



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

August 2, 2006

ACTION MEMORANDUM

SUBJECT: Reassessment of One Exemption from the Requirement of a Tolerance for Kerosene

FROM: Pauline Wagner, Chief *Pauline Wagner 8/2/06*
Inert Ingredient Assessment Branch
Registration Division (7505P)

TO: Lois Rossi, Director
Registration Division (7505P)

I. FQPA REASSESSMENT ACTION

Action: Reassessment of one inert ingredient exemption from the requirement of a tolerance for kerosene.

Chemical: See Table 1 below.

Table 1. Tolerance Exemption Expression

CFR Citation, CAS Reg. No., and CAS 9 th Collective Index Name				
40 CFR	Inert Ingredient	Limits	Uses	CAS Reg. No. and CAS 9CI Names
180.930 ^a	Kerosene, U.S.P. reagent ^b	None	Solvent, cosolvent	8008-20-6 Kerosine (petroleum) 64742-81-0 Kerosine (petroleum), hydrodesulfurized

^a Residues listed in 40 CFR 180.930 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.

^b A U.S.P. reagent grade specification for kerosene does not currently exist.

Use Summary: The predominant use of kerosene in the U.S. is as an aviation turbine fuel for civilian (Jet A or Jet A-1) and military (JP-8 or JP-5) aircraft. Kerosene is also used as a diesel fuel (No. 1), a domestic heating fuel (Fuel oil No. 1), and as a solvent, although this latter use is a minor one. As an inert ingredient, kerosene is used as a solvent, cosolvent in pesticide formulations applied to animals.

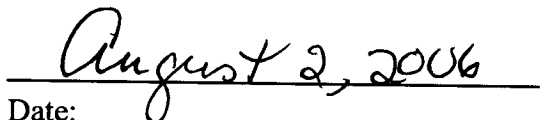
List Reclassification Determination: Because EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to kerosene when used as an inert ingredient (solvent, cosolvent) in pesticide formulations applied to animals, the List Classifications for kerosene will be moved from List 2 (for kerosene (petroleum), hydrosulfurized; CAS Reg. No. 64742-81-0) and List 3 (for kerosene (petroleum); CAS Reg. No. 8008-20-6) to List 4B.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the exemption from the requirement of a tolerance for the inert ingredient kerosene, as well as the List Reclassification Determination described above. I consider the one exemption established in 40 CFR 180.930 to be reassessed for purposes of FFDCA's section 408(q) as of the date of my signature, below. A Federal Register Notice regarding this tolerance exemption reassessment decision will be published in the near future.



Lois A. Rossi, Director
Registration Division



Date:

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD




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MEMORANDUM

SUBJECT: Reassessment of the Exemption from the Requirement of a Tolerance for Kerosene

FROM: Kerry Leifer 
Inert Ingredient Assessment Branch
Registration Division (7505P)

TO: Pauline Wagner, Chief
Inert Ingredient Assessment Branch
Registration Division (7505P)

BACKGROUND

Attached is the science assessment for kerosene. This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, environmental fate, and ecotoxicity of kerosene. The purpose of this document is to reassess the exemption from the requirement of a tolerance for residues of kerosene when used as an inert ingredient in pesticide formulations applied to animals as required under the Food Quality Protection Act (FQPA).

EXECUTIVE SUMMARY

This document evaluates the one inert ingredient exemption from the requirement of a tolerance for use on animals only for kerosene under 40 CFR 180.930. An inert ingredient is defined by the U.S. Environmental Protection Agency (EPA) as any ingredient in a pesticide product that is not intended to affect a target pest. The predominant use of kerosene in the U.S. is as an aviation turbine fuel for civilian (Jet A or Jet A-1) and military (JP-8 or JP-5) aircraft. These kerosene-based fuels consist of kerosene with small amounts of additives for the intended use and are virtually indistinguishable from kerosene.

Kerosene is a Toxicity Category III substance for acute oral, dermal, and inhalation toxicity and eye irritation and a Toxicity Category II substance for skin irritation. Kerosene is not a skin sensitizer.

Irritation is the main effect from kerosene in repeated dosing studies. A 90-day rat oral (gavage) study with kerosene had an LOAEL of 750 mg/kg/day based on stomach irritation and decreased lymphocytes. A NOAEL was not established. A 28-day dermal toxicity study with kerosene in rabbits had a LOAEL of 200 mg/kg/day based on skin irritation in males and females, decreased red blood cell count in males and increased absolute and relative spleen weight in females. A NOAEL was not established. A 90-day dermal toxicity study of kerosene in rats had a LOAEL of 165 mg/kg/day for skin irritation at the application site. A NOAEL was not established.

