 434 polycyclic aromatic hydrocarbons (PAH) from petroleum spray oils (US EPA 2007). Higher-level
- 435 treatments involve placing the feedstock in a stirring reactor, where the PAHs will react with added sulfur
- 436 trioxide or sulfuric acid. The sulfuric sludge will separate and be neutralized with an alkaline reagent –
- 437 either sodium hydroxide or potassium hydroxide and then extracted with either ethanol or propanol
- 438 (EFSA 2012). The process is repeated several times.

439 440 <u>Cracking</u>

- 441 Distillation by temperature alone is insufficient to obtain petroleum products suitable for making
- 442 petroleum spray oils. The use of temperatures above the distillation range can break molecular bonds and
- lead to further separation of more refined cuts this is called "thermal cracking" (Neumann and Rahimian
- 1984). More important is the use of various catalysts that cause chemicals in the petroleum to separate in
- their presence, which is called "catalytic cracking" (Neumann and Rahimian 1984). Catalysts include
- 446 aluminum silicate, montmorillonite, and zeolites (Decroocq 1984). The reaction of mineral oil with
- 447 molecular hydrogen (H_2) in the presence of a catalyst at various high temperatures, pressures, and
- velocities breaks the aromatic and naphthenic ring structures (Parkash 2003). These fragments broken from
- the heavier ring structures react with the hydrogen to form isoparaffinic or branched alkane structures in a
- 450 process known as "hydrocracking."
- 451

452 <u>Wax removal</u>

- 453 Wax removal is important for preparing petroleum distillates for application as horticultural oils because 454 the wax left after cracking is often phytotoxic. Some wax may be removed in the catalytic cracking process,
- 454 the wax left after cracking is often phytotoxic. Some wax may be removed in the catalytic cracking process 455 but residual wax will often need to be removed by crystallizing the wax through rapid cooling to -18°C
- 456 (0°F), desorbing it with another petroleum solvent such as toluene or MEK, methylation, or flushing it out
- 457 with ammonia (Neumann and Rahimian 1984; Agnello 2002; EFSA 2012; Pesticide Research Institute 2015).
- 458 Among the petroleum solvents typically used for wax removal are ketones, benzene, toluene, n-pentane, or
- 459 propane (Ackerson, Arabshahi, and Babcock 1993).
- 460 461 *Treatment*
- 462 The refined and dewaxed aliphatic fractions may be further treated with various chemicals in a process
- sometimes referred to as chemical conversion or chemical treatment. PDSOs are often further treated to
- remove residual PAHs and increase the unsulfonated residue content to meet specifications for
- 465 horticultural use (US EPA 2007). Treatments may include reaction with various acids, bases, and other
- 466 highly reactive substances; in particular, the unsulfonated residues of PDSOs can be treated with sulfuric
- 467 acid (Jacques and Kuhlmann 2002). This treatment step also further lowers the PAH content. Other
- 468 proprietary substances may be used as absorbents to remove naphthenic and nitrogen structures seen as
- 469 impurities in spray oils (Agnello 2002).
- 470

471Evaluation Question #3: Discuss whether the petitioned substance is formulated or manufactured by a472chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

473

474 Crude petroleum needs to be converted by chemical processes to be useful. There are essentially two types
475 of chemical conversion processes: 1) catalytic methods and 2) thermal methods (Neumann and Rahimian
476 1984). These account for thousands of chemical reactions that take place in oil refining, including those
477 used to produce horticultural oils. Once converted, the petroleum distillates are further refined by chemical
478 treatments to remove phytotoxic compounds while keeping in the compounds that are toxic to insects and

- 479 plant diseases.
- 480481 Petroleum refining, fractionation, and distillation is a chemical process where heat, pressure, and various
- catalysts are applied to crude petroleum, producing a wide variety of hydrocarbons and other substances.
- 483 As described in *Evaluation Question* #2, PDSOs are produced by a chemical process that involves thermal
- and vacuum distillation, catalytic cracking, and hydrogenation, among many other chemical processes. Oil

485 refineries are complex operations with highly specialized chemical processing equipment, including heat exchangers, atmospheric and vacuum distillation columns, fractionation (cracking) towers, alkylation 486 units, viscosity breaking units, coker units, isomerization units, and various strippers for removing various 487 488 gas (vapor phase) impurities. 489 490 The National Organic Standards Board (NOSB) previously determined that mineral oil was synthetic 491 during its initial review in 1995. Mineral oils were also subject to sunset review by the NOSB for use on 492 livestock (Pesticide Research Institute 2015). The NOSB unanimously voted that the substance was 493 synthetic in all previous recommendations (NOSB 1995, 2002). 494 495 Evaluation Question #4: Describe the persistence or concentration of the petitioned substance and/or its 496 by-products in the environment (7 U.S.C. § 6518 (m) (2)). 497 498 Given the complex molecular mixture of PDSOs, it is difficult to generalize about their persistence. 499 Biodegradability and persistence of mineral oils are a function of their chemical and physical characteristics 500 (Haus, German, and Junter 2001). While aromatic structures, particularly PAHs, are more volatile, they are 501 more resistant to biodegradation than aliphatic structures (Haus, German, and Junter 2001). Polar 502 structures also tend to resist biodegradation. A laboratory study found that highly refined paraffinic oils were 75 percent biodegraded in 21 days in secondary-treated sewage effluent (Haus, German, and Junter 503 504 2001). 505 506 Actual persistence in the field will vary according to temperature, precipitation, sunlight, application 507 method, and droplet size. Research sought to increase the persistence of spray oils to increase efficacy and 508 reduce the rate and number of applications required (Lyman 1939). Dormant oils are usually applied when 509 temperatures are low, when the oil will be more persistent and will provide longer residual effect. 510 However, with foliage oils, persistence increases the risk of phytotoxicity (Agnello 2002). For example, 511 more persistent PDSOs were found to be more effective against citrus leafminer (Phyllocnistis citrella) in 512 Australia than less persistent ones (Z. Liu et al. 2001). Although spray oils are not water soluble, they will 513 be washed off with heavy precipitation. Smaller droplets will dissipate more rapidly (Lyman 1939). Thus, 514 the factors that are important for degradation are removed from the active ingredient to the extent that is 515 technically feasible. 516 517 The microbial ecology is a principle factor in determining biodegradation rates, given that only certain 518 species are capable of biodegrading petroleum (Zobell 1946; Atlas 1981; Das and Chandran 2011). 519 Biodegradation requires soil temperatures to be sufficiently warm for microbiological activity. Maximum degradation occurs at temperatures between 20° and 30°C (86°-104°F). Soil particle size is also a factor. 520 521 One study showed that a silty soil treated with petroleum hydrocarbons in laboratory conditions had an 522 over 51 percent microbial degradation rate after 128 days, while a sandy soil had only a 25 percent 523 degradation rate (Scherr et al. 2007). Other factors related to the farming system – such soil type, organic 524 matter content, nutrient content, and tillage practices – may also influence persistence and degradation 525 (Das and Chandran 2011). One study found that lightly fertilized soils degraded crude oil more rapidly 526 than unfertilized soils, but that soils fertilized with relatively high levels of nitrogen, phosphorous, and 527 potassium (NPK) in the soil inhibited biodegradation of crude oil to the point it was not significantly 528 different from the degradation in unfertilized soil (Chaineau et al. 2005). More research is needed to 529 determine how much of a factor farming practices are and specifically the degradation rates under organic 530 farming conditions. PDSOs may also partially biodegrade, with short-chain aliphatic hydrocarbons 531 adsorbing to soil particles for indefinite periods of time. A given set of petroleum hydrocarbons may 532 degrade entirely within days or even hours under one set of environmental conditions and persist 533 indefinitely under a different set of conditions (Atlas 1981). 534

535 The EPA is equivocal on the persistence of aliphatic solvents used as pesticide in the environment (US EPA

536 2007). When used as a surface film on water as a mosquito larvicide, the expected persistence is 2–3 days (US EPA 2007). Its persistence in soil is rated as "low," with an average soil half-life estimated to be 10 days

537

(Vogue, Kerle, and Jenkins 1994). PDSOs do not contain functional groups that undergo photodegradation 538

539 in ultraviolet or the visible light spectrum (US EPA 2007). However, any aromatic portion would undergo Narrow-Range Oils

