Reregistration Eligibility Decision

Exposure and Risk Assessment on Lower Risk Pesticide Chemicals

CASE: Aliphatic Solvents (3004)

Active Ingredients: Mineral Oils (063502) & Aliphatic Petroleum Hydrocarbons (063503)

Special Review and Reregistration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard, 2777 Crystal Drive
Arlington, VA 22202

Interim Reregistration Eligibility Decision (IRED) Document for Aliphatic Solvents (Mineral Oil and Aliphatic Petroleum Hydrocarbons)

Approved by: _____

Debra Edwards, Ph. D.
Director
Special Review and Reregistration Division

Date: _____

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Background:

This document represents the Reregistration Eligibility Decision (RED) document for aliphatic solvents. The Aliphatic Solvents Case (3004) includes two closely related chemicals, the mineral oils and aliphatic petroleum hydrocarbons, which are products of various types of petroleum distillation processes, and thus, represented by several different CAS Numbers. This assessment summarizes available information on the uses, physical and chemical properties, toxicological effects, dietary assessment, and the environmental fate and ecotoxicity of these aliphatic solvents. These chemicals have insecticide and/or larvicide uses as spray oils on agricultural crops and by residential homeowners, as well as occupational and residential uses as acaricides, fungicides, herbicides, and virucides, in addition to aquatic uses as mosquito larvicides/pupacides. There are also inert ingredient uses for many of these same CAS Number chemicals; the exemption from the requirement for a tolerance for the inert ingredient uses of Mineral Oil has already been reassessed during 2005, and the exemptions from the requirement for tolerances for the inert ingredient uses of most of the other chemicals in this RED are being reassessed in a separate document.

I. Executive Summary:

The Aliphatic Solvents (Case 3004) includes both mineral oil (OPP Chemical Code 063502) and aliphatic petroleum hydrocarbons (063503). Twelve chemicals (individual CAS Numbers) are covered in this group.

These aliphatic solvents are the product of petroleum distillations processes, and thus, they are complex mixtures of long-chain aliphatic (paraffinic) compounds. They are formulated as liquid concentrates for use as insecticides and/or larvicides on crops, animal premises, commercial/industrial premises, medical premises, aquatic areas, and residential premises, as well as occupational and residential uses as acaricides, fungicides, herbicides, and virucides (for plant pathogens). The aquatic area applications are for usage as a mosquito larvicide/pupacide. Application equipment includes the following: for agricultural crops, by airplane, groundboom sprayer, airblast sprayer, handgun sprayer, low-pressure handwand sprayer, and/or high-pressure handwand sprayer; for use at commercial/industrial sites, by low-pressure handwand sprayer, handgun sprayer, airplane, truck-mounted ULV sprayer, airblast sprayer, rights-of-way sprayer, and/or high pressure handwand sprayer; and for residential settings, by hose-end sprayer, low pressure handwand sprayer, and trigger-pump sprayer. For the aliphatic petroleum hydrocarbons, several end-use products allow for application to agricultural crops via chemigation, and some products can be applied via dip to ornamental nursery stock, pineapples, and citrus.

These chemicals have a low degree of acute toxicity. For example, there was no mortality in rats at acute oral doses of 28,000 mg/kg body weight, and only slight eye irritation in rats and rabbits. Based on subchronic and chronic toxicity, these chemicals are virtually non-toxic by the oral or dermal route, and they have limited toxicity via the inhalation route, caused by their physical properties (i.e., the observed effects are not due

to chemical toxicity, but due to irritating effects, such as interstitial inflammation and alveolar histiocytosis, related to the body's defense mechanism against the exposure to a foreign material, when the aliphatic oils enter the lungs).

There is a short-term dermal NOAEL of 2000 mg/kg/day, from a 28-day dermal toxicity study. However, this is a very conservative estimate of dermal exposures, because it is based on a study in which no effects were seen even at the highest test concentration (2000 mg/kg/day). The actual NOAEL could potentially be much higher, with possibly virtually no adverse effects at any dose at which these oils might be applied to the skin.

There is a short-term inhalation LOAEL of 146.64 mg/kg/day, based on a 28-day inhalation study, in which effects were observed, even at the lowest inhalation dose tested, 0.52 mg/L, including the following: (1) various effects in the lungs, (2) increased white blood cell counts in males, (3) increased absolute liver weight, (4) accessory spleens and/or abnormally colored spleens, and (5) additional microscopic findings. There is also an intermediate-term inhalation NOAEL of 26.1 mg/kg/day, derived from a 90-day inhalation study, based on effects observed at 0.9 mg/L, with no adverse effects observed at 0.1 mg/L.

An HED memo by OREB (USEPA 1995a) determined that "because toxicity is very low (the FDA has recommended mineral oil for GRAS status), dermal exposure does not warrant an exposure study at this time for reregistration." In the same memo, it also was stated that "OREB does not require an inhalation exposure study for reregistration at this time," and the "OREB does not require a mixer/loader/applicator exposure study for reregistration." Consequently, this RED does not present any assessment for the potential occupational or residential handler dermal or inhalation exposures, nor any assessment for any occupational or residential postapplication exposures. Instead the Agency has qualitatively assessed these exposures, and has determined that risks are not of concern.

The overall dietary exposure, and the drinking water (only) dietary exposure, have also each been qualitatively assessed, based on the absence of acute and chronic oral effects from exposures to mineral oils and aliphatic petroleum hydrocarbons. These dietary exposures are not of concern to the Agency, nor does the Agency have concerns for the aggregate exposures to these chemicals.

The environmental fate assessment of these chemicals indicates they have low to very low vapor pressures, very low solubility in water, high octanol-water partition coefficients, and high sorption to organic matter. Thus, these chemicals will exhibit very poor migration, due to their high sorption, and low solubility in water, as well as low potential for volatility. Fugacity modeling suggests they would remain partitioned to the terrestrial phase, remaining sorbed to soil or the foliar surfaces to which they are applied.

The ecological toxicity assessment of these chemicals indicates they have virtually no toxic effects to mammals or birds (however, there is potential for impairing the hatching of bird eggs, if the spray oils are applied directly to the eggs in the nests). These chemicals are also virtually non-toxic to honey bees, based on the results from contact

toxicity testing. Testing of phytotoxic effects have not been submitted to the Agency, but very high levels of materials are applied to many different types of plants, without effects reported by applicators or growers, so the Agency does not have concerns for phytotoxicity, other than warnings which appear on a few of the labels among the many currently formulated products. (Evidence is available that most registrants have been moving to cleaner technical grade formulations, with lower amounts of polynuclear aromatic hydrocarbons (PAHs), those components of the spray oils which had historically been thought to contribute to phytotoxicity). The results of toxicity testing with fish, both estuarine/marine and freshwater species, have shown virtually no toxic effects, and there were no toxic effects in testing with estuarine/marine mysid shrimp. There is a study showing adverse effects on oyster shell deposition (EC50 = 6 mg/L), but this might be due to the mineral oils coating the surfaces of the food sources for the oysters, impairing their ability to digest their food. Studies with daphnia have shown effects, even at very low exposure concentrations, but many of the studies submitted to the Agency had been conducted with products no longer produced as registered products. In the most recently submitted study with daphnia, the effects observed included immobilization in the water column and/or floating on the surface, but visual observations with a microscope revealed the daphnia hearts were still beating. Thus, while immobilization and floating effects were observed even at the lowest test concentration (EC50 = < 0.9 mg/L), the study reported that "the test compound, VHVI-4, was not lethal to Daphnia magna at the highest test concentration (14 mg/L) after 48 hours exposure."

Three of the products are also registered solely as mosquito larvicides/pupacides, acting as surface film agents. Information has been received from the US Centers for Disease Control and Prevention (CDC) that these products have important public health benefits, compared with the various other mosquito larvicides, because these products are among the only pupacides, and "surface films provide a valuable option to an integrated mosquito control program." In addition, information was presented by CDC that "surface film larvicides generally have a shorter environmental persistence (approx. 2-3 days) than most chemical larvicide alternatives." The transient nature of these surface films may have a mitigating effect on the potential adverse impacts upon daphnia observed above.

The overall Ecological Risk Assessment for these mineral oils and aliphatic petroleum hydrocarbons indicates essentially no concerns for terrestrial effects (other than the potential for adverse effects on bird egg-hatching, if spray oils are applied directly to the nests). In addition, there were no effects on most aquatic organisms, including fish (both freshwater and marine) and water-column marine/estuarine invertebrates (mysid shrimp); however, some impacts were noted in an oyster shell deposition study, and there is a potential for adverse effects in daphnids, including immobilization and floating of the daphnia, in the transient surface films which might result from the applications of these end-use products, including off-site drift from airblast applications to orchards (the EFED Memo stated that "9.7% of the total amount of a product applied" is assumed to drift off-site). The Agency is proposing to mitigate these potential adverse impacts on aquatic invertebrates, effects which might be caused by off-site spray drift, by placing spray drift language on the revised labels to be submitted as part of the reregistration process.

II. Use Information:

The Aliphatic Solvents (Case 3004) include both "Mineral Oil – includes paraffin oil from 063503" (OPP Chemical Code 063502) and "Aliphatic Petroleum Hydrocarbons" (OPP Chemical Code 063503). In addition, according to the "Status of Pesticides in Registration, Reregistration, and Special Review" (Spring 1998), commonly called the Rainbow Report, the Case also includes Kerosene (063501), Mineral Spirits (063506), and Isoparaffinic Hydrocarbons (505200), although each of which are each listed in the Rainbow Report as "cancelled."

Note, however, that OPPIN Query does list some products in the Kerosene OPP Chemical Code; however, some of these products contain kerosene only as an inert ingredient, according to their Confidential Statements of Formula (CSFs). Based on their respective CSFs, each of the other products in OPPIN Query within the Kerosene Chemical Code are end-use products which are be formulated with various Technical Grade Active Ingredients (TGAIs) from each of the other two supported OPP Chemical Codes, 063502 and 063503, but none of these end-use products actually contains Kerosene as the active ingredient. Thus, while these products are clearly misclassified within OPPIN Query as "Kerosene", this information also suggests that the various TGAIs within each of these supported OPP Chemical Codes have very similar chemical characteristics, especially considering that these end-use product registrants are able to utilize these "Mineral Oil" and "Aliphatic Petroleum Hydrocarbon" TGAIs interchangeably on their respective CSFs.

There are currently about 165 products listed in OPPIN within OPP Chemical Codes covered in this Case (063501, 063502 [and 063503]). Based on a thorough search of the CSFs for the 165 products (a total of about 225 CSFs, accounting for both Basic and Alternate formulations), there are twelve different CAS Numbers included in this Case (Table 1). Each of these CAS Numbers is listed on one or more of the CSFs for one or more of the TGAIs within this Case. Some of these CAS Numbers have very similar components, because different CAS Numbers may represent petroleum distillates which are very closely related to each other, since the assigning of CAS Numbers for petroleum distillation products (by the Chemical Abstract Service (CAS) of the American Chemical Society) is based on the last step in the refining process. Thus, virtually identical distillation products, produced via alternative refining pathways, will have different CAS Numbers, although being essentially identical "oils." The materials represented by these CAS Numbers also have other uses, in addition being pesticide active ingredients and as pesticidal inert ingredients, including as various other types of oil-based products; for example, all these CAS Numbers (except for the mineral oils) are in the High Production Volume (HPV) data set submitted under the name Lubricating Oil Basestocks Category).

Table 1. Description of Chemicals included in the Aliphatic Solvents Case

Chemical Name	CAS number	Description
Mineral oil; Oil mist (mineral)	8012-95-1	Liquid hydrocarbons from petroleum.