A 28-day rat inhalation toxicity study with kerosene resulted in no treatment-related effects to rats exposed to a nominal concentration of 25mg/m³ kerosene. A 90-day mouse inhalation study with JP-5 resulted in hepatocellular fatty changes and vacuolization being observed at dose levels of 150 mg/m³. A NOAEL was not reported.

In vivo and *in vitro* genotoxicity studies with kerosene resulted in primarily negative results. A 2-year dermal carcinogenicity study of JP-5 at doses of 250 and 500 mg/kg provided no evidence of carcinogenicity for male and female B6C3F₁ mice.

In a rat developmental toxicity study with JP-8, decreases in fetal body weight compared to controls were seen at dose levels of 1,500 mg/kg/day JP-8 and decreases in maternal body weight gain were observed at 1,000 mg/kg/day. The NOAEL for maternal and developmental effects was 500 mg/kg/day.

In general, environmental releases of kerosene will predominantly result in partitioning to air, given the volatility of the individual hydrocarbon compounds that make up kerosene. In the air phase, photodegradation will be rapid, and for those fractions of kerosene that will partition to soil and water, biodegradation will occur.

Based upon the limited use pattern of products containing kerosene (i.e., livestock use), as well as the volatility and biodegradation of kerosene, the use of kerosene as an inert ingredient in pesticide products applied to animals is not expected to result in human exposure above any dose level that would produce an adverse effect.

Taking into consideration all available information on kerosene, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to kerosene when used as an inert ingredient in pesticide products when considering dietary exposure and all non-occupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the exemption from the requirement of a tolerance established for residues of kerosene can be considered reassessed as safe under section 408(q) of FFDCA.

I. Introduction

This report provides a qualitative assessment for kerosene, a pesticide inert ingredient which has one exemption from the requirement of a tolerance when used as a solvent/cosolvent in pesticide formulations applied to animals under 40 CFR 180.930.

II. Use Information

A. Pesticide Uses

The tolerance exemption expression for kerosene is provided in Table 1 below.

40 CFR	Inert Ingredient	Limits	Uses	CAS Reg. No. and 9CI Name
180.930 ^a	Kerosene, U.S.P. reagent ^b	None	Solvent, cosolvent	8008-20-6 Kerosine (petroleum) 64742-81-0 Kerosine (petroleum), hydrodesulfurized

^a Residues listed in 40 CFR 180.930 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.

^b A U.S.P (U.S. Pharmacopeia) reagent grade specification for kerosene does not currently exist.

B. Other Uses

The predominant use of kerosene in the U.S. is as an aviation turbine fuel for civilian (Jet A or Jet A-1) and military (JP-8 or JP-5) aircraft. Kerosene is also used as a diesel fuel (No. 1), a domestic heating fuel (Fuel oil No. 1), and as a solvent, although this latter use is a minor one (API, 2005).

III. Physical and Chemical Properties

Kerosene is derived from the petroleum refining process, and is a refinery stream complex mixture of petroleum hydrocarbons. The Chemical Abstracts Service defines kerosene as “[A] complex combination of hydrocarbons produced by the distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C₉ through C₁₆” (CAS, 2006). The deodorized form of kerosene is the same complex hydrocarbon mixture as kerosene, differing only in the removal of sulfur as part of the production process. Kerosene-based fuels such as JP-5 and JP-8 consist of kerosene with small amounts of additives for the intended use and are virtually indistinguishable from kerosene (API, 2005).

2. Some of the physical and chemical characteristics of kerosene are found in Table

CAS Reg. No.	8008-20-6	64742-81-0	CAS, 2006
9CI Name	Kerosine (petroleum)	Kerosine (petroleum), hydrodesulfurized	CAS, 2006
Physical State	liquid		API, 2005
Water Solubility	<1 x 10 ⁻³ to 52 mg/L (E)		API, 2005
Boiling Point	125 to 300 °C (M)		CONCAWE, 1996 as cited in API, 2005
Henry's Law Constant	not available		---
Vapor Pressure	>1 – 1.4 kPa @ 37.8 °C (M) = 1.3 to 1.8 x 10 ⁻¹ mmHg		Jokuty et al, 2002 as cited in API, 2005
Octanol/Water Partition Coefficient (Log P)	3.3 to >6 (E)		API, 2005

E=Estimated Value
M=Measured Value

IV. Hazard Assessment

A. Hazard Profile

The main sources of hazard information for this reassessment are the Agency for Toxic Substances and Disease Registry (ATSDR). Toxicological Profile for Jet Fuels JP-5 and JP-8 (ATSDR, 1998) and the High Production Volume (HPV) Challenge Program submission¹ by the American Petroleum Institute (API) on the Kerosene/Jet Fuel category (API, 2005).