540 direct photolysis. Oils are insoluble and do not undergo hydrolysis. The oils will biodegrade to an extent, 541 but because of the complexity and size of the molecules in the formulations, they are not considered readily 542 biodegradable and will not rapidly or completely break down into carbon dioxide and water (US EPA 543 2007). The breakdown products are simpler hydrocarbons that remain adsorbed to foliage to which they 544 are applied and to the soil. The soil organism Pseudomonas oleovorans is known to release enzymes that 545 degrade n-alkanes to primary alcohols in the presence of oxygen (McKenna and Coon 1970). 546 547 Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its breakdown 548 products and any contaminants. Describe the persistence and areas of concentration in the environment 549 of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)). 550 Compared with other pesticides, aliphatic solvents are relatively non-toxic (US EPA 2007). Table 5 provides 551 552 toxicity data for mineral oil, with values for CAS #8012-95-1 or an unspecified aliphatic oil unless 553 otherwise indicated. Highly refined mineral oil mists appear to have low acute and sub-acute toxicity in 554 laboratory animals (HSDB 2015). 555 556 The EPA has classified aliphatic solvents as Toxicity Category IV (lowest toxicity – regarded as practically non-toxic) for acute oral toxicity, and primary dermal irritation. Acute dermal and acute inhalation toxicity 557 558 results were inconsistent depending on the formulation, with some formulated products classified as 559 Category IV and some as Category III (slightly toxic) (US EPA 2007). 560 561 Sub-chronic toxicity of mineral oil is also relatively low. While results vary depending on the species and 562 breed of laboratory animals used, the hazards of exposure are considered negligible (Nash et al. 1996). Oral 563 force-feeding of mixed alkanes to Sprague-Dawley rats at doses of 500, 2,500, and 5,000 milligrams per kilogram of body weight per day (mg/kg-bw/day) over 13 weeks resulted in a_{2u} -globulin mediated 564 nephrotoxicity in all groups, and higher liver weights in males at the two higher doses (EFSA 2012). There 565 566 were also symptoms of irritation and thickening of the stomach mucosa. These symptoms were not 567 regarded to be relevant to human exposure (EFSA 2012). Subsequent studies determined that the No Observed Effect Level (NOEL) for these alkanes was 100 mg/kg/day. 568 569 570 A review of several studies also found that, when ingested by rodents, mineral oil will concentrate in the 571 liver. These studies determined a No Observed Adverse Effect Level (NOAEL) from 0.93 mg/kg to 1,951 572 mg/kg. The wide range was believed to be in part due to the different chemical and physical characteristics 573 of the oils used (EFSA 2012). 574 575 Chronic health effects of petroleum derivatives vary based on their PAH content and how refined they are. 576 The International Agency for Research on Cancer (IARC) found sufficient evidence to support the 577 conclusion that untreated and mildly treated mineral oils are carcinogenic to humans (IARC Group 2). 578 They concluded from the same body of evidence that highly refined oils are not classifiable as to their 579 carcinogenicity to humans (Group 3) (IARC 2012). None of the PDSOs classified as aliphatic solvents by 580 EPA appear on the California Proposition 65 list of chemicals known by the state to cause cancer or reproductive toxicity (Cal-EPA 2018). Food-grade mineral oils that were directly injected into the body 581 582 cavities of mice induced plasma cell neoplasms and reticulum cell sarcomas (IARC 2012). Repeated 583 exposure of animals and humans to untreated or mildly treated mineral oil mixtures is associated with 584 increased incidence of bladder, scrotal, skin, and stomach cancers (IARC 2012). 585 586 The mutagenicity of various mineral oils has been difficult to determine because of the poor water 587 solubility and suspended droplets (US EPA 2007). Ames test results were determined to be unacceptable

because the substance could not go into solution when applied to the growth media (Reilly and Stewart
Subsequent tests on other organisms showed no evidence of mutagenicity and the Ames test was not

required to be redone for the purpose of pesticide registration (US EPA 2007). A modified Ames test was

developed to overcome these problems. The results of this test on food-grade mineral oil were mixed, but

592 on the whole showed a weak mutagenicity (EFSA 2012).

594 As noted above, PDSOs work by several modes of action. Most studies consider that PDSOs work by a 595 physical, not chemical or toxic, mode of action. Specifically, the oils are thought to block gas exchange in 596 insects and mites, causing the target organisms to suffocate (Moore and Graham 1918; E. H. Smith and 597 Pearce 1948; Johnson 1994; Davidson et al. 1991; Buteler and Stadler 2011; Wins-Purdy et al. 2009). The 598 mode of action can be more broadly linked to penetration of the insect's cuticle, dissolution of internal 599 lipids, and penetration of internal cell structures (Buteler and Stadler 2011). The age or life stage of an 600 insect is an important determinant of susceptibility, with eggs and young larvae being more susceptible 601 than later stage instars, pupae, and adults (Herron et al. 1995). Efficacy varies by the volume, rate of 602 application, and equipment used. Broad and complete coverage is needed to cover the target pest 603 population. High-volume applications that get better coverage are more effective than low-volume or ultra-604 low-volume sprayers against aphids (Herron et al. 1998) and scale insects (G. A. C. Beattie et al. 1991). 605 606 PDSOs have also been observed to modify insect behavior (Buteler and Stadler 2011). For instance, 607 lepidopteran insects have been observed to be significantly less likely to lay eggs on surfaces treated with mineral oil (Larew 1988; Z. Liu et al. 2001; Erler 2004; Wins-Purdy et al. 2009). This egg-laying deterrence is 608 improved by greater persistence (Z. Liu et al. 2001). Insects may also be deterred from feeding on plant 609 surfaces treated with PDSOs (Buteler and Stadler 2011). Minerals oils were observed to repel Asian citrus 610 psyllid, Diaphorina citri (Leong et al. 2012; Ouyang et al. 2013; Yang et al. 2013). Various aphids, 611 612 leafhoppers, psyllids and whiteflies are believed to have their stylets prevented from penetrating leaf surfaces covered with a coating of PDSO (Agnello 2002; Cranshaw and Baxendale 2005; Yang et al. 2013). 613 This mode of action is also thought to reduce transmission of viruses transmitted by these vector insects, 614 615 such as watermelon mosaic virus and citrus greening (HLB) (Simons 1982; Yang et al. 2013). 616 617 Evaluation Question #6: Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)). 618 619 620 Each step of the petroleum manufacturing process – extraction, distillation, and refining – pollutes air and 621 water and generates a stream of solid waste. A comprehensive review of the environmental contamination 622 of each of these steps is beyond the scope of this review. However, they can each be briefly summarized. 623 624 Air Pollution 625 Greenhouse gases, such as methane and carbon dioxide, are released at wellheads and during the 626 distillation and refining process. The oil and natural gas industry is the largest source of emissions for volatile organic compounds (VOCs) (US EPA 2016). Oil refining releases carbon dioxide, methane, nitrogen 627 628 oxides (NO_x) and sulfur dioxide into the atmosphere (Petroleum Committee 1964; Amiry, Sutherland, and 629 Martin 1997). While technology for capturing these emissions has improved over the past 20 years, 630 petroleum production and refining remains a major global source of air pollution. Available pollution 631 control technology has not been installed in many cases and air quality continues to degrade – particularly 632 in rapidly developing countries - as petroleum production and consumption increases (Ragothaman and 633 Anderson 2017). 634 635 Water Pollution 636 Petroleum production, transportation, and refining all pose risks for surface and groundwater 637 contamination. Most historic incidents involved offshore oil platform blowouts, such as Deepwater 638 Horizon in the Gulf of Mexico in 2010, or ship tanker mishaps like the Exxon Valdez in 1989 (Allen et al. 2012). However, cumulative leakage may be a greater long-term concern (Allison and Mandler 2018). 639 640 Groundwater may be contaminated by cracked wellheads and casings, with the pollutants being a mix of crude oil, chemicals used during extraction, and brine water that is mixed with the petroleum deposit. 641 Drilling muds and solvents used to increase the yields of drilling can contaminate groundwater. These are 642 643 mixed with brine water that is extracted and separated from the crude oil, and naturally occurring

- radioactive material, including radium. Hazardous waste generated during the extraction process is
- 645 typically disposed of by deep-well injection. There is evidence that hydraulic fracturing (hydrofracking)
- 646 increases the risk of water pollution (Allen et al. 2012; NYS DEC 2015).