Table 1. Description of Chemicals included in the Aliphatic Solvents Case		
Chemical Name	CAS number	Description
Mineral oil; Hydrocarbon oils; paraffin liquid	8020-83-5	A mixture of liquid hydrocarbons obtained from petroleum.
White mineral oil, petroleum	8042-47-5	A highly refined petroleum mineral oil consisting of a complex combination of hydrocarbons obtained from the intensive treatment of a petroleum fraction with sulphuric 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.
Lubricating oils, petroleum C15-30, hydrotreated neutral oil based, containing. solvent deasphalted residual oil	72623-84-8	A complex combination of hydrocarbons obtained by treating light vacuum gas oil, heavy vacuum gas oil, and solvent deasphalted residual oil with hydrogen in the presence of a catalyst in a two stage process with dewaxing 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 10cSt at 40.degree.C (104.degree.F). It contains a relatively large proportion of saturated hydrocarbons.
Lubricating oils, petroleum, C15-30, hydrotreated neutral oil-based	72623-86-0	A complex combination of hydrocarbons obtained by treating light vacuum gas oil and heavy vacuum gas oil with hydrogen in the presence of a catalyst in a two stage process and dewaxing 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, petroleum, C20-50, hydrotreated neutral oil-based	72623-87-1	A complex combination of hydrocarbons obtained by treating light vacuum gas oil, heavy vacuum gas oil and solvent deasphalted residual oil with hydrogen in the presence of a catalyst in a two stage process with dewaxing being carried out between the two stages. It consists predominantly 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.
Distillates, petroleum, solvent-refined heavy paraffinic	64741-88-4	A complex combination of hydrocarbons obtained as the raffinate from a solvent extraction process. It consists predominantly of saturated hydrocarbons having carbon numbers predominantly in the range of C20 through C50 and produces a finished oil with a viscosity of at least 100 SUS at 100°F (19cSt at 40°C).
Distillates, petroleum, solvent-refined light paraffinic	64741-89-5	A complex combination of hydrocarbons obtained as the raffinate from a solvent extraction process. It consists predominantly of saturated hydrocarbons having 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, petroleum, hydrotreated heavy paraffinic	64742-54-7	A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C20 through C50 and produces a finished oil of at least 100 SUS at 100°F (19cSt at 40°C). It contains a relatively large proportion of saturated hydrocarbons.
Distillates, petroleum, hydrotreated light paraffinic	64742-55-8	A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having 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). It contains a relatively large proportion of saturated hydrocarbons.
Distillates, petroleum, solvent-dewaxed light paraffinic	64742-56-9	A complex combination of hydrocarbons obtained by removal of normal paraffins from a petroleum fraction by solvent crystallization. It consists predominantly of hydrocarbons having 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, petroleum, solvent-dewaxed heavy paraffinic	64742-65-0	A complex combination of hydrocarbons obtained by removal of normal paraffins from a petroleum fraction by solvent crystallization. It consists predominantly of hydrocarbons having 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.degree.F (19cSt at 40.degree.C).

Based on this review of the approximately 225 CSFs, it was observed that most of these CSFs have been recently submitted (within the last 10 years or so), even for products with a long history of registration. Discussions at the SMART Meeting indicated that many registrants have been converting their processes to produce TGAIs and to formulate end-use products which have lower amounts of undesirable components (i.e., with lower amounts of sulfur- and nitrogen-containing groups, and with fewer side-chains containing polynuclear aromatic hydrocarbons). These polyaromatic hydrocarbons have been found to be the source of some phytotoxicity, formerly causing concerns among growers using these spray oil products. (Some of the newer CSFs continue to show aliphatic petroleum distillates with some side-chains containing naphtha-groups [cyclic saturated rings, as opposed to unsaturated aromatic rings], because it has been reported by some registrants that small amounts of naphtha-containing side-chains are necessary for pourability; thus, with no naphtha-containing groups within these aliphatic materials, the petroleum distillates would have poor pourability, and would be classified as "waxes".)

These aliphatic solvents are formulated as liquid concentrates, with each TGAI being listed on the respective CSF as 100% active ingredient, with no impurities (Table 2). These TGAIs are then formulated into end-use products (often only with an emulsifier), usually with the active ingredient at 97% or greater, for use as insecticides and/or larvicides on crops, animal premises, commercial/industrial premises, medical premises, aquatic areas, and residential premises. In addition, there are three products specifically registered as mosquito larvicides/pupacides, thus there is direct application to water bodies. For the various OPP Chemical Codes, the number of total products (TGAIs, Manufacturing Use Products (MUPs), and end-use products) are as follows: Chemical Code 063502 (Mineral Oil), 130 total products; Chemical Code 063503 (Aliphatic Petroleum Hydrocarbon), 30 total products; and as indicated above, 5 total products in Chemical Code 063501 (Kerosene).

Table 2. Information on TGAIs Within Each OPP Chemical Code

Chem Code Number	Name	Number of TGAIs	CAS Numbers Represented on the Various CSFs within each Chemical Code
063501	Kerosene	None	(See text for explanation of this Chemical Code.)
063502	Mineral Oil	10 (including 1 MUP)	64742-55-8 64742-56-9 64742-65-0 72623-84-8 72623-86-0 72623-87-1 8012-95-1 8042-47-5
063503	Aliphatic Petroleum Hydrocarbon	16 (including 4 MUPs)	64741-88-4 64741-89-5 64742-54-7 64742-55-8 72623-84-8[1] 8002-05-9 8020-83-5

1 When revised CSFs are submitted during reregistration, it is likely that CAS Numbers 72623-86-0 and 72623-87-1 will also be included, because these newer CAS Nos. are not currently listed on the older CSFs from one registrant, but those CAS Nos. are listed on the CSFs for the TGAIs from which these products are formulated.

Based on the information in Table 2, many of the CAS Numbers are listed on the CSFs for the various TGAIs within both of the two different Chemical Codes; thus, there is overlap. In fact, one company has four TGAIs, all within 063502, while all five of their end-use products (formulated from only those four TGAIs) are within the other Chemical Code, 063503. Plus, as described in the section above, the end-use products within 063501 (Kerosene) do not contain kerosene as an active ingredient, but each product is formulated with TGAIs from both of the other two OPP Chemical Codes. Consequently, as part of this Reregistration Eligibility Decision, the Agency is planning to place all these products within the "Aliphatic Solvents" Case into a single OPP Chemical Code (possibly in a new Chemical Code, 063500, currently an unused, unassigned number designation for an OPP Chemical Code, and actually the number at the lower end of the series for most of these "aliphatic solvents" products).

These aliphatic solvents containing products are formulated as liquid concentrates. The application equipment includes airplane, groundboom sprayer, airblast sprayer, handgun sprayer, low-pressure handwand sprayer, and/or high-pressure handwand sprayer for applications to agricultural crops; for commercial/industrial sites, application equipment includes low-pressure handwand sprayer, handgun sprayer, airplane, truck-mounted ULV sprayer, airblast sprayer, rights-of-way sprayer, and/or high pressure handwand sprayer. In residential settings, typical application equipment includes hose-end sprayer, low pressure handwand sprayer, and trigger-pump sprayer. For petroleum hydrocarbons, several products have product labels which allow for application to agricultural crops via chemigation. In addition, some products can be applied via dip to ornamental nursery stock, pineapples, and citrus. The three currently registered mosquito larvicide/pupacide products are applied by ground equipment, with one product also having a label listing aerial applications.

Appendix C contains more detailed information on the crops/use sites, application equipment, timing of application, maximum application rate, and re-entry interval (if applicable). These data were derived by the Biological and Economic Assessment Division (BEAD) in the EFED spreadsheets (for the Environmental Fate and Effects Division). In some cases, the entries in the EFED table did not provide pounds active ingredient per gallon for the mineral oils or the aliphatic petroleum hydrocarbons. A review of the physical/chemical characteristics obtained through a literature search provided a range of densities for both chemicals. As a default, the highest density found for each chemical (7.7 lb ai/gal for mineral oil, and 8.0 lb ai/gal for aliphatic petroleum hydrocarbons, respectively) was used as an estimate for adjusting the application rates for the respective active ingredient, when necessary.

The information presented in Appendix C indicates many different types of application methods and many different use sites for these Mineral Oil and Aliphatic Petroleum Hydrocarbon products. According to the BEAD Screening Level Usage Assessment (SLUA), there may be as much as 75 million pounds of these products used in the United States annually. (See Appendix A for additional details concerning the BEAD SLUA.)

Mineral oil (8012-95-1) has recently been designated by the US Food and Drug Administration (U.S. FDA) as Generally Recognized as Safe (GRAS); the specific usage which is GRAS is as a release agent sprayed on potato processing equipment, resulting in a presence on food of no more than 5 ppm (GRAS Notice No. GRN 00071; April 21, 2001). In addition, there are many other uses for Mineral Oil listed in USFDA website, Everything Added to Food in the United States (EAFUS), under their FDA regulations pertaining to food additives, especially 21CFR 172.878, specifically describing the uses of "White Mineral Oil", but there are many other listings identified in EAFUS, including listings as food additives for direct addition (172.842), as well as for secondary additives (173.340), various indirect additives (175.105, 175.210, 175.230, 175.300, 176.170, 177.1200, 177.2260, 177.2600, 177.2800, 178.2010, 178.3570, 178.3620, 178.3740, 178.3910), and food additives permitted in feed and drinking water of animals (573.680). The citations in EAFUS specifically refer to "Mineral oil, white" CAS No. 8012-95-1, and not any of the other mineral oil CAS Numbers; in addition, a search by CAS Number of EAFUS indicates there are no listings for any of the other chemicals in this RED, the aliphatic petroleum hydrocarbons.

The tolerance exemptions being reassessed in this RED, with the respective citation in the Code of Federal Regulations (CFR) and use pattern as an active ingredient, are listed in Table 3. Table 3 also includes the inert ingredient uses of these chemicals. The exemptions from the requirement of a tolerance for the inert ingredient uses of Mineral Oils (180.910 and 180.930) have already previously been reassessed, in a document dated December 30, 2005, while the other petroleum hydrocarbon exemptions as inert ingredients are currently undergoing reassessment, within the Registration Division, with a completion date on or before August 3, 2006.

Table 3. Tolerances and Exemptions Being Reassessed for the Aliphatic Solvents

Tolerance Expression; and Specific Tolerance		40 CFR	PC Code	Use Pattern
Active Ingredient				
Mineral oil	"Corn, grain, post-harvest": 200 ppm	180.149	063502	Insecticide
	"Sorghum, grain, grain, postharvest": 200 ppm			
Petroleum oils	Exempt from the requirement for a tolerance	180.905	063502 / 063503	Pesticide
"Inert (or occasionally active) Ingredient"				
"Mineral oil, U.S.P., or conforming to 21 CFR 172.878 or 178.3620(a) (CAS Reg. No. 8012-95-1)"		*180.910*	*063502*	*Diluent, carrier and solvent*
"Petroleum hydrocarbons, light odorless conforming to 21 CFR 172.884"		*180.910*	*063503*	*Solvent, diluent*
"Petroleum hydrocarbons, synthetic isoparaffinic, conforming to 21 CFR 172.882"		*180.910*	*063503*	*Solvent, diluent*
"Mineral oil, U.S.P., or conforming to 21 CFR 172.878 or 178.3620(a) (b)"		*180.930*	*063502*	*Solvent, diluent*
"Petroleum hydrocarbons, light odorless conforming to 21 CFR 172.884 or 178.3650"		*180.930*	*063503*	*Solvent, diluent*
"Petroleum hydrocarbons, synthetic isoparaffinic, conforming to 21 CFR 172.882 or 178.3530"		*180.930*	*063503*	*Solvent, diluent*

The active ingredient use listed in Table 3 for 180.149 predates the establishment of the Environmental Protection Agency. Spray Oils (petroleum oils) have been utilized for insect control on crops and trees for over 130 years, while the post-harvest uses on corn and sorghum to combat storage insect infestation were in a Tolerance Petition in the 1950s. BEAD and SRRD conducted a review of the EFED spreadsheets (data complied based on the existing labels), and this search did not detect any Mineral Oils products with a current label for this grain storage use, as listed at 40 CFR 180.149; thus, as part of the RED process, SRRD will publish a notification in the Federal Register proposing to cancel this use, and to revoke this tolerance at 40 CFR 180.149.

Some of the maximum application rates on some of the labels are very high. For example, for one suite of pests on citrus, in Florida, Texas, and California, various labels indicate that applications may be made at up to 4500 gallons of spray mix (prepared as a thorough coverage spray mix of up to 1.5 gallons of end-use product in 100 gallons of water). These registrants have voluntarily agreed to reduce this maximum amount applied to only 1500 gallons in Florida and Texas, and to 1800 gallons in California. This higher rate in California was proposed by researchers at the University of California, Kearney Ag Center, due to a unique citrus pest found in California; this feedback resulted from the Agency requesting that USDA seek guidance from researchers, growers, and other stakeholders.

There currently are few labels with application restrictions on the number of applications per year, or the timing between applications, although there are some residential products for homeowner use that do include such reapplication restrictions.

III. Physical/Chemical Properties:

Table 4 provides physical/chemical properties that are available for certain aliphatic solvents. Information was not found for all CAS Numbers included in this RED.