Narrow-Range Oils

648 Petroleum refining may also result in surface and groundwater pollution (Allen et al. 2012). Effluents from 649 petroleum refining include acids, salts, waste oil, sulfides, ammonia, nitrate, cyanides, heavy metals, suspended solids, and various toxic hydrocarbons (Amiry, Sutherland, and Martin 1997; Wake 2005; Allen 650 651 et al. 2012). Areas near the outfall of petroleum refinery effluent may be almost completely devoid of life 652 (Wake 2005). 653 654 Land Use and Soil Contamination 655 Petroleum and natural gas production can disrupt existing land use patterns (NYS DEC 2015). Horizontal 656 drilling may reduce the amount of land on the surface that is disturbed, but it can also lead to an increased 657 overall area of geological disturbance (Allison and Mandler 2018). Extraction may result in subsidence and 658 low-level earthquakes. 659 660 Oil spills from a wide range of sources, including pipeline leaks and oil tanker spills, can contaminate soils. A large volume spill of petroleum can remain in the soil for a long time. A comprehensive review of 661 remediation technologies for oil contaminated soil indicates that no single technique will be effective for all 662 cases (Lim, Von Lau, and Poh 2016). 663 664 665 Solid waste produced by oil refineries include both hazardous and non-hazardous wastes, and separating 666 the two can be an engineering challenge (Amiry, Sutherland, and Martin 1997). The waste may be 667 incinerated (which further contributes to air pollution), landfilled, or deep well injected. 668 There have been several reviews of the vast literature of the degradation of petroleum and its derivatives 669 670 (Zobell 1946; Atlas 1981; Das and Chandran 2011). Because of their complexity, petroleum and its fractions are difficult to generalize. Petroleum is insoluble and therefore does not degrade by hydrolysis. While the 671 aromatic fractions are photodegradable, the aliphatic fractions - which would be the main constituents of 672 673 PDSOs – are only photodegradable to a point. One review of petroleum spills found that while aliphatic 674 petroleum fractions were reduced by photodegradation and branched structures became linear, short-chain 675 aliphatic structures were stable when exposed to solar radiation (Nicodem et al. 1997). Because sunlight 676 does not penetrate much below the soil surface, photodegradation is not a significant factor in the 677 breakdown of environmental contaminants (McBride 1994). Historically, aliphatic fractions were 678 considered biologically inert, but various soil organisms were observed to degrade paraffin as early as 1906 679 (Söhngen 1906; Zobell 1946). Because PDSOs do not degrade via hydrolysis or photolysis and are not readily biodegradable, petroleum spray oils are likely to remain in the environment. For the most part, they 680 will adsorb to soil particles and not actually biodegrade (Cornish, Battersby, and Watkinson 1993). 681 682 683 The environmental fate and long-term ecological effects of large-scale petroleum releases into the aquatic 684 and terrestrial environments have been studied extensively (Albers 1995; Albers 2007; Chang et al. 2014). 685 Most field studies have been conducted in the wake of numerous accidental releases, such as oilfield 686 gushers, off-shore platform blowouts, pipeline leaks, train tanker derailments, ocean tanker shipwrecks, and refinery explosions. These high-profile accidents account for less total petroleum released into the 687 environment compared with the cumulative effects of continuous, incidental low-level losses, leaks, and 688 seepage from wells, refineries, and storage facilities (Morgan and Watkinson 1989). Incidental releases are 689 690 more widely distributed over time and space than accidental releases. 691 692 PDSOs are not the only source of use and misuse of petroleum products in the environment, with the main 693 ones related to the improper storage and handling of petroleum-based hydrocarbons as fuels. The primary use of petroleum is gasoline, which accounted for about 47 percent of petroleum used in 2017 (US EIA 694 695 2018); about 84 percent of petroleum was used for gasoline and other fuels. PDSOs can be characterized as 696 a relatively minor use of petroleum. A detailed analysis of the extensive literature on environmental 697 contamination by all petroleum product releases into the environment is beyond the scope of this review. 698 Evaluation Question #7: Describe any known chemical interactions between the petitioned substance 699 700 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)). 701 702

PDSOs are generally non-reactive with the other substances used in organic crop production, such as limesulfur, sulfur, or botanicals. The longer chain structures tend to be stable and may adsorb to leaves or soil
(US EPA 2007). However, mixtures with sulfur are known to damage plants (Cranshaw and Baxendale
2005).

707

Evaluation Question #8: 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)).

711

PDSOs can interact with the agro-ecosystem in several different ways. Because PDSOs are biocidal to mites and insects, they can reduce the populations of these organisms. The effects of PDSOs on soil organisms can be expected to vary by species, soil type, temperatures, water, and gas exchange conditions. PDSOs' suffocating mode of action is non-selective; when released into the environment, it will smother aerobic organisms, reduce light, and modify habitats through altered pH, decreased dissolved oxygen, and

- 717 decreased food availability (Albers 1995).
- 718

719 Scientific literature has extensively reviewed the impact of petroleum contamination on soil and soil

microorganisms, petroleum's biological degradation, and the potential for its bioremediation (Atlas 1981;

721 Morgan and Watkinson 1989; Leahy and Colwell 1990; Van Hamme, Singh, and Ward 2003; Varjani 2017).

722 However, very few of these specifically refer to PDSOs; most are reviews of crude oil contamination, with

some referring to heavy mineral oil, PAHs, or various petroleum fuel products. Crude petroleum appears

- to have a mixed effect on soil bacteria and fungi, favoring some species while suppressing others (Jensen
- 1975; Llanos and Kjøller 1976; Pinholt, Struwe, and Kjøller 1979; Atlas 1981; Morgan and Watkinson 1989;
 P.-W. G. Liu et al. 2011).
- 727

728 Early experiments examined the effect of petroleum on soil microbial ecology, with subsequent research 729 focused on the selection of species and manipulation of ecological conditions for bioremediation of 730 contaminated soils. Populations of most bacterial groups tend to increase in soil media treated with 731 mineral oil and oily waste under laboratory conditions, although Streptomyces and spore-forming bacteria 732 were observed to decrease (Jensen 1975). Similarly, for fungi, some species were completely absent 733 following treatment with crude petroleum, several showed no difference from a no-treatment control, and 734 some fungal species thrived on petroleum (Llanos and Kjøller 1976). Besides species selection, soil 735 properties that influence biological activity on petroleum are temperature, pH, salinity, and soil structure 736 (Atlas 1981; Morgan and Watkinson 1989; Van Hamme, Singh, and Ward 2003). Linear and branched 737 alkane structures - the predominate hydrocarbons in PDSOs - are considered the most readily 738 biodegradable of the petroleum fractions (Van Hamme, Singh, and Ward 2003). Increased organic matter in 739 soil can slightly accelerate biodegradation of petroleum under certain conditions, but the differences are 740 small and inconsistent (Sarkar et al. 2005).

741

742 The effect of spray oils on beneficial organisms seems to vary based on the mobility of the organism, its 743 stage of development, and its ability to reinvade after the application (Davidson et al. 1991). There have 744 been a few controlled studies examining survival of predators and parasites exposed to mineral oils alone 745 in field conditions. Orange trees in Australia treated for red scale (Aonidiella aurantii) with a summer oil 746 also saw a drop in the scale predator Aphytis melinus (Campbell 1975). The predators recovered faster with 747 summer oil treatments, and their populations fully recovered after 8 days. By contrast, there were no 748 predators at all in the malathion-treated trees until 16 days after treatment, and the population never fully 749 recovered to the levels seen with the no-treatment control.

750

A Washington state study examined the relative survival of pests and their natural enemy complexes in
 apple orchards treated with PDSOs (Fernandez et al. 2005). PDSOs were used as ovicides for codling moth
 (*Cydia pomonella*) and leafroller (*Pandemis pyrusana*), and as foliar sprays for apple leafhopper (*Typhlocyba pomaria*), wooly apple aphid (*Eriosoma lanigerum*), European red mite (*Panonychus ulmi*), two-spotted spider

mite (*Tetranychus urticae*), McDaniel spider mite (*Tetranychus mcdanieli*), and apple rust mite (*Aculus*

schlectendali) and compared with an untreated control orchard. Aphid predator lacewing and syrphid fly

757 populations were not significantly different between the treated and control orchards. Similarly, parasitism

758 rates of leafhoppers by Anagrus and Aphelopus wasps were found not to be significantly different between 759 the PDSO-treated and control orchards. However, the populations of the beneficial mite species western predatory mite (Galendromus occidentalis) and the stigmaeid predatory mite (Zetzellia mali) were suppressed 760 761 at rates comparable to those of the pest mites (Fernandez et al. 2005). 762 763 A Florida study compared different pesticides – including PDSO – both for efficacy in controlling citrus 764 leafminer and the survival of its natural enemy, the parasitic wasp Ageniaspis citricola. PDSO caused 765 mortality for both species within one hour, with a higher death rate for citrus leafminer larvae (Villanueva-766 Jiménez and Hoy 1998). Within 24-48 hours, adults of both pest and parasitoid recovered, with a higher 767 rate of parasitism in the surviving pest population. The authors concluded that PDSOs were compatible 768 with integrated pest management (IPM) and biological control (Villanueva-Jiménez and Hoy 1998). 769 770 Narrow-range mineral oil was applied under laboratory conditions to soybean aphids (Aphis glycines) and 771 that aphid's key predator, the multi-colored Asian lady beetle (Harmonia axyridis) at various life stages (Kraiss and Cullen 2008). The study found mineral oil to cause 100 percent mortality of the soybean aphids. 772 773 Mineral oil was moderately toxic to the larval stages of the lady beetle, with 48.9 percent and 31.9 percent 774 mortality for the first and third instars, respectively. Mineral oil was not toxic to either pupae or adult lady 775 beetles (Kraiss and Cullen 2008). 776 777 Citrus trees treated with two different brands of mineral oil for two-spotted spider mite in Spain were 778 compared with other treatments and a no-treatment control for their relative impacts on natural enemies 779 (Urbaneja et al. 2008). Mineral oil was highly effective against the target pest, with results comparable to or 780 better than acaricides with toxic modes of action. The mortality of the beneficial mite Neoseiulus californicus 781 populations after one and three days was no different from the no-treatment control. By day six, beneficial 782 mite mortality was higher than the no-treatment control, but lower than the other pesticides used. Mineral 783 oil was also found to be non-toxic to the aphid parasitoid Aphidius colemani and the mealybug destroyer 784 (Cryptolaemus montrouzieri), a predator related to lady beetles (Urbaneja et al. 2008). 785 786 Mineral oils appear to be non-toxic to pollinators. A study reviewed by EPA determined that the 48-hour 787 acute contact toxicity of a petroleum distillate to honey bees (*Apis mellifera*) was greater than $25 \,\mu g/ai/bee$, which was also the NOEL (Hoxter, Palmer, and Krueger 1999). PDSOs are rated as "low" for pesticide 788 789 movement through the soil profile into the water table, and have an estimated average half-life of 10 days 790 in soil (Vogue, Kerle, and Jenkins 1994). Researchers considered the impact of mineral oils on soil 791 microorganisms to be minimal, given that the oils will readily bind to soil particles and not be biologically 792 available (Cornish, Battersby, and Watkinson 1993). 793 794 The earliest descriptions of the use of PDSOs acknowledged that they can injure plants (Jones 1919; deOng, 795 Knight, and Chamberlin 1927; P. J. Chapman, Pearce, and Avens 1943). Petroleum-contaminated soils are

Knight, and Chamberlin 1927; P. J. Chapman, Pearce, and Avens 1943). Petroleum-contaminated soils are
noted to have lower plant biomass than uncontaminated soils (Merkl, Schultze-Kraft, and Infante 2005).
Development of commercial products required removal of aromatics and sulfur-bearing compounds to
reduce the amount of damage to the crops (Volck 1929; Voorhees 1937; P. Chapman et al. 1962; J. Baker
1970). In general, lower molecular weights correlate with greater plant damage and systemic injury (J.
Baker 1970). Thus, petroleum products with aromatic, naphthenic, and PAH structures have the greatest
ecological impact when released in the ecosystem (Albers 1995). Highly refined PDSOs that have low levels
of these structures will have a short-lived and limited impact by comparison.

803

Certain common soil bacteria are reported to metabolize and biodegrade petroleum fractions. *Pseudomonas oleovorans* appears to metabolize certain petroleum fractions as a carbon source (McKenna and Coon 1970).
 Bacillus subtilis and *Bacillus cereus* – as well as some species of soil fungi – are reported to degrade

petroleum fractions (Pesticide Research Institute 2015). Various grasses and legumes may also be an

effective means of removing petroleum hydrocarbons from the soil (Merkl, Schultze-Kraft, and Infante

2005; Gaskin, Soole, and Bentham 2008). Microorganisms that biodegrade petroleum are believed to be

810 stimulated by root exudates.

812 813	<u>Evaluation Question #9:</u> 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)
814	(i)).
815 816	When released into the environment, mineral oils are moderately persistent and are partitioned into soils
817	and suspended solids. The EPA regards aliphatic solvents as practically non-toxic to fish and birds (US
818	EPA 2007). However, mineral oil is highly toxic to the model aquatic invertebrate, <i>Daphnia magna</i> . Mineral
819	oil had a 48-hour half maximal effective concentration (EC ₅₀) value for <i>D. magna</i> of 0.10 ppm, with a No
820	Observed Effect Concentrate (NOEC) of 0.023 ppm ai (Drotter and Krueger 1999). On the other hand, the
821	lethal concentration (LC ₅₀) for <i>D. magna</i> varied widely based on the formulation and ranged from 0.2 mg/L
822 823	to 14 mg/L (US EPA 2007). The most toxic formulations are no longer registered with EPA.
824	Oils applied to plants reduce respiration and transpiration, and may have systemic effects that injure
825	growing foliage (J. Baker 1970). Mineral oils that contain significant amounts of aromatic and naphthenic
826 827	structures are also less biodegradable than those that are more highly refined paraffinic oils.
828	Evaluation Question #10: Describe and summarize any reported effects upon human health from use of
829	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
830	(m) (4)).
831	Minerel ail touisity require a coording to ail composition and here it is treated. The EDA concluded that when
832 833	Mineral oil toxicity varies according to oil composition and how it is treated. The EPA concluded that when compared with other pesticides, aliphatic solvents are practically non-toxic. Highly refined white mineral
834	oil has a long history of safe use (Nash et al. 1996). In assessing aggregated exposure through all sources,
834 835	aliphatic solvents have a "virtually insignificant impact on human health" (US EPA 2007). EPA has
836	exempted petroleum oils from the requirement of a tolerance [40 CFR 180.905(a)(1)].
837	exempted perioteun ons nom me requirement of a tolerance [40 CFR 100.905(a)(1)].
838	Despite the longstanding conclusion of low or non-toxicity, there is a growing concern about the health
839	effects from the ingestion of mineral oil hydrocarbons through direct use as a food additive as well as from
840	multiple sources of environmental contamination (EFSA 2012). Specifically, mineral oils have been linked
841	to lipogranulomas in human livers (Dincsoy, Weesner, and Macgee 1982), though the causality has been
842	questioned (Nash et al. 1996). Exposure to mineral oil hydrocarbons in food is greater than was once
843	expected, requiring dietary intake as a direct food additive to be reconsidered (Grob 2018).
844	
845	The scientific literature on the oral ingestion of mineral oil has been reviewed extensively (Nash et al. 1996;
846	Kimber and Carrillo 2016). Most of the ingestion of mineral oil is as a direct, secondary, and indirect food
847	additive used in food processing. Relatively few studies have examined ingestion as a pesticide
848	contaminant of food. The complex aliphatic chains are not easily metabolized and/or bioavailable. What
849	little gets absorbed in the digestive process accumulates in the liver, spleen, lymph nodes, and body fat
850	(Nash et al. 1996). Some fat-soluble contaminants may be incorporated in aliphatic hydrocarbons.
851 852	There was avidence of linked subinemunity in miss with supposed to mineral ail between the subsequent.
852 853	There was evidence of linked autoimmunity in mice with exposure to mineral oil; however, the subsequent
853 854	studies failed to generate a dose-response curve or link the incidents in the rodent model to human health (Kimber and Carrillo 2016). Both the avenues of exposure and the causes of autoimmunity are not
855	understood well enough to consider the evidence conclusive. The authors concluded that dietary exposure
856	to mineral oils does not represent a health risk for the development of autoimmune disease, or the intuition
857	or enhancement of autoimmune responses.
858	
859	Dermal penetration of mineral oil was reviewed with other topically applied substances used in cosmetics.
860	The data showed that only a small fraction of mineral oil reaches the deeper layer of skin, with no evidence
861	that mineral oils are percutaneously absorbed with other ingredients (Petry et al. 2017).
862	
863	EPA classifies aliphatic solvents as either practically non-toxic (Category IV) or slightly toxic (Category III)
864	(US EPA 2007). Applicators may be at some inhalation risk when exposed to fine droplet size, such as
865	would be produced by an air-blast sprayer. Labels usually advise against inhaling the mist. Repeated or
866	prolonged exposure to petroleum distillates may result in adverse health effects (InChem 1982).