Based on the data in Table 4, as well as various estimates derived from EPIWIN and other models for developing physical and chemical properties information (and characterizations for the CAS Numbers in the HPV submission), it is not feasible to report specific data for each property, due to the diversity of different compounds present as components within each of these mineral oils and aliphatic petroleum hydrocarbons. However, certain patterns are evident in describing these oils. The melting points (pour point, or temperature at which flow characteristics appear) are below 0 °C. The actual boiling points listed are a reflection that they are mixtures of compounds, dependent on the types and order of distillation and refining processes employed, with constituent hydrocarbons of these oils having boiling points ranging from 300 to 800°C. Similarly, their vapor pressures exhibit a very wider range, ranging from 10^{-4} Pa to 10^{-16} Pa (about 10^{-3} to 10^{-14} mm Hg), ranging from the smaller to larger constituents. Their octanol-water partition coefficients are high, with log K_{ow} values ranging from about 5 to about 20, from the smaller chain-length to the larger chain length molecules. The constituents of the oils are also very poorly water soluble, with solubility values ranging from 0.001 to 0.6 mg/L, being least soluble for the larger constituents.

Table 4. Physical/Chemical Properties of the Aliphatic Solvents									
CAS No.	8012-95-1	8042-47-5	64742-55-8	64741-97-5	72623-87-1	72623-84-8	64742-56-9	64741-88-4	Various[1]
Appearance, Physical State, Color	Oily, colorless	Clear, water white liquid	Bright, clear, straw colored	Liquid	Clear and bright neutral	Light straw	White, clear liquid	Amber, viscous liquid	Viscous liquid; colourless to light yellow
Odor	Odorless	Essentially odorless	Mild lube oil odor	--	None	Hydrocarbon odor	Hydrocarbon	Mild or faint; petroleum	Odourless or mild petroleum oil like
Solubility in water	Insoluble	Insoluble	Insoluble	--	Negligible	Insoluble	Nil	Insoluble	Insoluble
Boiling point	360°C	>260°C / 500°F	>500°F	150-600°C	600-894 (temperature scale not provided)	0°F	560 – 760°F	150-600°C	Not available
Density/ Specific Gravity	0.875-0.905	<1	0.86	~0.84-0.94 at 15°C	0.8493	0.875	0.86	~0.84-0.94 at 15°C	0.851 to 0.863 kg/L at 15°C
Vapor density	--	>1	--	--	NA	NA	>1	>5	Not available
Vapor pressure	<0.5 mmHg @20°C	--	--	--		0.0225 mmHg @ 20°C	NA	<1 mmHg @68°F	Negligible at ambient temperature and pressure

1: Various CAS #s are listed, as follows: 8042-47-5, 64742-46-7, 64742-52-5, 64742-54-7, 72623-84-8, 72623-85-9, 72623-86-0, 72623-87-1, 178603-64-0, 178603-65-1, 178603-66-2, 445411-73-4

References: 8012-95-1: HSDB, 2002

8042-47-5: MSDS, 2002b

64742-55-8: MSDS, 1994

64741-97-5: ICSC, 2001a

72623-87-1: MSDS, 2003a

72623-84-8: MSDS, 2004

64742-56-9: MSDS, 2003b

64741-88-4: ICSC, 2001b; MSDS, 2002a

IV. Hazard Assessment:

The toxicity data available for various chemicals in the aliphatic solvents group are provided in Appendix B. These data were obtained from the MRIDs submitted by registrants and EPA's Health Effects Division (HED) Toxicity Data Evaluation Reviews (DERs) of these MRIDs, as well as from the Registry of Toxic Effects of Chemical Substances (RTECS) of the National Institute for Occupational Safety and Health, and from High Production Volume (HPV) Robust Summaries, various Material Safety Data Sheets (MSDSs), and the open literature.

Acute toxicity data for representative chemical constituents are provided in Table 5. In general, these mineral oils and aliphatic petroleum hydrocarbons exhibit a very low degree of acute toxicity in mammalian testing.

Table 5. Summary of Representative Acute Toxicity Data for the Aliphatic Solvents (Mineral Oil and Aliphatic Petroleum Hydrocarbons) (See Appendix B for additional data and further details)

Study Type	Species	Data Source (MRID, or citation)	CAS Number	Results	Toxicity Category
Acute oral	Rat	(Hine and Zuidema (1970); also cited in INCHEM (WHO), 1982)	Various (lower range of carbon lengths)	LD_{50} > 25.0 mL/kg (>28,000 mg/kg) no deaths observed	IV[a]
Acute dermal	Rabbit	(NIOSH, 1997a)	64742-54-7	LD50 >5 g/kg	IV
	Rat	(EPA, 1994a)	64742-56-9	LD50 > 5 g/kg for males and females	IV
Acute inhalation	Rat	(NIOSH, 2000)	64742-55-8	LD_{50} = 3,900 mg/m^3 (3.9 mg/L) for 4 hr [1]	III
Acute eye irritation	Rabbit	(NIOSH, 2003)	8012-95-1	Moderate effect at 500 mg	III
	Rat	(EPA, 1994c)	"Mineral Oil"	Slight eye irritation; did not clear at day 14 (last day of observation)	III
Acute dermal irritation	Guinea pig	(NIOSH, 2003)	8012-95-1	Mild effect at 100 mg for 24 hour	IV
	Rabbit	(NIOSH, 2003)	8012-95-1	Mild effect at 100 mg for 24 hour	IV
Skin sensitization	Guinea pig	(EPA, 1994a)	64742-56-9	Not a dermal sensitizer	

1. Most other reports from inhalation toxicity testing indicated no lethality was observed.

Based on the subchronic toxicity data in Appendix B, representative data are presented in Table 6. For certain specific aliphatic solvents, it has been reported that the effects of short-term exposure include mild irritation to the skin, and if swallowed, aspiration into the lungs may result in chemical pneumonitis. The effects of long-term exposure include possible dermatitis with repeated or prolonged contact with skin (Inchem, 2001a,b; MSDS, 1994, 2002).

Table 6. Summary of Selected Sub-Chronic Toxicity Tests for Aliphatic Solvents				
Study	Test material	Test animal	Doses	Results
28-day dermal MRID 413688-22 (EPA, 1996)	Light neutral oil, Gulf (purity not provided)	C3H/HeNCrlBR mice (15/sex/dose)	Undiluted test material or 42.5% (w/v) solution in heavy mineral oil once daily, 3x/week for 4 weeks	**NOEL > 2000 mg/kg/day**
28-day inhalation MRID 413688-24 (EPA, 1996)	Light Neutral Oil, Gulf (purity not provided)	Fischer 344 rats (10/sex/dose)	0, 0.52, 0.76, or 1.53 g/m^3 or g/mL for 6-hours/day. Five days/week, for total of 28 days	LOEL = 520 mg/m^3 or mg/mL (**146.64 mg/kg/day**)
90-day inhalation MRID 450029-01 (Ulrich, 1999)	GB-1111	Crl:CD®(SD)IGS BR rats	Target concentrations: 0.01, 0.1, and 1.0 mg/L Actual concentrations: 0.012, 0.10, and 0.9 mg/L 6 hr exposure	NOEL = 0.1 mg/L (**26.1 mg/kg/day**)[a]

A short-term exposure duration dermal NOAEL of 2000 mg/kg/day was observed in a 28-day repeat-dose study, in which no adverse effects were observed at the highest test concentration (2000 mg/kg/day) (EPA, 1996; MRID 413688-22). The actual NOAEL could potentially be very much higher, because it is quite possible that there would be no adverse effects from dermal exposures, even at the highest possible dosage which could be applied to the skin.

A short-term exposure duration inhalation LOAEL of 146.64 mg/kg/day was observed in a 28-day inhalation study. Adverse effects were reported at the lowest exposure dosage, 0.5 mg/L, based on the following observations: (1) multiple lung effects, (2) increased white blood cell counts in males, (3) increased absolute liver weight, (4) accessory spleens and/or abnormally colored spleens, and (5) additional microscopic findings (EPA, 1996; MRID 413688-24). An intermediate-term exposure duration inhalation NOAEL of 26.1 mg/kg/day was observed in a 90-day inhalations study, in which effects were observed at 0.9 mg/L, but there were no adverse effects observed at 0.1 mg/L (EPA, 1996; MRID 450029-01).

Metabolism / absorption:

Oral doses of mineral oils and aliphatic petroleum hydrocarbons are poorly absorbed across the gastrointestinal tract lining, and most are rapidly eliminated unchanged in the feces (75 to 98%, within 8 hours to 4 days). In addition, these materials also show very poor permeability across the dermal barrier (very little is absorbed through the skin). Similarly, any of these materials which enter the lungs are also generally not absorbed, but there may be phagocytosis by the surrounding lung cells, with some materials then

being transported to the spleen and liver, with eventual elimination occurring, mostly unmetabolized, within the feces.

The April 1997 data call-ins for the Mineral Oils (GCDI-063502-17721) and for Aliphatic Petroleum Hydrocarbons (GCDI-063503-17722) did not require data for various types of repeat dose toxicity studies, including either reproductive/developmental or carcinogenicity toxicity testing, via either oral or dermal exposure dosing. Thus, these data have not been submitted by registrants, and the information presented was derived from various review documents. Data were required for Mutagenicity/Genotoxicity (Gene mutation – Ames [84-2a; 870.5100]) and for Structural Chromosomal Aberration [84-2b; 870.5375]); a number of studies have been submitted, and DERs written for most.

Reproduction/Developmental Effects:
In the HPV Submission for Lubricating Oils Basestocks (for most of the CAS Numbers as in this RED), various repeat dose studies were reviewed for reproductive and developmental toxicity effects. It was concluded from dermal dosing studies, that mineral oil had no effects (on mortality, clinical signs of toxicity, on body weight, food consumption, absolute organ weights, microscopic changes in reproductive organs of parental animals, number of corpora lutea, implantation sites, live pups per litter, no gross anomalies, and body weights of pups or weight gains of pups). In a 4-week inhalation study, there were no treatment related effects on sperm morphology. In a one-generation reproduction study, both males and females were dosed by gavage, and there were no adverse effects (no clinical findings, growth weights and food consumption was normal, no effects on fertility and mating indices in either males or females, and at necropsy, organ weights and histopathology were considered normal by the study authors). Two other studies were reported with white mineral oil, both via single daily gavage doses. In one study, both sexes were dosed, and some effects were observed, which the study authors concluded were within the "spectrum of malformations [which] occurs spontaneously in Sprague-Dawley rat." In the companion study in which only pregnant females were dosed, fetal effects were noted, but "the study authors considered these malformations to be minor and within the normal ranges for the strain of rat" (Sprague-Dawley). In general, these studies were performed at very high dosages, from about 900 mg/kg-bw/day (1 mL/kg-bw/day) to about 4500 mg/kg-bw/day (5 mL/kg-bw/day).

Carcinogenicity:
The following information has been reported for the aliphatic solvents with regards to carcinogenicity (IARC, 1987):

> Untreated and mildly-treated oils are carcinogenic to humans (Group 1), and
> Highly-refined oils are not classifiable as to their carcinogenicity to humans (Group 3).

The chemicals included in this RED are categorized as highly to severely refined oils and, therefore, are classified as Group 3, meaning the evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals.

Mutagenicity/Genotoxicity:
In DERs written by HED (EPA, 1994d), the mutagenicity of various test materials were all characterized as being in general non-mutagenic, but with problems due to the presence of suspended oil droplets, due to the poor water solubility of the test materials. Results reported show the following: no treatment related increases in the number of revertants to histidine in either the plate incorporation or liquid suspensions assays (Ames tests); in a mouse lymphoma forward mutation assay, there were no adverse effects (but problems were encountered in removing the test material from the cells, due to the insolubility with the aqueous media); the test material did not appear to be clastogenic in an *in vivo* mammalian cytogenetics assay with bone marrow, but the DER stated evidence must be submitted to indicate that the test material is absorbed from the gastrointestinal tract and transports to target tissue [bone marrow] in effective concentrations.

In the HPV Submission for Lubricating Oils Basestocks (HPV, 2004), it was concluded that the *in vitro* (mutagenicity) tests, the results had low mutagenicity indices, and that the *in vivo* results would probably be negative, due to the low bioavailability of these test materials, and due to the negative results observed in *in vitro* mutagenicity testing and dermal carcinogenicity studies.