- 868 Environmental exposure to petroleum hydrocarbons is difficult to measure, and human exposure is difficult to predict because of their widespread use. It is hard to determine what portion of mineral 869 870 hydrocarbon ingestion is caused by PDSOs, particularly since similar substances are applied in large quantities as inactive as well as active ingredients. One study found that grape seed oil had higher levels of 871 872 paraffins of mineral oil, suggesting an environmental source of contamination (Fiorini et al. 2008). 873 However, the study did not specifically mention pesticide applications as the source. 874 875 Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be 876 used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed 877 substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)). 878 879 Vegetable oils are among the non-synthetic alternatives to suffocating oils (Davidson et al. 1991). Castor, 880 corn, cottonseed, linseed, and soybean oils are all exempt from the requirement of EPA registration in the 881 United States under section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These active ingredients are considered to pose minimum risk to human health and the environment (Baker and 882 Grant 2018). Canola, safflower, and sunflower oils have also been tested for efficacy against many of the 883 884 target insects of petroleum spray oils. Vegetable oils fully degrade in the soil, while mineral oils will only 885 partially degrade (Cornish, Battersby, and Watkinson 1993). 886 887 Castor, cottonseed, and linseed oils were compared with a PDSO for the control of various citrus pests, 888 particularly red scale (Chrysomphalus aurantii) (DeOng et al. 1927). All the vegetable oils were more toxic to 889 scale than PDSO, which had a fatal immersion time of 240-1,400 minutes. Cottonseed oil was the most 890 effective with lethal immersion times of 14-1,400 minutes. Linseed oil had a fatal immersion time of 30-1,300 minutes. However, the vegetable oils were all more toxic to the citrus plants than PDSO (DeOng et al. 891 892 1927). 893 894 Early laboratory experiments compared the penetrating action of various contact insecticides, including 895 vegetable and essential oils, with lubricating oils (Moore and Graham 1918). Vegetable oils had comparable 896 penetrating actions with lubricating oils, or early PDSOs. Natural essential oils – including citronella oil – 897 had greater penetrating effect on the trachea (Moore and Graham 1918). 898 899 Soybean oil adheres to leaf surfaces longer than PDSOs, even under conditions of heavy precipitation 900 (Bondada et al. 2000), which may make soybean oil a more effective alternative than PDSOs for some 901 conditions and applications. One study compared the efficacy of soybean oil with a PDSO for controlling terrapin scale (Mesolecanium nigrofasciatum), San Jose scale (Quadraspidiotus perniciosus) and European red 902
- mite (*Panonychus ulmi*) on apples and peaches. Fruit tree stems dipped in a 7.5 percent solution of
 degummed soybean oil for one second resulted in 93 percent mortality of terrapin scales (Pless et al. 1995).
- 905 No red mites survived at a rate of either 5 percent or 7.5 percent soybean oil, making its efficacy
- 906 comparable to petroleum oil. The same article reported field tests where one application of 2.5 percent
- 907 petroleum oil or 5.0 percent soybean oil sprayed on apple trees killed over 95 percent of *Q. perniciosus*
- populations. One application of 5.0 percent soybean oil and 0.6 percent emulsifier killed 85 percent of *M*.
- nigrofasciatum populations, and two applications killed over 98 percent (Pless et al. 1995). Two applications
- of 2.5 percent soybean oil killed only 72 percent of the *Q. perniciosus* populations.
- 911
- 912 In another study, apple trees infested with *M. nigrofasciatum* were treated with 3 percent petroleum oil, and
- 913 with 6 percent degummed soybean oil with 0.6 percent emulsifier (Latron B-1956). Both sprays
- significantly reduced the numbers of first- and second-generation crawlers by more than 90 percent over
- 915 two seasons compared to the no-treatment control, and were not significantly different from each other 916 (Hix et al. 1999).
- 917
- 918 Soybean oil showed comparable efficacy to PDSOs sprayed on apple trees in the summer at a rate of
- 919 1 percent reduced *P. ulmi* populations by 94 percent, a rate comparable to the efficacy of a petroleum oil
- 920 (Moran et al. 2003). Higher rates of 4 percent and 6 percent did not result in any greater *P. ulmi* control but
- 921 did result in significantly greater phytotoxicity.

- 923 Summer sprays of soybean oil were effective in reducing populations of two-spotted spider mites 924 (Tetranychus urticae) on burning bush (Euonymus alatus) (Lancaster et al. 2002). T. urticae populations were 925 reduced by between 97-99 percent by single sprays of 1, 2, or 3 percent degummed soybean oil emulsified 926 with Latron B-1956 and diluted with water. The control was a water spray (Lancaster et al. 2002). Soybean 927 oil at the 2 percent and 3 percent concentrations suppressed photosynthesis for a short time but were not 928 phytotoxic. The same researchers conducted a second experiment involving 0.75, 1.0, or 1.5 percent 929 degummed soybean oil, again with a water-only control. One application reduced the *T. urticae* population 930 by more than 95 percent compared to a water control. A second application of 0.25–1.5 percent emulsified 931 degummed soybean oil resulted in \geq 93 percent control of *T. urticae* compared to the water control, but a 932 third spray provided little additional control. Beneficial mites were not affected by a single spray of 933 soybean oil. At concentrations \leq 1.5 percent, a single application of soybean oil did not significantly reduce 934 photosynthesis. The efficacy of soybean oil was comparable to PDSO against *T. urticae*, and both had 935 similar effects on photosynthesis. In the first experiment, soybean oil was less phytotoxic and caused less 936 defoliation of stressed plants than the PDSO. In the other two experiments, defoliation was not 937 significantly different between the soybean oil- and PDSO-treated plants. 938 939 Castor oil and peanut oil each inhibited the hatching of sweet potato whitefly (Bemisia tabaci) eggs, with 940 19 percent of the eggs being viable (Fenigstein et al. 2001). The result was significantly better than 941 cottonseed, soybean, and sunflower oils, and comparable to using peanut oil alone. The same study showed that a 3 percent solution of castor oil effectively reduced survival rates of larvae, with 7.9 percent 942 943 survival for the first instar, 4.1 percent for the second instar, 14.0 percent for the third instar, and
- 944 19.0 percent for the fourth instar. Used against adults, 3 percent castor oil caused 3 percent mortality after
 945 2 hours, and 75 percent mortality after 24 hours. Another study found that 10 percent cottonseed oil
 946 reduced *B. tabaci* larval populations by 99 percent (Butler, Coudriet, and Henneberry 1991).
- 946 947

Essential oils such as citronella, clove, lemongrass, thyme, rosemary, peppermint, and corn mint oils may
be more effective and less damaging to plants as summer or foliar sprays in some cases (Regnault-Roger
1997; Isman and Miresmailli 2011).

951

Various polysaccharides derived from vegetable gums were compared with PDSOs for the control of citrus
leafminer (G. Beattie, Liu, et al. 1995). PDSOs were unequivocally more effective than the polysaccharides
at all life stages and on all target citrus pest species. However, a mixture of PDSOs and polysaccharide gum
may have a synergistic effect.

956

957 Fish oils have also long been used as an alternative to PDSOs as dormant sprays in deciduous tree fruit 958 (Kelley 1930; Sams and Deyton 2002). Fish oil is not registered as an insecticide, and it is mainly used in 959 dormancy as an adjuvant with lime-sulfur or as a foliar fertilizer with kelp. The combination is somewhat 960 effective for fruit thinning (McArtney et al. 2006; Yoder et al. 2009). Organic apple farmers in Washington 961 State reported fish oil provided mixed results with control of codling moth and aphids (Granatstein 2003). Fish oil was found to be slightly less effective in controlling citrus leafminer compared with PDSOs, but the 962 963 difference was not significant. Fish oil was found to reduce the survival of citrus leafminer adults, but was 964 ineffective against immature leafminers (Villanueva-Jiménez and Hoy 1998). It was selective for the citrus 965 leafminer predator Ageniaspis citricola, so fish oil would be compatible with a biological control program.

966

Biopesticides may also be used as alternatives to PDSOs. One study compared the use of a 2 percent horticultural oil with a 0.5 percent wetting agent (Silwet L-77) with the biopesticidal active ingredient

horticultural oil with a 0.5 percent wetting agent (Silwet L-77) with the biopesticidal active ingredient
 Chromobacterium subtsugae (brand name Grandevo) for three orchid pests: *T. urticae*, the Phalaenopsis mite

970 (*Tenuipalpus pacificus*) and the long-tailed mealybug (*Pseudococcus longispinus*). The horticultural

oil/wetting agent combination caused mortality of at least 82 percent of all pest species, but also killed the

972 beneficial mites *Metaseiulus occidentalis* and *Hemicheyletia wellsina*. By comparison, Grandevo had a

comparable level of control for *T. pacificus*, failed to kill either of the other pests, and did not kill any of the

974 beneficial mites (Ray and Hoy 2014).

Bacillus thuringiensis (Bt) is a natural alternative for the control of Lepidopteran insects. A study of sweet
corn grown in New England compared mineral oil with corn oil, Bt, and the fungal entomopathogen
Beauveria bassiana for the control of Ostrinia nubilalis, Helicoverpa zea, and Spodoptera frugiperda. The
combination of corn oil and Bt provided the greatest and most consistent control of the three pests

980 (Hazzard et al. 2003).

Another study conducted in Iran compared garlic oil-soap emulsion, a blend of plant extracts in emulsion, and *Bt* with mineral oil for citrus leafminer. The garlic oil-soap emulsion was the most effective, with 68 percent mortality, followed by the plant emulsion at 63 percent, with the two treatments not significantly different. With a larval mortality of 49 percent, *Bt* was a more effective larvicide than mineral oil (38 percent mortality) (Amiri-BeSheli 2008). Mineral oil was the least effective of the four treatments. However, the study noted mineral oil deterred egg laying and served as an ovicide, while *Bt* did not.