Special Considerations for Infants and Children:

The data found on reproductive or developmental toxicity for the aliphatic solvents (the mineral oils and aliphatic petroleum hydrocarbons) indicate that for most CAS Numbers, there are few effects that suggest any reproductive impairment or adverse fetal impacts that occur at doses not also having maternal impacts. In general, most of the studies reported in the HPV submission were conducted at very high dosing levels, whether by the dermal, inhalation, or oral route of exposure. Overall, therefore, there are no concerns at the present time for potential sensitivity of infants and children to these mineral oils and aliphatic petroleum hydrocarbons, because any reproductive and developmental toxicity effects only occurred at doses much greater than those expected from use of these chemicals as active ingredients.

V. Exposure Assessment:

There is a potential for dermal and inhalation exposure to aliphatic solvents (both mineral oils and aliphatic petroleum hydrocarbons) in occupational scenarios from handling aliphatic solvent-containing products during the mixing, loading and application process (i.e., mixers/loaders/applicators). Short-term exposures are likely (from 1 to 30 days); however, it is less certain that pesticide handlers would have intermediate-term exposures (i.e., continuous exposures of greater than 30 days, that is, from 1 month to 6 months). However, as part of the earlier Phase 4 Reregistration Process, the Occupational and Residential Exposure Branch (OREB) of HED (USEPA 1995b) determined that, for the Mineral Oils and Aliphatic Petroleum Hydrocarbons the "toxicity is very low (the FDA has recommended mineral oil for GRAS status), dermal exposure does not warrant an exposure study at this time for reregistration." In addition "OREB does not require an inhalation exposure study for reregistration at this time," and "OREB does not require a

mixer/loader/applicator exposure study for reregistration." Thus, various Guidelines were waived by OREB, and not required as part of a GDCI, including Guidelines 133-4, Inhalation Exposure (new # 875.2500), as well as the following applicator exposure monitoring: Guideline 231, Estimation of Dermal Exposure at Outdoor Sites (new # 875.1100), Guideline 232, Estimation of Inhalation Exposure at Outdoor Sites (new # 875.1300), Guideline 233, Estimation of Dermal Exposure at Indoor Sites (new # 875.1200), and Guideline 234, Estimation of Inhalation Exposure at Indoor Sites (new # 875.1400).

Thus, the Agency has determined that only a qualitative exposure assessment is required for these scenarios, and that the application rates, anticipated use patterns, and current labels for the aliphatic solvents products are not of concern to the Agency. This qualitative exposure/risk assessment suggests there are no concerns for handlers, reentry workers, or residential homeowners.

A review of many of the current labels indicates that about half of these labels list requirements for gloves as Personal Protective Equipment (PPE). This qualitative assessment of human exposure risk has indicated there are no risk concerns; any PPE requirements needed for end-use products will be determined based on the acute toxicity testing review data developed during reregistration for these end-use products.

Cancer risks were not calculated, since no toxicological endpoint for cancer was selected, because these materials described in this RED are not carcinogens.

VI. Dietary (Food) Exposure:

There has been a tolerance of 200 ppm established for mineral oil, for post harvest uses on corn and sorghum (40 CFR 180.149). However, an HED Memo (EPA, 1995a) indicated that residue data would not be required for Mineral Oil, and specifically that the following data requirements were "not applicable": 171-4(a), Nature of residue – plants; 171-4(b), Nature of residue – animals: 171-4(c), Residue analytical method – plant; 171-4(d), Residue analytical method – animals; 171-4(e), Storage stability; 171-4(f), Magnitude of residue – potable water; 171-4(g), Magnitude of residue – fish; 171-4(h), Magnitude of residue – irrigated crop; 171-4(i), Magnitude of residue – food handling; 171-4(j), Magnitude of residue – meat/milk/poultry/eggs; 171-4(k/l), Crop field trials/process.

The Agency has no concerns for food uses of these mineral oils and aliphatic petroleum hydrocarbons, as a result of their use as an active ingredient. As described in previous sections, the acute and chronic oral toxicity of these materials is extremely low, and thus, no quantitative assessment of dietary (food only) risk is deemed necessary.

VII. Drinking Water Exposure:

The HED Memo (EPA, 1995a), which indicated that various types of residue data would not be required for Mineral Oil, specifically indicated that the data requirement for

Magnitude of residue – Potable water (Old Guideline Number: 171-4(f), New Guideline Number 860.1400) was "not applicable": Thus, residue data have not been collected for drinking water concentrations of these active ingredients. One use of mineral oil has been granted GRAS status, and many other uses of mineral oil have been permitted under various other food use regulations by US FDA. Based on the available data concerning the absence of acute and chronic oral toxicity for both mineral oil and aliphatic petroleum hydrocarbons, these active ingredients are not of concern to the Agency.

VIII. Aggregate Exposure Assessment:

For aggregate exposure, the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408 directs the Agency to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act [FFDCA, Section 408(b)(2)(A)(ii)] require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." In assessing the aggregate exposure for the aliphatic solvents, the Agency has determined in the preceding sections that risks from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure are minimal, having virtually insignificant impact on human health.

IX. Cumulative Exposure:

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether the Aliphatic Solvents have a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to the Aliphatic Solvents and any other substances, and the Aliphatic Solvents do not appear to produce toxic metabolites produced by other substances.

For the purposes of this tolerance action, therefore, EPA has not assumed that Aliphatic Solvents have a common mechanism of toxicity with other substances. For information regarding the Agency's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

X. Environmental Fate/Ecotoxicity/Ecological Risk Assessment:

X.I. Environmental Fate and Transport:

There is a wide range of components present in each of these various mineral oils and aliphatic petroleum hydrocarbons products, but the EFED Memorandum concluded that "based on the broad descriptions of the CAS Numbers, it appears that the composition of the oils are similar across the two PC Codes. Therefore, the toxicological and fate properties may be similar."

The information for most of the physical and chemical properties (Table 4) is based on various estimates derived from EPIWIN and other models for developing physical and chemical properties information. Thus, any description of the environmental fate and transport of these mixtures of components will require some degree of generalization in characterizing the environmental fate. For example, their vapor pressures exhibit a very wide range, from somewhat volatile to very poorly volatile (i.e., 10^{-4} Pa to 10^{-16} Pa [about 10^{-3} to 10^{-14} mm Hg]). Their octanol-water partition coefficients are, in general, high, with log K_{ow} values ranging from about 5 to about 20, for the smaller chain-length to the larger chain length molecules. Thus, these components are also likely to have high K_{oc} values, indicating a high degree of sorption to the organic matter in soils, as well as to foliar surfaces onto which they are sprayed. In addition, their constituent components are also very poorly water soluble, with solubility values ranging from 0.001 to 0.6 mg/L, being least soluble for the larger constituents. Thus, these sorption characteristics and water solubility data suggest very poor migration in dissolved phase of water. Fugacity modeling to determine the distribution of these components in the environment suggest that most would partition to the terrestrial phase, and remain sorbed to soil or the foliar surfaces onto which they are sprayed.

These aliphatic oils do not contain functional groups which would undergo photo-degradation in the ultraviolet or visible light ranges, although if any have aromatic components, they can undergo direct photolysis (however, most registrants now produce TGAIs with substantially reduced amounts of aromatic components, compared with the spray oils formerly formulated). While many of the components are poorly volatile, if some do volatilize, they might contain substituent groups that may undergo atmospheric gas-phase oxidation reactions. While these components are poorly soluble in water, they do not contain functional groups that are susceptible to hydrolysis in aqueous suspensions. Due to the complexity in size of the components of these oils, they may slowly undergo some primary biodegradation, but do not readily undergo rapid mineralization (i.e., complete breakdown to carbon dioxide and water).

X.II. Ecological Effects Toxicity Data:

Based on their review of the environmental effects data submitted to the Agency and on the literature from other sources consulted to augment these submitted data, the EFED Memorandum Describing the Ecological Risk Assessment on Aliphatic Oils (PC Codes 063502 and 063503) compiled a summary table concerning the toxic effects data with the

key biological components of the terrestrial and aquatic ecosystem (Table 7).

Table 7. Summary of eco-toxicity values used in the Aliphatic Oils screening level ecological risk assessment.

Surrogate Species	Toxicity Data Used in the Ecological Risk Assessment [a]	Comment	Data Source for toxicity value used in assessment
Fish	None used (Essentially no lethality observed to any fish species)	No effects were observed in fish species in any of the multiple studies conducted at the limit concentrations for these types of studies.	Weight of evidence was used to estimate potential risks.
Daphnia	EC50 = < 0.9 mg/L LC50 = > 14.0 mg/L	LC50s: 0.02, 0.1, 0.41, "<0.9", and 2.4 mg/L. (The data for the three lowest values are based on test materials no longer appropriate for risk estimation, and therefore, the next highest LC50 was utilized.)	44637337
Oysters	6 mg/L	EC50: 6 mg/L	44762002
Aquatic Plants	No data	None	N/A
Mammals	> 28 g/kg-bw (no deaths occurred at 25 mL/kg-bw)	Data obtained from secondary literature; no chronic or reproduction toxicity studies were submitted to the Agency. (See Appendix C of EFED Memorandum for discussion of various of these data.)	Hine and Zuidema (1970)
Birds	LD50: >2250 mg/kg-bw LC50: >5620 ppm	No chronic or reproduction toxicity studies were submitted.	44608001;41793202; 41742101; 4780903; 44780902
Terrestrial Plants	No data	None	N/A

a No chronic or reproduction studies have been submitted to the Agency.

In general, these aliphatic oils (mineral oils and aliphatic petroleum hydrocarbons) are not toxic to most aquatic and terrestrial organisms. There was essentially no lethality observed in any of the tests conducted with fish species (both with freshwater and with estuarine/marine species), mammals (rats and mice), or birds (in both acute, oral, single-dose and subchronic dietary feeding tests). Data were cited in the EFED Memorandum that in one fish toxicity test, up to a 50% mixture (500,000 mg/L) did not result in any observed mortality. Data were also presented indicating no treatment-related effects in various honey bee contact studies. The EFED memo did report that some types of oils have been tested on bird eggs, and have caused smothering (lack of oxygen transport, and impaired hatching ability); however, the data provided in that EFED memo do not appear to indicate the likelihood that off-site drift of spray applications would have demonstrated impacts on bird egg hatching.

The EFED memo indicated that no testing information had been submitted on the effects of these oils on plants. However, there is some information in the EFED EIIS (Ecological Incidents Information System) database concerning reports of incidents involving plant damage. The HPV submission did review data on toxicity testing with various freshwater algae, and reported there were "no adverse effects" at the levels tested. There does not appear to be much information on actual testing with terrestrial plants, however, it is clear that for some crops, high amounts of spray oils are applied onto the foliar surfaces for insecticidal purposes. Historically, there had been reports of phytotoxic effects on plants ("burned" leaves, and some labels currently list phytotoxicity warnings); however, many of the newer TGAIs being formulated by most Technical

registrants do not appear to have these same adverse effects (possibly because of the reductions in the amounts of polyaromatic hydrocarbons (PAHs) present in newer TGAIs, the PAHs postulated as having been the cause of some of the phytotoxic effects).

There was an oyster shell deposition study, in which there was statistically significant reduction of shell deposition, with the 96-hr EC_{50} reported in the study as 5.57 mg/L. This study was conducted in 1998-99 for Golden Bear Oil Specialties, Inc. with a test material which is no longer formulated, and thus not applied to the environment. (The registrant for this test material, GB-1111, is now Clark Mosquito Products.) It is possible that one reason for the reduced oyster shell deposition could be due to the oils coating onto the outer surface of the algal materials made available of food to these filter-feeding oysters, thus, rendering the oysters less able to break-down and utilize these food materials for nutrition.

There are also two toxicity studies available with mysid shrimp (*Mysidopsis bahia*, an estuarine/marine species of invertebrates). One study (MRID 446254-01), conducted in 1998-99 for Golden Bear Oil Specialties, Inc. (with the same no-longer formulated test material as described above), yielded a 96-hr LC_{50} value of 1.2 mg/L. Another study MRID 450513-02) was conducted in 1997, for Petro-Canada (with a test material still being utilized as a TGAI, and described as severely hydrotreated [i.e., more highly refined that the Golden Bear product]); for this test material, a 96-hr LC_{50} value could not be calculated, because the data reported did not indicate 50% mortality, even at the highest test concentration, (nominal) 500,000 mg/L. The study reported that "most observed mortality appeared to occur when organisms swam toward the top of the test container and became trapped in the overlying layer." The nominal concentrations, and mortality data, were reported as follows: control, 10%; 31,250 mg/L, 20%; 62,500 mg/L, 20%; 125,000 mg/L, 15%; 250,000 mg/L, 25%; and 500,000 mg/l, 30% mortality.

The organism utilized for the ecological risk assessment was the water flea, *Daphnia magna*. Based on the data reported in the EFED Memorandum (Table 7), a number of different studies have been submitted, describing the results of daphnia toxicity testing. However, detailed analyses of some of the studies submitted reveal that a few of the test materials utilized in aquatic toxicity testing are no longer used in formulating TGAIs or end-use products for spray oils. For example, the lowest LC_{50} value reported in Table 7 for Daphnia, 0.02 mg/L, was from a 1990-91 study, conducted for Unocal Corporation / PureGro Company, with 90 Neutral Oil; however, according to the Agency REFS database, this product was apparently cancelled in 1993. The next higher LC_{50} value reported in Table 7, 0.1 mg/L, was a test conducted for Golden Bear Oil Specialties, Inc. (with a test material no longer formulated, and thus not applied to the environment). (Note also that the registrant for this test material, GB-1111, is now Clark Mosquito Products, and a review of the CSF for their product indicates their product is formulated with an unregistered technical; thus, RD and SRRD have suggested that when Clark submits a revised CSF as part of the reregistration process, that the CSF utilize a registered TGAI.) The next higher LC_{50} value for Daphnia, 0.41 mg/L, is from a toxicity test conducted in 1983, with a product called 100 Paraffine Oil. This study was submitted in support of four products, two of which have since been cancelled (Chevron

Ag Base Lite Neutral and Chevron Ag 100), and for the two other products, revised CSFs have been submitted in the 1990s (Valent Orchard Spray, with a revised CSF submitted in 1992, and Volck Supreme Spray, with a newer, revised CSF in 1996); therefore, it is clear that daphnia toxicity testing data developed with "100 Paraffine Oil" is no longer still appropriate for characterizing currently formulated TGAIs and end-use products.

The daphnia toxicity study (MRID 446373-37) with the next higher toxicity results was conducted for Petro-Canada, in 1997, with a product designated in the report as VHVI-4, referred to as "N100DW basestock which is one of the raw materials used to make the final Spray Oil 10, 13, 15, 22 products." These products are still being formulated by Petro-Canada, with their most recent CSFs dating from 1995 and 1997, so clearly this test material is representative of Petro-Canada's currently formulated TGAIs and end-use products, as well as the TGAIs and end-use-products for some other registrants who also purchase their TGAIs from Petro-Canada. The static testing (i.e., not with continuous flow conditions) was conducted for 48 hours, and samples were collected for "later verification of the test concentrations if required", but test concentrations were not clearly reported, so the reported levels will be considered to be only nominal (i.e., unmeasured, or estimated). The highest concentration tested, 14 mg/L, was reported to be "the maximum solubility of VHVI-4 in water;" however, the text reported that the "test solutions had a thin film of oil on the surface prior to addition of test organisms." In describing the test results, the report stated "there was no mortality in any of the test treatments. This was confirmed by examination under a microscope for the presence of a heartbeat. Several neonates in all test concentrations were floating on the surface of the test solutions in all VHVI-4 concentrations, at 24 hours and 48 hours." The actual data results reported in Appendix C of MRID 446373-37 also list a number of daphnia being counted as I for "immobilized," or F for "floating", with 20 of 20 test organisms floating in both 14 mg/L and 7 mg/L, 19 floating and 1 immobilized at 3.5 mg/L, 10 floating and 10 immobilized at 1.8 mg/L, 17 floating and 3 immobilized at 0.9 mg/L (the lowest nominal test concentration), and all 20 normal in the control. Based on these data, it is clear that there are some effects on the daphnia, although apparently not lethality, even at the lowest test concentration, so the EC_{50} is < 0.9 mg/L. It is also possible that these effects may be transient, and might be reversible, with the daphnia becoming free of their "immobilized" conditions when the surface films break up. Thus, in light of the absence of any significant mortality, even at the highest concentration tested, it might also be inferred that the LC_{50} could be reported as "> 14 mg/L." (The EFED Memorandum had indicated that the LC_{50} was "<0.9 mg/L (100% mortality occurred at all concentrations)", but that is not in agreement with the actual text reported in the body of MRID, or with the data, as report in the body and appendix of the MRID.)

The EFED Memorandum did conclude that there was uncertainty whether the effects observed in the daphnid toxicity studies were caused by the physical effects resulting from the oils coating the organism or from a different mode of action (such as the organisms becoming entrapped in the oils floating on the surface), although some studies did report that daphnids were also immobile in the bottom or in the middle of the test containers. The EFED memo concluded that entrapment in surface oil slicks would be less likely to occur in streams and rivers (moving water bodies), and oil slicks would be a

higher concern in quiescent waters, such as wetlands and stagnant lakes.

It is not surprising that there would be some disparity among the various MRIDs reporting the results of toxicity tests with daphnia. These mineral oils and aliphatic petroleum hydrocarbons have very low water solubility, based on information available, including for 10 of these same CAS Numbers reported in the Lubricating Oils Basestocks Category for the HVP submissions. In fact, the HPV submission dataset provides data indicating that these CAS Numbers are essentially non-toxic to daphnid invertebrates, with the following reported data in the Test Plan and Robust Summaries: no mortality, based on Water Accommodated Fractions (WAFs), for 48-hr at 1000 mg/L exposures to *Daphnia magna* and 96-hr at 10,000 mg/L exposures to *Gammarus pulex*; and for various CAS Numbers, there were no effects on mortality or reproduction after 21 days exposure at 1000 mg/L for *Daphnia magna* in static renewal tests (with the following CAS Nos.: 64741-88-4; 64741-89-5, 64742-55-8, and 64742-65-0). The differences observed in the toxicity between the registrant-submitted MRIDs and the HVP data may be partly due to the methods of attempting to get these poorly soluble oils into the water column into a solution/suspension.

X.III. Estimated Environmental Concentrations:

Terrestrial Concentration Estimates

The EFED Memorandum described the procedure utilized to develop estimated environmental concentrations (EECs) on terrestrial systems by using the Tier I exposure model, T-REX (Version 1.2.3.). This procedure was utilized to estimate the potential dietary exposures for terrestrial organisms, as a result of applications of mineral oils and aliphatic petroleum hydrocarbons (aliphatic spray oils) at various applications rates, 10, 50, 150, and 477 lbs/acre (single application) (Table 8).

Table 8. EECs for Selected Terrestrial Animal Food Items After Applications of Oils .

Food Item	EEC (ppm), as predicted, resulting from application rates of 10 to 477 lbs a.i./Acre			
	10 lbs a.i./Acre	50 lbs a.i./Acre	150 lbs a.i./Acre	477 lbs a.i./Acre
Short grass	2400	12,000	36,000	114,000
Tall grass	1100	5500	17,000	52,000
Broadleaf forage, small insects	1350	6800	20,000	64,000
Fruits, seeds, pods, large insects	150	750	2300	7200

This estimation procedure analysis indicates that the aliphatic spray oils may be found on animal feed items at extremely high concentrations (up to 114,000 ppm). These concentrations were then converted to doses (mg/kg-bw) for 15-, 35-, and 1000-gram mammals, and 20-, 100-, and 1000-gram birds. (See Appendix B of the EFED Memorandum for details concerning these calculations, including the body weight adjusted EECs for 10, 150, and 477 lbs/acre applications for both the birds and mammals.)

Aquatic Concentration Estimates

The EFED Memorandum also described the procedure utilized to develop EECs in aquatic systems. EFED performed separate modeling efforts for spray drift alone, and for off-site runoff. For the off-site spray drift alone, the modeling to develop EECs was performed for airblast applications, known to have the highest off-site drift for the various ground application procedures (Table 9). EFED assumed that "9.7% of the mass applied to a 10 hectare field would drift off-site into an adjacent 20,000,000 L water body (standard drift assumption in GENEEC2 for orchard airblast applications, and EFED's standard ecological water body volume)." The EECs in Table 9 assume no runoff, but do assume an off-site drift of 9.7% of the total amount of a product applied, and also assume no degradation, partitioning, or differential distribution of the various components within the spray oil end-use product. It is known that some components of these spray oils (the lower molecular weight fractions) may be more volatile than others, but this model also does not take into consideration any volatilization of components during off-site drift.

Table 9. Preliminary Aquatic EECs from Spray Drift Into a Standard Ecological Pond

Application Rate	EEC: Resulting Only from Off-Site Spray Drift (9.7% of Amount Applied)
477 lbs a.i./Acre	2.6 mg/L
150 lbs a.i./Acre	0.82 mg/L
50 lbs a.i./Acre	0.27 mg/L
10 lbs a.i./Acre	0.05 mg/L

The EFED Memorandum reported that the simple screening level analysis, GENEEC, was the procedure used to qualitatively evaluate the contribution of off-site runoff to the overall aquatic EECs. GENEEC was run assuming that these aliphatic spray oils were being applied by granular application (not a labeled use), explaining that this procedure was a convenience to minimize spray drift in the model run to zero. In the absence of environmental fate data for these complex mixtures, EFED assumed that the relevant processes (aerobic soil and aquatic metabolism, hydrolysis, and photolysis) were all stable. GENEEC was run across a very wide potential range of Koc values that might be expected for the various constituents within the aliphatic spray oils (Table 10).

Table 10. EECs Predicted Using GENEEC, Assuming Only Off-Site Runoff [1]

Koc	Application Rate (lbs a.i./Acre)	EEC (ppm)
0.001	477	26.79
	150	8.44

Table 10. EECs Predicted Using GENEEC, Assuming Only Off-Site Runoff [1]		
Koc	Application Rate (lbs a.i./Acre)	EEC (ppm)
	50	2.82
0.01	477	26.79
	150	8.44
	50	2.82
0.1	477	26.79
	150	8.44
	50	2.82
1	477	26.76
	150	8.43
	50	2.81
10	477	26.35
	150	8.30
	50	2.77
100	477	22.79
	150	7.18
	50	2.39
1000	477	10.04
	150	3.16
	50	1.05
10,000	477	2.51
	150	0.79
	50	0.26
100,000	477	1.41
	150	0.44
	50	0.15

1. GENEEC Model with No Spray Drift, and with a "Complete Stability" Assumption for All Dissipation Processes

The GENEEC modeling analysis (Table 10) suggests that even with the wide range of Koc values used, the predicted EECs vary by only a factor of 20 (from 26.79 ppm to 1.41 ppm, at the current maximum application rate, 477 lbs a.i./Acre). This analysis also indicates that from a Koc of 0.001 and 100, there is very little difference in resulting EECs, but as Koc increases from 100 to 1000, there is a dramatic drop in EEC. This pattern is significant, because most of the components which make up the spray oils will

be in the higher Koc range. The EFED Memorandum presented estimates from the Horticultural Oil Spray Task Force (HSOTF), that the typical Koc would be 47,860. The EFED Memorandum also presented data from a study (Nudelman et al., 2002, as cited by HSOTF) which reported that for many aliphatic spray oils, the Koc values range from 900 to 6600. The EFED Memorandum concluded, based on the weight of evidence for the aliphatic spray oils, that a reasonable estimate of Koc for these complex mixtures would be between 1000 and 100,000, with a GENEEC estimate based on a Koc of 10,000 being a reasonable assumption of exposure due to runoff. Thus, at the current highest single application of 477 lbs a.i./Acre, the contribution to the EEC from runoff would not be expected to exceed 2.5 ppm (mg/L), at 150 lbs a.i./Acre predicted to be 0.97 ppm, and for the more typical average application rate, 50 lbs a.i./Acre, the EEC would be 0.26 ppm (Table 10).

The registrants with the highest maximum application rates have voluntarily agreed to lower these rates by about a third. Thus, their maximum rates are now more in line with the 150 lbs a.i./Acre estimates included in Tables 9 and 10, with off-site spray drift and off-site runoff EECs of 0.82 ppm and 0.79 ppm, respectively, and a combined estimate of off-site EEC of 1.6 ppm, resulting from a single application with 150 lbs a.i./Acre.

X.IV. Ecological Risk Assessment:

Terrestrial Organisms

The EFED Memorandum compiled a summary of terrestrial risk estimates (Table 11), based on the toxic effects data for terrestrial animals (Table 7) and the EECs of aliphatic spray oils which would occur on animal food items (Table 8). Table 11 shows the application rate associated with the following key toxicity endpoints, respectively: for birds, a behavioral endpoint (specifically a "slightly reduced reaction to external stimuli (sound and movement)"), and data from an acute gavage test and from a dietary feeding test, and for mammals, data from an acute gavage test.