988

981

Other biopesticides sometimes used for target pests of PDSOs include baculoviruses and other pathogens that infect Lepidopteran pests (Moscardi 1999). Examples are the codling moth granulosis virus (CMGV) (Swezey et al. 2000) and the nuclear polyhedrosis viruses (NPV) of the beet armyworm (*Spodoptera exigua*) and corn earworm (*Helicoverpa zea*) (Kolodny-Hirsch et al. 1997; Farrar and Ridgway 2000). Baculoviruses face several problems that make formulation and commercialization difficult (Black et al. 1997), however, there is renewed interest in developing them (Szewczyk et al. 2006). These biocontrol agents are not applied at the dormant stage and are not seen as direct substitutes for PDSOs; they may be applied with

- 996 PDSOs as adjuvants or co-active agents.
- 997

Kaolin clay (Surround), a non-synthetic mined material, has been found to protect apples from a wide
range of pests (Thomas et al. 2004; Marko et al. 2008). Kaolin clay also reduces fungal disease pressure and
heat stress in apples (Glenn et al. 2001; Thomas et al. 2004). When applied as a dormant dust to apples,
kaolin clay resulted in fewer Oblique-banded leafroller (*Choristoneura rosaceana*) larvae hatching, lower
larvae survival, and reduced egg laying by adult female moths (Knight et al. 2000).

1003

1004 The botanical insecticides neem and pyrethrum may also be used as alternatives to PDSOs for a number of 1005 pests (Buss and Park-Brown 2002; Zehnder et al. 2007; Daniels, Miles, and Murray 2013). The fungal 1006 derivative, spinosad, is also a broad-spectrum insecticide used for aphids, whiteflies, leafhoppers, thrips, 1007 and other pests (Delate et al. 2008; Peck and Merwin 2010; Caldwell et al. 2013). However, these 1008 insecticides are not considered substitutes for dormant sprays. Botanicals and spinosad are not necessarily 1009 less toxic to non-target organisms and may disrupt populations of beneficial organisms when used as a 1010 foliar spray. For example, neem oil was found to prevent adult lady beetles (Coccinella undecimpunctata) 1011 from emerging from their pupae, and partially suppressed the emergence of syrphids (Eupeodes 1012 *fumipennis*), both natural enemies of the green peach aphid (*Myzus persicae*) (Lowery and Isman 1995). 1013 Neem oil alone was also found to be less effective against citrus leafminer than a mix of neem oil and 1014 PDSO, and slightly reduced the adult survival of the leafminer parasitoid A. citricola. However, parasitism 1015 remained high in the neem oil treatment (Villanueva-Jiménez and Hoy 1998). Spinosad can also adversely 1016 impact natural enemy populations, particularly those of parasitic wasps (Williams, Valle, and Viñuela 2003; 1017 Ndakidemi, Mtei, and Ndakidemi 2016).

1018

1019 Vegetable oils have long been known to suppress various fungal plant diseases.. Castor, canola (rapeseed), 1020 cottonseed, olive, and peach seed oils were all found to have comparable control of powdery mildew of 1021 hops (Sphaerotheca humuli) to various PDSOs (Martin and Salmon 1931). Emulsified canola, corn, olive, 1022 safflower, soybean, and sunflower oils each showed over 95 percent control values for powdery mildew 1023 (Sphaerotheca fusca) on cucumber leaf surfaces in a greenhouse test, with canola oil being the most effective 1024 at a rate of 98.9 percent control of leaf surface areas (Jee et al. 2009). Soybean oil was less effective in 1025 controlling powdery mildews (Oidium tuckeri and Uncinula necator) and downy mildew (Plasmopara viticola) 1026 in grapes. More specifically, soybean oil applied to grapes had marginal control of the two species that 1027 cause powdery mildew in Ontario, and was ineffective against the downy mildew pathogen (Northover 1028 and Schneider 1996).

Narrow-Range Oils

Reasons for PDSOs instead of vegetable oils seem to vary by crop, target organism, and region. For citrus,
vegetable oils may results in higher phytotoxicity in some cases (DeOng, Knight, and Chamberlin 1927).
The natural origin of plant and animal oils makes them more variable than PDSOs in their composition and
quality (Bográn, Ludwig, and Metz 2006). While vegetable oil efficacy in experimental trials may be
comparable or even superior, there is a perception that they perform less consistently than PDSOs under
field conditions (Agnello 2002; Cranshaw and Baxendale 2005). Cost may also be a factor, depending on the
relative prices of petroleum and vegetable oils.

1037

1038 Vegetable and fish oils may be formulated with synthetic emulsifiers or other inert ingredients. However,
1039 vegetable and fish oils without emulsifiers are widely available. Any non-synthetic oil used in organic
1040 production would need to meet the requirements for inert ingredients in 7 CFR 205.601(m), just as PDSOs
1041 would. The synthetic portion of such formulations would be in the range of 1-5%, instead of 100% as in the
1042 case of PDSOs. For minimum risk (FIFRA 25b) formulations, the inert ingredients would also need to be
1043 minimum risk and would be reported on the label. Inert ingredients in vegetable oils that are EPA
1044 registered would be confidential business information (CBI).

1045

1046 <u>Evaluation Question #12:</u> Describe any alternative practices that would make the use of the petitioned 1047 substance unnecessary (7 U.S.C. § 6518 (m) (6)). 1048

1049 Increased biodiversity has been shown to reduce pest pressure in a wide range of agro-ecosystems (M. A. 1050 Altieri and Letourneau 1982; M. Altieri and Nicholls 2004; Zehnder et al. 2007; Vandermeer, Perfecto, and Philpott 2010). Crop rotation, inter-cropping, and permaculture designs offer possible cultural methods for 1051 1052 reducing pest pressure overall in annual crops (Yepsen 1984; Mollison 1988; Holmgren 2002; Zehnder et al. 1053 2007). For example, apple orchards intercropped with aromatic species such as peppermint (Mentha 1054 canadensis), ageratum (Agerarum houstonianum), French marigold (Tagetes patula), and basil (Ocimum 1055 *basilicum*) decreased herbivore abundance, increased predator populations, and shifted the arthropod 1056 community structure from being herbivore-dominated to being predator-dominated (Song et al. 2012). 1057 Aphid species in particular were significantly reduced by such intercropping. . Varietal choice, habitat management, and mass releases of beneficial organisms are all part of an overall strategy for organic apple 1058 1059 orchard management (Swezey et al. 2000; M. Altieri and Nicholls 2004; Wyss et al. 2005). However, these 1060 guides do not preclude the use of PDSOs in conjunction with an integrated strategy that relies primarily on 1061 cultural practices. Increased biodiversity has been shown to reduce pest and disease pressure in orchard 1062 systems (Altieri, Davis, and Burroughs 1983; Simon et al. 2011). Native beneficial organisms including insects, spiders, and birds all help control pests in these systems. 1063

1064

1065 Alternative cultural methods for managing aphids, mites, and other soft-bodied plant pests include releasing predators and parasites. Aphids, mealybugs, and whiteflies are favored prey of lady beetles 1066 1067 (Hippodamia convergens) and other coccinellid predators (Obrycki and Kring 1998). However, these 1068 predators are limited in their effectiveness against adult scale. Lacewings (*Chrysoperla* spp.) can also be 1069 effective when released in vineyards for pests such as the grape leafhopper and grape mealybug. In two 1070 California vineyards, inundative lacewing releases reduced grape leafhopper populations by 33.6 percent 1071 in the first generation and 31.4 percent in the second generation. (Daane et al. 1996). Lacewings are also 1072 broad predators in apple orchards (Szentkirályi 2001). Natural enemies are generally active during the 1073 season when foliage is present in deciduous orchards and annual crops. While they may be an alternative 1074 to summer oils, these predators are not a practical alternative to dormant oils used on deciduous perennials. Lacewings show distinct seasonality with their predation (Szentkirályi 2001).

1075 1076

1077 The nematode *Steinernema carpocapsae* was found to provide comparable control of citrus leafminer to
1078 PDSOs in Australia (Beattie, Somsook, et al. 1995). High rates of release of the beneficial nematodes
1079 performed better than the highest application rate for PDSOs. However, the nematode's cost of control at
1080 those rates was considered commercially unacceptable to citrus producers.