Table 11. Application Rates Associated with Key Toxicity Endpoints in Terrestrial Organisms

Application Rate	Toxicity Endpoint	Comment
Birds		
4 lbs a.i./Acre	Application rate associated with lowest dietary concentration that produced a toxic effect in birds (NOAEC 1000 ppm, and LOAEC 1780 ppm; MRID 417421-01).	Toxic effects in bobwhite quail included a slight reduced reaction to external stimuli. (However, no mortality occurred at the highest dose tested, 5620 ppm.)
6 lbs a.i./Acre	Application rate associated with highest body weight adjusted dose tested in available acute oral gavage bird studies (1620 mg/kg-bw; adjusted from 2250 mg/kg-bw for a 20-gram bird).	No mortality occurred at this dose.
23 lbs a.i./Acre	Application rate associated with highest dietary concentration tested in available bird studies (5620 ppm).	No mortality occurred at this concentration.
Mammals		

12.7 lbs a.i./Acre	Application rate associated with EECs on short grass that is 1/10th of the limit dose tested in mammals, 28,000 mg/kg-bw.	No mortality occurred at this concentration. (Hine and Zuidema, 1970)

The EFED Memorandum stated that the toxic effects data available for acute risk to terrestrial organisms are difficult to use, because no mortality was observed at the limit dose in acute and subacute bird studies, even though the levels tested in the various studies were not as high as the potential exposures from the high application rates. However, it could be interpreted that because there was no mortality observed in any of the studies, these test materials are innocuous (virtually without any toxic effects, even at very elevated doses, except for the self-limiting aspects of producing diarrhea or vomiting). In addition, utilizing a startle reflex in birds or even assessing the potential risk based on limit doses, at which no mortality was observed, would result in an overestimate of the potential for terrestrial risks of these potentially innocuous test materials.

The EFED Memorandum concluded that there was much uncertainty in the ecological risk assessment, due to the absence of mortality. However, the information presented also did postulate that there might be a potential for risks to the eggs of egg-laying animals, in or adjacent to the treated field, although the Agency does not generally regulate based on egg-smothering within application sites. Further, there was limited information on which to predict the off-site drift estimates of the amount of the test material which would impair egg-hatching in off-site nests. In addition, it is stated that the high application rates (especially the 477 lbs a.i./Acre currently on some labels, but even some lower rates) "do not allow for a definitive conclusion with respect to potential risks to terrestrial animals," because the concentrations estimated (by modeling) to be on food items could actually be higher than levels tested in submitted studies in birds and mammals. (However, as stated above, these test materials may be "innocuous," at virtually any dose administered, because none of the testing data have revealed any mortality in birds or mammals.) In addition, the EFED Memorandum pointed out that no chronic or reproduction toxicity data in terrestrial animals have been submitted to the Agency under FIFRA (although apparently none have ever been required under a GDCI), and that no plant toxicity data have been submitted; therefore, the EFED Memorandum continued, "definitive risk conclusions cannot be made at this time with respect to these surrogate species."

In conclusion, the following factors characterize the terrestrial risk assessment for the spray oils: 1) a lack of mortality data observed in any testing with mammalian and avian species; 2) the absence of current reports of phytotoxicity data in these important agricultural crops, even at high application rates; and 3) the reductions which have been voluntarily proposed by registrants for the very high, maximum application rates. Based on this weight of evidence, the Agency has concluded that it does not have any concerns regarding the reregistration of these mineral oil and aliphatic petroleum hydrocarbon products, due solely to terrestrial risk assessment.

Aquatic Organisms

The EFED Memorandum presented preliminary aquatic risk estimations. The available

data from various toxicity studies had revealed no mortality, including for various fish species and for estuarine/marine invertebrates, mysid shrimp. The aquatic risk assessment information presented in the EFED Memorandum was preliminary risk quotients (RQs) based on the reported toxicity data for aquatic invertebrates. These RQ values were based on EECs developed on only the off-site spray drift and on the direct application to water. The EFED Memorandum pointed out that the contribution of runoff to the EEC is only discussed qualitatively, because the composition of the runoff component might not be toxicologically similar to the composition of oils that enters water via spraydrift or those which were used in the available toxicity studies. The EFED Memorandum also acknowledged by that during runoff, there may be a differential separation of the components, due to differences in solubility, or some components becoming very highly sorbed to soil and/or foliar surfaces, or that some components might degrade, or others become volatilized, and enter the atmosphere.

Table 12. Preliminary Aquatic EECs from Drift Into a Standard Ecological Pond Compared with Aquatic Invertebrate Toxicity Data

Application Rate	EEC from 9.7% Drift Only into a 20,000,000 L ecological pond	Daphnid RQs, based on:			Oyster RQ, based on EC50 of 6 mg/L
		EC50 = 0.02 mg/L	EC50: < 0.9 mg/L	LC50: > 14 mg/L	
477 lbs a.i./Acre	2.6 mg/L	130	2.9	0.19	0.43
150 lbs a.i./Acre	0.82 mg/L	41	0.91	0.059	0.14
50 lbs a.i./Acre	0.27 mg/L	14	0.31	0.02	0.045
10 lbs a.i./Acre	0.05 mg/L	2.5	0.056	0.0036	<0.01
Direct Application EEC	2.1 mg/L	105	2.3	0.15	0.35

For their daphnia RQs, the EFED Memorandum relied only on the toxicity data reported for 90 Neutral Oil (MRID 419028-03; EC50 = 0.02 mg/L); however, Table 12 lists additional RQ estimates from a study with a different test material, VHVI-4. These estimates are included because, as explained in the section above describing the Ecological Effects Toxicity Data, many of the available daphnia toxicity studies, previously submitted to the Agency, had been conducted with materials which are no longer appropriate for risk assessment purposes (the products tested are no longer registered, or registrants have agreed to submit revised CSFs with different TGAIs). Thus, a range of RQs are presented in Table 12, with the data for the EC50 = 0.02 mg/L retained for comparative purposes (although that product was cancelled in 1993, thus, these values are no longer appropriate and are overly restrictive).

There should be some clarification presented on the other two data columns. In the study with VHVI-4 (MRID 446373-37), almost all the daphnia were either immobilized or floating, so the EC_{50} is less than 0.9 mg/l, the lowest nominal test concentration; however, the RQs reported in Table 12 are based on the actual 0.9 mg/L value, the lowest nominal concentration tested. The actual situation is that immobilization/floating may actually occur at even lower concentrations, so based on the "immobilization/floating"

endpoint, the true RQs might be higher than in that data column. It is not known from the study report how long the daphnia would remain immobilized, or how long the surface film would remain in place, which is contributing to their entrapment. However, the CDC stated in a letter, dated June 13, 2006, that "surface film larvicides generally have a shorter environmental persistence (approx. 2-3 days) than most chemical larvicide alternatives." Thus, the surface film should break up within a few days. In addition, that study did report microscope observations of the daphnia, revealing that their hearts were still beating, thus that they were not dead at the conclusion of the 2-day test period. Therefore, the actual LC_{50} value would be greater than the highest dose tested, 14 mg/L, also reported to be the "the maximum solubility of VHVI-4 in water." If the daphnia survive their immobilization, and are able to break-free from the oils, then the RQs presented in that data column in Table 12 may actually be overestimates of the true RQs, and even for daphnia, the Agency would not have any concerns regarding the reregistration of these mineral oil and aliphatic petroleum hydrocarbon products, based on the aquatic risk assessments.

XI. Mosquito Larvicide/Pupacide Uses:

There are three end-use products with labels solely for mosquito larvicide/pupacide applications:

- Bonide Mosquito Larvicide, EPA Reg. No. 4-195;
- Clarke Mosquito Control Products, Mosquito Larvicide GB-1111, EPA Reg. No. 8329-72; and
- BVA 2 Mosquito Larvicide Oil, EPA Reg. No. 70589-1.

These registered products (at least one is each of the OPP Chemical Codes, in Mineral Oils and in Aliphatic Petroleum Hydrocarbons) have labeled uses for direct application to water bodies. To address this use, the EFED Memorandum described a process which assumed that the maximum labeled application rate (37 lbs/acre, the highest among the three products) would be applied directly to the treated water body. In order to develop EECs for the ecological risk assessment, EFED assumed that the application would occur to EFED's standard EXAMS water body of 20,000,000 L. (See the EFED Memorandum for additional details of the EXAMS model). According to the results of this model, assuming instantaneous equilibrium, the EEC for these mosquito larvicide/pupacide products, when applied directly to the water body, would be 2.1 mg/L (ppm), based on the description from the EFED Memorandum (see Table 12 for RQs, based on this EEC).

Due to the characteristics of these mosquito control products, however, it is likely that the oils would not mix within the water column, and that the exposures would be restricted to a much higher concentration at the film layer on the surface of the water. Thus, there would be a higher EEC exposure at the surface, but in a smaller proportion of the entire water body, and a lower EEC throughout the vertical extent of the water body. Thus, any possible adverse effects on the critical components of the aquatic ecosystem would be much lower within the water column.

Concerning these mosquito larvicide/pupacide uses, the Agency has solicited a benefits consultation from the Centers for Disease Control and Prevention (CDC). In a letter (dated June 13, 2006), Dr. Michael A. McGeehin described the comparative benefits of

Aliphatic Oils, as follows:

- "Surface film larvicides generally have a shorter environmental persistence (approx. 2-3 days) than most chemical larvicide alternatives."
- "They are very quick acting, making them well suited to situations where rapid control is required, such as habitats in which most of the mosquitoes are in late larval or pupil stages, or in ephemeral habitats in which the active ingredient need not be present for a long time."
- "Surface film larvicides like the oils kill all immature mosquito stages (all larval stages and pupae). Therefore, timing of application is not as critical as with other products that require the active ingredient be consumed by feeding larvae (e.g., those containing *Bacillus thurinigensis israelensis, Bti*) or during key periods in larval development (e.g., the insect growth regulators)."
- "Surface films kill pupae, while most other products do not. As such, they often provide the only alternative for control of immature mosquitoes in certain habitats before they become adults."
- "Surface films perform effectively under most field conditions, regardless of water quality (pH, turbidity, and BOD don't impact performance), and on all mosquito species that use the water surface to breathe (e.g., excluding members of the genera *Mansonia* or *Coquillettidia*). Other larvicides, such as those using *BTI, bacillus sphaericus*, and methoprene, often don't perform well in highly polluted water that can produce large numbers of *Culex pipiens* or *Culex quinquefasciatus* mosquitoes (important West Nile virus vectors). *Bti* doesn't work well with anophelines, because of their habit of feeding near the water surface. As such, surface films provide a valuable option to an integrated mosquito control program."

The letter from McGeehin of CDC further went on to describe the types of areas where these surface film mosquito larvicides/pupacides have advantages. For example, these surface film mosquito larvicides/pupacides are utilized in any habitat where pupae and late 4th instar larvae are found and/or the organic content of the water is extremely high. The most common type of this situation would be where the organic matter in the water would reduce the efficacy of other types of larvicides (sites such as storm sewer catch basins, sewage treatment plants, storm water impoundments collecting runoff in urban areas, dairy lagoons, or agricultural processing facilities where waste water accumulates, such as sugar beet plants in the Great Plains States). The surface film mosquito larvicides/pupacides are also effective in areas known to produce mosquitoes for only a very short time duration, sites which are expected to be dry for some time periods, or where the use of longer duration products would not be warranted, such as swales along rivers and lakes, and certain types of floodwater habitats. If longer term control is needed, surface film oils would not be reapplied, but instead, a product would be used which would provide a longer duration of control (such as *Bti*, *B. sphaericus*, or methoprene). These surface film oils would not be routinely utilized in marsh or swamp habitats, unless the mosquitoes were found to be in the pupil stage and concentrated within a discrete area, and in these situations, the surface film products would be targeted

in that discrete area, rather than broadcast over a very large area.

In conclusion, the CDC letter from McGeehin summarized the findings by stating that the "mineral oils and aliphatic petroleum hydrocarbons used as surface films provide a valuable option in integrated mosquito control programs that target mosquitoes of public health importance."