1081

1082 It is unclear whether dormant oils enable natural enemies to be more effective during the growing season
1083 by reducing the target pest population, or if their ovicidal activity reduces the populations of natural
1084 enemies as well as pests (Davidson et al. 1991). The two may be complimentary strategies, with releases to

1085 1086 1087 1088 1089 1090 1091 1092 1093 1094 1095 1096 1097 1098	restore beneficial organism populations a few days following a knock-down spray with PDSOs. Commercial delivery of live beneficial organisms is a practical option, but it can present challenges (Tauber et al. 2000). Predator and parasitoid populations can be enhanced by planting and maintaining habitat plants that provide shelter and food throughout their life-cycles. Again, PDSOs are compatible with managed habitat and are not an "either/or" alternative. Since the energy crisis of the 1970s and the on-set of peak oil, there is a recognition that agriculture needs to develop sustainable alternatives to petroleum (Rosset and Altieri 1997; Youngquist 1999; Peters et al. 2009). Research has focused on developing sustainable alternative fuels for mechanized farm equipment and transportation of food to market. However, the analyses also recognize the need to replace petrochemical inputs with agroecological techniques (Rosset and Altieri 1997).
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4	
1101 1102 1103 1104	The following individuals were involved in research, data collection, writing, editing, and/or final approval of this report:
1105 1106 1107 1108 1109	 Brian Baker, Consultant, Organic Materials Review Institute Tina Jensen Augustine, Senior Bilingual Technical Coordinator, Organic Materials Review Institute Lindsay Kishter, Director, Nexight Group Rachel Lanspa, Communications Associate, Nexight Group
1110 1111 1112 1113	All individuals are in compliance with Federal Acquisition Regulations (FAR) Subpart 3.11 – Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.
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Appendix 1 Table 1 Physical and Chemical Properties of Mineral Oil		
Property	Characteristic / Value	
Physical state at 25°C / 1 Atm. (CAS #8012-95-1) ¹	Liquid	
Color ²	Colorless	
Odor ²	Essentially odorless	
Density / Specific Gravity ²	0.875-0.905	
API Gravity (various spray oils) ⁴	32.8-34.3 API Gravity	
Melting point ³	-91.21°F (-68.45°C)	
Boiling point (various spray oils) ⁴	50% b.p: 415° to 440°F ±8°F (212° to 227°C ±4°C)	
Pour point (various spray oils) ⁴	-5° to -20° F (-21° to -29°C)	
Flash point ⁴	380°F (193°C)	
Solubility ²	Insoluble in water	
Vapor pressure ²	<0.5 mm Hg @ 20°C	
Log K _{ow} coefficient ³	5.18	
Viscosity (various spray oils) ⁴	57-83 seconds (10-38 cP)	
Miscibility (CAS #8012-95-1) ¹	Miscible with most fixed oils; not miscible with	
	castor oil; soluble in volatile oils	
Storage stability (CAS #8012-95-1) ¹	Oxidizes at a logarithmic rate	
Persistence ^{2,3}	Half-life of 74 hours; 2–3 days as a surface film	

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Sources: 1. HSDB 2015; 2. US EPA 2007; 3. EPI 2012 4. UC IPM 2017

Table 2 Description of the Various Active Ingredients found in Mineral Oil Pesticides

Chemical Name	CAS #	Description	
Mineral oil, Oil	8012-95-1	Liquid hydrocarbons from petroleum	
mist (mineral)			
Mineral oil;	8020-83-5	A mixture of liquid hydrocarbons obtained from petroleum	
Hydrocarbon oils;			
paraffin liquid			
White mineral oil,	8042-47-5	A highly refined petroleum mineral oil consisting of a complex	
petroleum		combination of hydrocarbons obtained from the intensive	
		treatment of a petroleum fraction with sulfuric acid and oleum,	
		or by hydrogenation, or by a combination of hydrogenation and	
		acid treatment. Additional washing and treating steps may be	
		included in the processing operation. It consists of saturated	
		hydrocarbons having carbon numbers predominantly in the	
		range of C15 through C50.	
Distillates,	64741-88-4	A complex combination of hydrocarbons obtained as the raffinate	
petroleum.,		from a solvent extraction process. It consists predominantly of	
solvent-refined		saturated hydrocarbons having carbon numbers predominantly	
heavy paraffinic		in the range of C20 through C50 and produces a finished oil with	
		a viscosity of at least 100 Sabolt Universal Seconds (SUS) at 100°F	
		(19 centistokes [cSt] at 40°C).	
Distillates,	64741-89-5	A complex combination of hydrocarbons obtained as the raffinate	
petroleum.,		from a solvent extraction process. It consists predominantly of	
solvent-refined		saturated hydrocarbons having carbon numbers predominantly	
light paraffinic		in the range of C15 through C30 and produces a finished oil with a viscosity of loss than 100 SUS at 100° E (196St at 40° C)	
Distillator	(474) 54 7	a viscosity of less than 100 SUS at 100°F (19cSt at 40°C).	
Distillates,	64742-54-7	A complex combination of hydrocarbons obtained by treating a	
petroleum, hydrotreated		petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly	
heavy paraffinic		in the range of C20 through C50 and produces a finished oil of at	
neavy paramine		least 100 SUS at 100°F (19cSt at 40°C). It contains a relatively large	
		proportion of saturated hydrocarbons.	
Distillates,	64742-55-8	A complex combination of hydrocarbons obtained by treating a	
petroleum,	017 12 00 0	petroleum fraction with hydrogen in the presence of a catalyst. It	
hydrotreated light		consists of hydrocarbons having carbon numbers predominantly	
paraffinic		in the range of C15 through C30 and produces a finished oil with	
r		a viscosity of less than 100 SUS at 100°F (19cSt at 40°C). It	
		contains a relatively large proportion of saturated hydrocarbons.	
Distillates,	64742-56-9	A complex combination of hydrocarbons obtained by removal of	
petroleum,		normal paraffins from a petroleum fraction by solvent	
solvent-dewaxed		crystallization. It consists predominantly of hydrocarbons having	
light paraffinic		carbon numbers predominantly in the range of C15 through C30	
		and produces a finished oil with a viscosity of less than 100 SUS	
		at 100°F (19cSt at 40°C).	
Distillates,	64742-65-0	A complex combination of hydrocarbons obtained by removal of	
petroleum,		normal paraffins from a petroleum fraction by solvent	
solvent-dewaxed		crystallization. It consists predominantly of hydrocarbons having	
heavy paraffinic		carbon numbers predominantly in the range of C20 through C50	
		and produces a finished oil with a viscosity not less than 100 SUS	
		at 100° F (19cSt at 40°C).	

Crops

Chemical Name	CAS #	Description	
Lubricating oils,	72623-84-8	A complex combination of hydrocarbons obtained by treating	
petroleum C15-30,		light vacuum gas oil, heavy vacuum gas oil, and solvent	
hydrotreated		deasphalted residual oil with hydrogen in the presence of a	
neutral oil based,		catalyst in a two-stage process with dewaxing being carried out	
containing.		between the two stages. It consists predominantly of	
solvent		hydrocarbons having carbon numbers predominantly in the	
deasphalted		range of C15 through C30 and produces a finished oil having a	
residual oil		viscosity of approximately 10cSt at 40°C (104°F). It contains a	
		relatively large proportion of saturated hydrocarbons.	
Lubricating oils,	72623-86-0	A complex combination of hydrocarbons obtained by treating	
petroleum, C15-		light vacuum gas oil and heavy vacuum gas oil with hydrogen in	
30, hydrotreated		the presence of a catalyst in a two-stage process and dewaxing	
neutral oil-based		being carried out between the two stages. It consists	
		predominantly of hydrocarbons having carbon numbers	
		predominantly in the range of C15 through C30 and produces a	
		finished oil having a viscosity of approximately 15cSt at 40°C. It	
		contains a relatively large proportion of saturated hydrocarbons.	
Lubricating oils,	72623-87-1	A complex combination of hydrocarbons obtained by treating	
petroleum, C20-		light vacuum gas oil, heavy vacuum gas oil and solvent	
50, hydrotreated		deasphalted residual oil with hydrogen in the presence of a	
neutral oil-based		catalyst in a two-stage process with dewaxing being carried out	
		between the two stages. It consists primarily of hydrocarbons	
		having carbon numbers predominantly in the range of C20	
		through C50 and produces a finished oil with a viscosity of	
		approximately 32cSt at 40°C. It contains a relatively large	
		proportion of saturated hydrocarbons.	
Source: (LIS EDA 2007)	\ \		

Source: (US EPA 2007)