XII. Labeling for Aliphatic Solvents Products:

A summary of the various label changes are included in the Label Table. Key changes, and the important reasons, are as follows:

- Due to concerns that maximum label rates for citrus on some labels that were as high as 4500 gallons of spray mix per acre (equal to 477 lbs a.i../Acre), these registrants have voluntarily agreed to reduce their highest rate on citrus, with revised labels which will indicate that applications in Texas and Florida should not exceed 1500 gallons of spray mix, and in California, should not exceed 1800 gallons of spray mix (based on Thorough Coverage Spray, with 1.5 gallons of product mixed in 100 gallons of water).

- Due to concerns for the potential for spray drift to travel off-site, and deposit onto surface waters, possibly resulting in toxic effects to aquatic invertebrates, the revised labels submitted in fulfillment of reregistration activities should include the following statement concerning the restrictions on the use of airblast equipment on the outer edges of orchards: "For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. To minimize spray loss over the top in orchard applications, spray must be directed into the canopy. For aerial applications of agricultural products, do not release spray at a height greater than 10 feet above the ground, top of crops, or above the orchard canopy, when spraying within 1000 feet of water bodies or aquatic habitat."

XIII. Tolerance Reassessment:

The Tolerance Expression at 40 CFR 180.149 for active ingredient use for Mineral Oil (Table 3), the post-harvest uses on corn and sorghum (to combat storage insect infestation) predates the establishment of the Environmental Protection Agency, having been first proposed in the 1950s. A review of the EFED spreadsheets developed by BEAD and an extensive search of the existing labels failed to detect any Mineral Oil products with a current label for this grain storage usage. Thus, as part of the reregistration process, SRRD will publish a notice of intent to revoke this tolerance (40 CFR 180.149) in the Federal Register.

Taking into consideration all available information presented herein on the aliphatic solvents, including the mineral oils and aliphatic petroleum hydrocarbons, the Agency has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to these chemicals when considering

exposure through food commodities and as well as any occupational or non-occupational sources for which there is reliable information. Therefore, the current exemption from the requirement of a tolerance established for "Petroleum Oils" when applied to growing crops, in accordance with good agricultural practice, under 40 CFR 180.905, is reassessed as being safe under section 408(q) of the FFDCA.

XIV. References:

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Appendix A. SLUA

Paraffin Oil (063503)

Screening-level Usage Analysis (SLUA)

Date: 12/13/05

What is a Screening Level Usage Analysis (SLUA)?

- Available estimates of pesticide usage data for a particular active ingredient that is used on **agricultural** crops in the United States.

What does it contain?

- Pesticide usage data for a **single** active ingredient only.
- Agricultural use sites (crops) that the pesticide is *reported* to be used on.
- Available pesticide usage information (i.e., does not include all of the United States).
- Annual percent of crop treated **(average & maximum)** for each agricultural crop.
- Average annual pounds of the pesticide applied for each agricultural crop (i.e., for the states surveyed, not for the entire United States).

What assumptions can I make about the reported data?

- **Average pounds of active ingredient applied** - Values are calculated by merging pesticide usage data sources together; averaging by year, averaging across all years, & then rounding. ***Note:*** *If the estimated value is less than 500, then that value is labeled <500. Estimated values between 500 & <1,000,000 are rounded to 1 significant digit. Estimated values of 1,000,000 or greater are rounded to 2 significant digits.)*
- **Average percent of crop treated** - Values are calculated by merging data sources together; averaging by year, averaging across all years, & rounding to the nearest multiple of 5. ***Note:*** *If the estimated value is less than 1, then the value is labeled <1.*
- **Maximum percent of crop treated** - Value is the single maximum value reported across all data sources, across all years, & rounded up to the nearest multiple of 5. ***Note:*** *If the estimated value is less than 2.5, then the value is labeled <2.5.*

What are the data sources used?

- **USDA-NASS** (United States Department of Agriculture's National Agricultural Statistics Service) – pesticide usage data from 1999 to 2004.
- **NCFAP** (National Center for Food and Agricultural Policy) – pesticide usage data from 1997 and used ***only*** if data are not available from the other sources.
- **Private Pesticide Market Research** – pesticide usage data from 1999 to 2004.
- California DPR data can be requested separately.

What are the data limitations?

- Additional registered uses may exist but are not included because the available surveys do not report usage (e.g., small acreage crops).
- Lack of reported usage data for the pesticide on a crop **does not imply** zero usage.
- Usage data on a particular site may be noted in data sources, but **not quantified**. In these instances, the site would not be reported in the SLUA.

- Non-agricultural use sites (e.g., turf, post-harvest, mosquito control, etc.) are not reported in the SLUA. A separate request must be made to receive these estimates.
- Some sites show some use, even though they are not on the label. This usage could be due to Section 18 requests, existing stocks of the chemical, data collection errors, experimental use permit (EUP), and/or because of an illegal use.

Who do I contact for further information and/or questions on this SLUA?

- Jenna Carter (703 308-8370)
- Art Grube (703 308-8095)

Thursday, December 8, 2005 10:28
Screening Level Estimates of Agricultural Uses of Paraffin Oil (063503)
Sorted Alphabetically

	Crop	Lbs A.I.	Percent Crop Treated	
			Avg.	Max.
1	Almonds	8,300,000	25	60
2	Apples	6,600,000	30	65
3	Apricots	400,000	35	65
4	Avocados	600,000	20	35
5	Beans, Green	6,000	<1	5
6	Blackberries	3,000	5	10
7	Blueberries	6,000	5	5
8	Broccoli	30,000	<1	<2.5
9	Cabbage	5,000	<1	<2.5
10	Cantaloupes	2,000	<1	<2.5
11	Carrots	5,000	<1	<2.5
12	Cauliflower	90,000	5	5
13	Celery	20,000	5	5
14	Cherries	1,300,000	15	30
15	Corn	60,000		
16	Cotton	30,000		
17	Cucumbers	10,000	<1	5
18	Grapefruit	4,900,000	40	80
19	Grapes	1,200,000	5	10
20	Hazelnuts (Filberts)	90,000	5	10
21	Lemons	2,100,000	30	45
22	Limes	100,000	80	80
23	Nectarines	1,200,000	60	75
24	Olives	90,000	5	10
25	Onions	5,000	<1	<2.5
26	Oranges	35,700,000	40	75
27	Peaches	2,100,000	25	45
28	Pears	3,700,000	45	85
29	Peas, Green	<500	<1	<2.5
30	Pecans	200,000	<1	<2.5
31	Peppers	7,000	<1	<2.5
32	Pistachios	1,100,000	15	40
33	Prunes & Plums	2,000,000	30	50
34	Pumpkins	7,000	<1	<2.5
35	Raspberries	10,000	5	10
36	Squash	50,000	5	10
37	Strawberries	7,000	<1	5
38	Sweet Corn	20,000	<1	<2.5
39	Tangelos	600,000	80	95
40	Tangerines	1,400,000	60	70
41	Tomatoes	100,000	<1	<2.5
42	Walnuts	200,000	5	10
43	Watermelons	20,000	<1	<2.5

All numbers rounded.
'<500' indicates less than 500 pounds of active ingredient.
'<2.5' indicates less than 2.5 percent of crop is treated.

Appendix B. Mammalian Toxicity Data for Aliphatic Solvents

ACUTE TOXICITY

Table B-1. Summary of Acute Toxicity for the Aliphatic Solvents (Mineral Oil and Petroleum Hydrocarbons)				
Study Type	Test species: Result Reference			
PC Code: 063502				
Test Material: Mineral Oil	CAS#: 8012-95-1	Gowan Spray Oil (EPA Reg. 10163-RLU)	MRD-87-984; mineral oil	90 Neutral Oil ; mineral oil (100% purity)
Acute oral	Mouse: LD_{50} = 22 g/kg (NIOSH, 2003 [document cited is in German; translation indicates that mineral oil was not tested alone, only in combination with other chemicals]) Rat: LD_{50} = > 25 mL/kg (> 28 g/kg) no deaths observed (Hine and Zuidema (1970) also cited in INCHEM (WHO), 1982)	Rat: LD50 >5 g/kg (EPA, 1992)	Rat: LD50 > 5 g/kg for males and females (EPA, 1994c)	NF[a]
Acute dermal	NF[a]	Rabbit: LD50 > 2 g/kg (EPA, 1992)	Rat: LD50 >2 g/kg for males and females (EPA, 1994c)	Rat: LD50 >2 g/kg for males and females (EPA, 1994b)
Acute inhalation	NF[a]	Rat: LC50 > 4.6 mg/L (EPA, 1992)	Rat: LC50 > 4.7 mg/L (EPA, 1994c)	Rat: LC50 > 3.5 mg/L (EPA, 1994b)
Acute eye irritation	Rabbit: Moderate effect at 500 mg (NIOSH, 2003)	NF[a]	Rat: Slight eye irritation; did not clear at day 14 (last day of observation) (EPA, 1994c)	NF[a]

Table B-1. Summary of Acute Toxicity for the Aliphatic Solvents (Mineral Oil and Petroleum Hydrocarbons)				
Study Type	Test species: Result Reference			
PC Code: 063502				
Test Material: Mineral Oil	CAS#: 8012-95-1	Gowan Spray Oil (EPA Reg. 10163-RLU)	MRD-87-984; mineral oil	90 Neutral Oil ; mineral oil (100% purity)
Acute dermal irritation	Guinea pig: Mild effect at 100 mg/24 hour (NIOSH, 2003)	NF[a]	NF[a]	NF[a]
	Rabbit: Mild effect at 100 mg/24 hour (NIOSH, 2003)			
Skin sensitization		NF[a]	NF[a]	NF[a]

Table B-1. Summary of Acute Toxicity for the Aliphatic Solvents (Mineral Oil and Petroleum Hydrocarbons)				
Study Type	Test species: Result Reference			
PC Code: 063502				
Test Material: Mineral Oil	CAS#: 8012-95-1	Gowan Spray Oil (EPA Reg. 10163-RLU)	MRD-87-984; mineral oil	90 Neutral Oil ; mineral oil (100% purity)
PC Code: 063503				
Test Material: Petroleum hydrocarbons	Hydrotreated light paraffinic petroleum distillates (64742-55-8)	Hydrotreated heavy paraffinic petroleum distillates (64742-54-7)	Paraffinic oil (API 78-9/64742-56-9*) *CAS number found in HPV Robust Summary	
Acute oral	NF[a]	Rat: LD_{50} = >15 g/kg (NIOSH, 1997a)	Rat: LD50 >5 g/kg for males and females (EPA, 1994a)	
Acute dermal	NF[a]	Rabbit: LD_{50} = >5 g/kg (NIOSH, 1997a)	Rat: LD50 >5 g/kg for males and females (EPA, 1994a)	
Acute inhalation	Rat: LD_{50} = 3,900 mg/m^3 (3.9 mg/L) for 4 hr (NIOSH, 2000 [from an OTS document, published in 01/06/83, submitted by BP Oil, conducted by Gulf Life Sciences Center 1983; original document not seen])	NF[a]	NF[a]	
Acute eye irritation	NF[a]	NF[a]	Rabbit: Not an eye irritant (EPA, 1994a)	
Acute dermal irritation	NF[a]	NF[a]	Rabbit: Slight skin irritant (EPA, 1994a)	
Skin sensitization	NF[a]	NF[a]	Guinea pig: Not a dermal sensitizer (EPA, 1994a)	

[a] NF = Not found

Description of Specific Acute Toxicity References from Table B-1:

Hine CH, Zuidema HH. (1970) The toxicological properties of hydrocarbon solvents. Industrial Medicine. 39(5):39-44.

NIOSH (1997a). National Institute for Occupational Safety and Health: The Registry of Toxic Effects of Chemical Substances. Mineral oil, petroleum distillates, hydrotreated (mild) heavy paraffinic (CAS# 64742-54-7). RTECS#: PY8035500.

NIOSH (2000). National Institute for Occupational Safety and Health: The Registry of Toxic Effects of Chemical Substances. Mineral oil, petroleum distillate, hydrotreated (severe) light paraffinic (CAS# 64742-55-8). RTECS#: PY8036501.

NIOSH (2003). National Institute for Occupational Safety and Health: The Registry of Toxic Effects of Chemical Substances. Mineral Oil (CAS# 8012-95-1). RTECS#: PY8030000.

INCHEM (1982) WHO. Environmental Health Criteria 20. Selected Petroleum Products. IPCS (International Programme on Chemical Safety)

EPA (1992). EPA File Symbol/EPA Reg. No.: 10163-RLU Gowan Spray Oil. Memorandum dated 9/1/92 from Mark Perry (Precautionary Review Section, Registration Support Branch, Registration Division) to Dennis Edwards (Insecticide-Rodenticide Branch, Registration Division). (HED Doc# 009979)

Summary: Acute toxicity tests on product: Gowan Spray Oil (EPA Reg. 10163-RLU – not found in PPIS nor in HED label spreadsheet), which contains 99% mineral oil (no CAS number provided) by weight.