1577 1578	Crop	
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 Table 3

 EPA Labeled Food Crops, Target Organisms, and Applications for Mineral Oil

Сгор	Pests and Diseases	Time(s) of Application	Max. App. Rate (lb ai/A unless noted otherwise)
Acerola	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly, Powdery Mildew	When needed	0.07 lb ai/gal
Alfalfa	Aphids, Mites, Leafminers, Rootworm, Whitefly	When needed	14.0
Almonds	Aphids, Scales, Spider mites	Dormant & Summer	123.3
Apples	Aphids, Codling moth, Scales, Mites, Fruit Tree Leaf Rollers, Apple red bug, Powdery mildew	Dormant & Summer	164.4 dormant 84.2 summer
Apricot	Scales, Mites	Dormant & Summer	123.3 dormant 84.2 summer
Artichoke (Chinese)	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly, Powdery Mildew	When needed	0.07 lb ai/gal
Asparagus	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Atemoya	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly, Powdery Mildew	When needed	0.07 lb ai/gal
Avocados	Aphids, Mealybugs, Mites, Scales, Whitefly	When needed	209.6
Bananas/Plantains	Black leaf streak, Yellow sigatoka	Year-round	10.6
Balm	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Basil	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Beans	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Beets (unspecified)	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Blueberries	Scales, Mites, Rust, Powdery mildew	Dormant & Summer	10.6
Caneberries (blackberries, boysenberries, raspberries)	Mites, Scales, Rust, Powdery mildew	Dormant & Summer	10.6
Celery	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Cherries	Scales	Dormant	123.3 dormant 84.2 summer
Citrus (unspecified)	Mites, Scale, Whiteflies, Greasy spot disease, Sooty mold	Year-round	139.2
Coffee	Scales	Year-round	42.4
Cole Crops (Broccoli, Cabbage, Chinese Broccoli, Cauliflower	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal

Сгор	Pests and Diseases	Time(s) of Application	Max. App. Rate (lb ai/A unless noted otherwise)
Corn	Aphids, Mites, Leafminers, Ear Worms, Fall Army Worm, Corn Root Worm, Whitefly	When needed	7.0
Cucurbits (Gourds, Melons, Pumpkins, Squash)	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly, Powdery Mildew	When needed	0.07 lb ai/gal
Eggplant	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Fig	Scales	Dormant	21.17
Ginger	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly, Powdery Mildew	When needed	0.07 lb ai/gal
Ginseng	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly, Powdery Mildew	When needed	0.07 lb ai/gal
Grapefruit	Mites, Scales	When needed	469.2
Grapes	Mealybugs, Scales, Leafhopper, Powdery mildew	Dormant, Postharvest	41.6
Hops	Mites, powdery mildew	Foliar & Postharvest	38.5
Kiwi Fruit	Scales	When needed	42.3
Lemon & Lime	Mites, Scales	When needed	469.2
Lettuce	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Mango	Aphids, Mealybugs, Mites, Scales, Whitefly, Powdery mildew	When needed	10.6
Marjoram/Oregano ¹	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Mint/Peppermint/ Spearmint	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Nectarines	Fruit Tree Leaf Rollers, Scales, Psylla, mites	Dormant	123.3 dormant 84.23 summer
Olives	Scales	Post-harvest, Pre-bloom	156.4
Oranges	Mites, Scales, Whitefly, Blackfly, Sooty mold	When needed	469.2
Papaya	Mites, Powdery mildew, Papaya ringspot	When needed	10.584
Peaches	Scales	Dormant	123.3
Pears	Aphids, Mites, Psylla, Scale, Codling moth (eggs)	Dormant & Summer	164.4
Pecan ²	Aphids, Scale, Mites, Phylloxera	When needed	56.5
Pepper	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Persimmons	Leafrollers, Scales, Book Lice	When needed	0.07 lb ai/gal
Pineapple	Mealybugs, Bud Moth, Chinese Rose Beetle	When needed	14.1
Pistachio	Mites, Scales	Dormant	123.3
Plums/Prunes	Mites, Scales	Dormant &	123.3 summer
		Summer	84.2 dormant
Potatoes (white/ Irish)	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal

Crops

Сгор	Pests and Diseases	Time(s) of Application	Max. App. Rate (lb ai/A unless noted otherwise)
Radish	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Spinach	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly, Powdery Mildew		0.07 lb ai/gal
Strawberries	Aphids, Mites	When needed	0.05 lb ai/gal
Sugar beets	Mites, Leaf miner	When needed	0.14 lb ai/gal
Sweet potatoes	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Tangelo/Tangerines ³	Mites, Scale, Whiteflies, Greasy spot disease, Sooty mold	When needed	469.2
Tobacco	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Tomatoes	Aphids, Mites, Beetle larvae, Leafminers, Thrips, Leafhopper, Whitefly	When needed	0.07 lb ai/gal
Walnuts	Scales, Aphids, Mites, Whiteflies	Dormant & Summer	55.7

1579 Source: (US EPA 2007; US EPA PPLS 2018)

¹Dests and diseases extrapolated from "Herbs and spices."

¹⁵⁸¹ ²Pests and diseases extrapolated from TGAI labels and extension recommendations.

¹⁵⁸² ³Pests and diseases extrapolated from "Citrus (unspecified)."

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 Table 4

 EPA Inert Ingredient Statuses for Aliphatic Solvents

EPA Inert Ingredient Statuses for Aliphatic Solvents				
Chemical Name	CAS #	Cleared	List	
		Uses		
Mineral oil, Oil mist (mineral)	8012-95-1	Food and	3	
		Nonfood		
Mineral oil; Hydrocarbon oils; paraffin liquid	8020-83-5	Not found	3	
White mineral oil, petroleum	8042-47-5	Food and	4A	
-		Nonfood		
Distillates, petroleum., solvent-refined heavy paraffinic	64741-88-4	Not found	3	
Distillates, petroleum., solvent-refined light paraffinic	64741-89-5	Food,	3	
		Nonfood,		
		and		
		Fragrances		
Distillates, petroleum, hydrotreated heavy paraffinic	64742-54-7	Food and	2	
		Nonfood		
Distillates, petroleum, hydrotreated light paraffinic	64742-55-8	Not found	2	
Distillates, petroleum, solvent-dewaxed light paraffinic	64742-56-9	Food and	2	
Conforming to 21 CFR 172.844 or 21 CFR 178.3650		Nonfood		
Distillates, petroleum, solvent-dewaxed heavy	64742-65-0	Food and	2	
paraffinic		Nonfood		
Lubricating oils, petroleum C15-30, hydrotreated	72623-84-8	Not	3	
neutral oil based, containing. solvent deasphalted		found		
residual oil				
Lubricating oils, petroleum, C15-30, hydrotreated	72623-86-0	Not	3	
neutral oil-based		found		
Lubricating oils, petroleum, C20-50, hydrotreated	72623-87-1	Not	3	
neutral oil-based		found		
(IIS EPA 2004 2018)				

1586 (US EPA 2004, 2018)

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Toxicity of Mineral Oil			
Study	Results	Source(s)	
Acute oral toxicity	Rat: >5 g / kg	(Chin and Stewart 1994)	
Acute dermal toxicity	Rabbit: >2 g / kg (CAS 64742-54-7)	(Chin and Stewart 1994; US	
	Rat: > 5 g / kg (CAS 64742-56-9)	EPA 2007)	
Acute inhalation	Rat: > 4.7 mg / L	(Chin and Stewart 1994)	
	Rat: 3,900 mg / m ³ (CAS 64742-55-8)		
Acute eye irritation	Rat: Slight eye irritant. Eye irritation (slight	(Chin and Stewart 1994;	
	conjunctival redness) did not clear at day 14 (last	NIOSH 2003)	
	day of observation);		
	Moderate effect at 500 mg		
Acute dermal	Guinea pig: Mild effect at 100 mg for 24 hr	(NIOSH 2003)	
irritation	Rabbit: Mild effect at 100 mg for 24 hr		
Skin sensitization	Guinea pig: Not a dermal sensitizer	(US EPA 2007)	
28-day dermal	Mice: NOEL > 2,000 mg/kg/day	(US EPA 2007)	
28-day inhalation	Rats: LOEL = 520 mg/m^3	(US EPA 2007)	
	(146.6 mg/kg/day)		
90-day inhalation	Rats: NOEL=0.1 mg/L	(US EPA 2007)	
5	(26.1 mg/kg/day)	, , , , , , , , , , , , , , , , , , ,	
Reproduction /	Minor malformations within the normal ranges	(US EPA 2007)	
development toxicity	observed at doses between 900-4,500 mg/kg-		
screening test	bw/day		
Mutagenicity	Ames test: Inconclusive or Weakly mutagenic	(Reilly and Stewart 1994;	
		EFSA 2012)	
Carcinogenicity	Untreated and mildly-treated mineral oils are	(IARC 2012)	
0 1	carcinogenic to humans; highly refined oils are		
	not classifiable as to their carcinogenicity to		
	humans.		
Fish	No lethality observed in any fish species tested.	(US EPA 2007)	
Daphnia	EC50=0.1->0.9 mg/L	(Drotter and Krueger 1999;	
1	NOEC: 0.023 ppm	US EPA 2007)	
	LC50=0.2->14.0 mg/L		
Oysters	EC=6 mg/L	(US EPA 2007)	
Birds	Northern Bobwhite: LD50>2,250 mg/kg-bw	(Long et al. 1990; Gallagher,	
	Mallard & Northern Bobwhite: LC50>5,260 ppm	Grimes, and Beavers 1998,	
		1999a, 1999b; US EPA 2007)	

Table 5