- Acute oral, acute dermal and eye irritation studies accepted as core guideline data.
- Acute inhalation and dermal irritation studies acceptable as core minimum data.
    - Acute inhalation study: particle size distribution only determined once during exposure period
    - Dermal irritation: study failed to include a 48 hour evaluation period
- Eye and dermal irritation studies do not support product registration because of the presence of an inert.

Acute Toxicity data for Gowan Spray Oil (99% mineral oil) (EPA, 1992)		
Study Type	Results	Toxicity Category
Acute oral – rat	LD50 >5 g/kg	IV
Acute dermal – rabbit	LD50 > 2 g/kg	III
Acute inhalation – rat	LC50 > 4.6 mg/L	III

EPA (1994a). EPA ID# 063503: Aliphatic petroleum hydrocarbons – Review of 10 Acute Toxicity Studies. Memorandum dated 3/3/94 from Paul Chin, Ph.D. (Section 2, Toxicology Branch I, HED) to Kathryn Davis/Bonnie Adler (PM52, Reregistration Division). (HED Doc# 010813; PC Code: 063503)

CAS numbers were found in the HPV Robust Summaries. **API 78-10 is not included in the list of CAS numbers provided by EPA for the aliphatic solvents RED.

Summary of Acute Toxicity data for Aliphatic Petroleum Hydrocarbons from EPA (1994)				
Study Type	Test material (API 78-9/64742-56-9 & API 78-10/64742-56-0)	MRID	Results	Toxicity Category
063503				
Acute oral: rat	Paraffinic oil (API 78-10)	416853-13	LD50 >5 g/kg for males and females	IV
	Paraffinic oil (API 78-9)	416853-14		
Acute dermal: rat	Paraffinic oil (API 78-9)	416853-15	LD50 >5 g/kg for males and females	IV
	Paraffinic oil (API 78-10)	416853-16		
Primary eye irritation: rabbit	Paraffinic oil (API 78-9)	416853-17	Not an eye irritant	IV
	Paraffinic oil (API 78-10)	416853-18		
Primary dermal irritation: rabbit	Paraffinic oil (API 78-9)	416853-19	Slight skin irritant	IV
	Paraffinic oil (API 78-10)	416853-20		
Dermal sensitization: guinea pig	Paraffinic oil (API 78-10)	416853-21	Not a dermal sensitizer	NA
	Paraffinic oil (API 78-9)	416853-22		

EPA (1994b). EPA ID# 063502: Mineral Oil – Review of Acute Toxicity Studies. Memorandum from Paul Chin, Ph.D. (Section 2, Toxicology Branch I, HED) to Kathryn Davis/Bonnie Adler (PM52, Reregistration Division). (HED Doc# 010809; PC Code: 063502, No CAS numbers provided)

EPA (1994c). EPA ID# 063502: Mineral Oil – Review of Acute Toxicity Studies. Memorandum from Paul Chin, Ph.D. (Section 2, Toxicology Branch I, HED) to Kathryn

Davis/Bonnie Adler (PM52, Reregistration Division). (HED Doc# 010810; PC Code: 063502, No CAS numbers provided.)

Summary of Acute Toxicity data for Mineral Oil (EPA, 1994b and 1994c)				
Study Type	Test materials	MRID	Results	Toxicity Category
Acute oral – rat	MRD-87-984; mineral oil	416853-07	LD50 > 5 g/kg for males and females	IV
Acute dermal - rat	90 Neutral Oil ; mineral oil (100% purity)	416853-11	LD50 >2 g/kg for males and females	III
	MRD-87-984; mineral oil	416853-08	LD50 >2 g/kg for males and females	III
Acute inhalation - rat	90 Neutral Oil ; mineral oil (100% purity)	416853-12	LC50 > 3.5 mg/L	IV
	MRD-87-984; mineral oil	416853-09	LC50 > 4.7 mg/L	IV
Primary eye irritation - rat	MRD-87-984; mineral oil	416853-10	Slight eye irritation; did not clear at day 14 (last day of observation)	III

SUB-CHRONIC TOXICITY

Description of Data from Sub-chronic Toxicity Studies and Referenced DERs:

EPA (1996). Petroleum Oils. Review of Toxicology Data. Memorandum from Raymond Locke (Section 2, Toxicology Branch I, HED) to Kathryn Davis/Bonnie Adler (PM52, Reregistration Division). (HED Doc # 012030)

Petroleum oils – Review of toxicology data (PC Code 063503; no CAS numbers provided)

Summary of Subchronic toxicity tests for Petroleum Hydrocarbons (EPA, 1996)					
Study	Test material	Test animal	Doses	Results	Study classification
NOTE: Memo indicates that for MRIDs 413688-06, 413688-29, 413688-21, 413688-22, 413688-07, 413688-23, and 413688-24: Since petroleum oils tests for inhalation toxicity elicited adverse lung effects in rats, all of the available dermal and inhalation toxicity data must be reviewed by the HED's TES Committee					
28-day dermal MRID 413688-22	Light neutral oil, Gulf (purity not provided)	C3H/HeNCrlBR mice (15/sex/dose)	Undiluted test material or 42.5% (w/v) solution in heavy mineral oil once daily, 3x/week for 4 weeks	LOEL > 2000 mg/kg/day	Unacceptable, but upgradable due to lack of purity and stability data on test material. Based on lack of toxicity, a repetition of the study was not required
14-day dermal MRID 413688-29	100 Paraffine Oil, Gulf (purity not provided)	New Zealand white rabbits (3/sex/dose)	0, 1 or 2 g/kg/day for 5 days/week for 2 week period	Systemic LOEL > 2000 mg/kg/day	Unacceptable, but upgradable due to lack of purity and stability data on test material. Based on lack of toxicity, a repetition of the study was not required

Summary of Subchronic toxicity tests for Petroleum Hydrocarbons (EPA, 1996)					
Study	Test material	Test animal	Doses	Results	Study classification
14-day dermal MRID 413688-06	Gulf Orchard Spray 70 (purity not provided)	New Zealand white rabbits (3/sex/dose)	0, 1, or 2 g/kg/day for 5 days/week for 2-week period	Systemic LOEL > 2000 mg/kg/day	Unacceptable, but upgradable due to lack of purity and stability data on test material. Based on lack of toxicity, a repetition of the study was not required
5-day dermal MRID 413688-21	Light Neutral Oil, Gulf (purity not provided)	Fischer 344 rats (5/sex/dose)	0, 0.85, 1.0, or 2.0 g/kg/day for 5 days/week for 1-week period	Systemic and dermal LOEL > 2000 mg/kg/day	Unacceptable, but upgradable due to lack of purity and stability data on test material. Based on lack of toxicity, a repetition of the study was not required
28-day inhalation MRID 413688-24	Light Neutral Oil, Gulf (purity not provided)	Fischer 344 rats (10/sex/dose)	0, 0.52, 0.76, or 1.53 g/m^3 or g/mL for 6-hours/day. Five days/week, for total of 28 days	LOEL = 520 mg/m^3 or mg/mL (146,640 mg/kg/day)[a]	Unacceptable, but upgradable due to lack of purity and stability data on test material.

Summary of Subchronic toxicity tests for Petroleum Hydrocarbons (EPA, 1996)					
Study	Test material	Test animal	Doses	Results	Study classification
9-day inhalation MRID 413688-07	70 Orchard Spray (purity not provided)	Fischer 344 rats (5/sex/dose)	0, 0.70, 1.60 g/m^3 or g/mL for 6-hours/day for total of 9 exposures	LOEL $\leq$ 700 mg/m^3 or mg/mL (197,400 mg/kg/day)[a]	Unacceptable, but upgradable due to lack of purity and stability data on test material. Does not satisfy the guideline requirement for subchronic inhalation study, but is satisfactory for use as a range-finding study
5-day inhalation MRID 413688-23	Light Neutral Oil, Gulf (purity not provided)	Fischer 344 rats (5/sex/dose)	0, 0.54, 1.70 or 2.79 g/m^3 or g/mL for 6-hours/day for total of 5 exposures	LOEL = 1700 mg/m^3 or mg/mL (479,400 mg/kg/day)[a] NOEL = 540 mg/m^3 or mg/mL (152,280 mg/kg/day)[a]	Unacceptable, but upgradable due to lack of purity and stability data on test material. Does not satisfy the guideline requirement for subchronic inhalation study, but is satisfactory for use as a range-finding study

a Conversion of g/mL to g/kg/day performed using route-to-route extrapolation method. Assumed default values for respiratory volume and body weight based on test species.

Equation: mg/kg/day = mg/L * A * CF * D * AF
Where: mg/L = NOEL/LOEL in mg/L;
A = absorption or ration of deposition and absorption in the respiratory tract compared to another route; assumed to be 100% ;
CF = Conversion factor based on default respiratory volume and body weight (L/hr/kg);
D = Duration of exposure (hr/day);
AF = Activity factor – default for animals = 1.

Ulrich, Charles. (1999) "A 90-day (with recovery) nose-only inhalation toxicity study of GB-1111 Technical in Albino Rats". WIL Research Laboratories, Inc., Ashland, OH. Project Number WIL-357008. December 2, 1999. MRID 450029-01.

Test Material: GB-1111; EPA Reg. #8239-72, lists active ingredient as CAS# 8002-05-9: petroleum distillates, naptha)
EPA Reg. # 8239-72 is listed as GB-1313 in HED label spreadsheet

Summary of Subchronic toxicity test (Ulrich, 1999)				
Study	Test material	Test animal	Doses	Results
90-day inhalation	GB-1111	Crl:CD®(SD)IGS BR rats	Target concentrations: 0.01, 0.1, and 1.0 mg/L Actual concentrations: 0.012, 0.10, and 0.9 mg/L	NOEL = 0.1 mg/L (26.1 mg/kg/day)[a]

a Conversion performed using assumption of body weight and respiratory volume since exact conversion factor is not known for this species of rat. Used minimum default conversion factor provided for all species of rats.

API (2004). High Production Volume: Robust Summary of Information on Lubricating Oil Basestocks. Prepared by American Petroleum Institute (API).

Summary: Provides acute as well as repeat dose testing. Not all identify NOELs and LOELs, or assess the CAS numbers listed for the aliphatic solvents RED.

Summary of Robust Summary Sub-chronic Information from the HPV Submission					
Study	Test material	Test animal	Doses	Results	Study classification
28-day inhalation from HPV Robust Summary	WTO (white oil, CAS# 8042-47-5) & HBO (hydrotreated base oil, CAS# 64742-54-7)	Male/female Sprague-Dawley rats (10/sex/dose)	0, 50, 220, and 1000 g/m^3 for 6 hr/day, 5 days/week, 4 weeks	LOAEL: 210 mg/m^3 (54,810 mg/kg/day) NOAEL: 50 mg/m^3 (13,050 mg/kg/day)	?

Miscellaneous Toxicity Information provided:

EPA (1995a). OPP Official Record, Health Effects Division, Scientific Data Reviews, EPA Series 361. CBRS Transmittal Sheet for Phase 4 Reviews, Case No. 3004; Chemical No(s): 63502/63503, .

Summary: Residue data for mineral oil (PC code: 063502; no CAS number provided): Based on CBRS Transmittal Sheet for Phase 4 Reviews dated 9/7/95, CBRS will not require residue data for mineral oil is the Toxicology Branch I, HED, concludes that there are no toxicological concerns. In addition, a recommendation will be made for the exemption of mineral oil from tolerance requirements for food/feed uses.

EPA (1995b). OPP Official Record, Health Effects Division, Scientific Data Reviews, EPA Series 361. OREB Transmittal Sheet for Phase 4 Reviews, Case No. 3004; Chemical No(s): 63502/63503.

Summary: Aliphatic petroleum hydrocarbons (#63503; no CAS numbers provided) information specific to postapplication exposure monitoring test guidelines subdivision K:

- Indicated that dermal exposure does not warrant an exposure study since mineral oil is applied by either low volume spray or high volume ground spraying and because toxicity is low (FDA recommended it for GRAS status).
- Indicated that OREB does not require inhalation exposure study for same reasons.

Appendix C. Detailed Information on the Use Rates for Aliphatic Solvents