¹ High Production Volume (HPV) chemicals are those which are manufactured in, or imported into, the United States in amounts equal to or greater than one million pounds per year. The HPV Challenge Program, a collaborative partnership whose goal was to ensure that the American public had access to the type of information that would allow it to actively participate in environmental decision making. Sponsorship involves a commitment to develop data summaries of relevant existing information and to conduct testing to fill any data gaps. This collection of screening-level hazard data will provide the public with basic information about the chemicals that are produced in the largest quantities.

The ATSDR toxicity profile included the derivation of an intermediate inhalation Minimal Risk Level (MRL)² of 3 mg/m³ for JP-5 and JP-8. No acute or chronic inhalation MRLs were derived for JP-5 or JP-8 and no acute, intermediate, or chronic oral MRLs were derived for either JP-5 or JP-8.

B. Toxicological Data

Acute Toxicity

Kerosene is a Toxicity Category III³ substance for acute oral, dermal, and inhalation toxicity and eye irritation. Reported oral LD₅₀ values for kerosenes range from >2 to >20 g/kg (API 1982, 1985a as cited in API, 2005); dermal LD₅₀ values are all >2 g/kg (API, 1982, 1985 as cited in API, 2005); and inhalation LC₅₀ values are >5 mg/L (API, 1983, 1987 as cited in API, 2005). A rabbit eye irritation study demonstrated reversible eye irritation within 24 hours with no corneal opacity (API, 1985a as cited in API, 2005).

In a rabbit skin irritation study with kerosene, moderate to severe skin irritation was observed (API, 1985a as cited in API, 2005) which would result in a Toxicity Category II assignment for skin irritation. Kerosene has not produced skin sensitization in guinea pigs (API, 1985a as cited in API, 2005).

Subchronic Toxicity

Oral

Male Sprague-Dawley rats were treated with 0, 750, 1,500 and 3,000 mg/kg/day of neat JP-8 by gavage for 90 days. A no-observed-adverse-effect level (NOAEL) was not established with stomach irritation and decreased lymphocytes noted at doses of 750 mg/kg/day (Mattie et al, 1995 as cited in ASTDR, 1998).

Dermal

A 28-day dermal toxicity study was conducted with New Zealand white rabbits in which undiluted kerosene was applied dermally at 0, 200, 1000, and 2000 mg/kg/day. The LOAEL was 200 mg/kg/day based on skin irritation in males and females, decreased red blood cell count in males and increased absolute and relative spleen weight in females. A NOAEL was not established (API, 1985 as cited in API, 2005).

² An MRL is defined by ATSDR as an estimate of daily human exposure to a substance that is likely to be without an appreciable risk of adverse effects (noncarcinogenic) over a specified duration of exposure. MRLs are derived when sufficient, reliable data exist to identify the most sensitive health effects (s) reported for a specific duration within a given route of exposure. MRLs are based on noncancerous health effects only and do not consider carcinogenic effects. MRLs can be derived for acute, intermediate, and chronic duration exposures for inhalation and oral routes. Appropriate methodology does not exist to develop MRLs for dermal exposures.

³ Acute toxicity classification as defined under 40 CFR 156.62

A 90-day dermal toxicity study was conducted in which kerosene was dermally applied to Sprague-Dawley rats in concentrations of 20%, 40% or 60% v/v at a rate of 1 mL/kg/day which is equivalent to doses of 0, 165, 330, and 465 mg/kg/day. There were no test substance-related effects on survival, clinical observations (apart from skin irritation), neurobehavioral signs, or ophthalmological findings. The only clinical observations were related to skin irritation at the application site. There was a dose-related increase in the incidence and severity of erythema, edema, epidermal scaling, scab formation, thickening of the skin, and ulceration at the treated site. At necropsy, the only substance-related observations made were the suggestion of a possible treatment-related effect consisting of skin crusts or ulceration at the site of application of the test material. Hematological, serum clinical parameters, and organ weights were unaffected by treatment. There were no treatment-related microscopic changes in the tissues except for the skin findings (API, 1985 as cited in API, 2005).

Inhalation

Sprague-Dawley rats were exposed to a nominal concentration of 25 mg/m³ kerosene by inhalation for 28 days. There were no treatment-related effects on clinical condition, growth rate, organ weights, organ-body weight ratios, or on any of the hematological or clinical chemistry determinations. No treatment-related microscopic changes were observed in any of the examined organs or in the respiratory tract. (API, 1986 as cited in API, 2005).

Hepatocellular fatty changes and vacuolization were observed in mice exposed to JP-5 vapor at 150 mg/m³ continuously for 90 days. Similar effects on the liver were also observed in mice at 750 mg/m³ (Gaworski *et al*, 1984, as cited in ATSDR, 1998). A NOEL was not reported.

Chronic Toxicity

Oral

No chronic oral toxicity studies on kerosene were identified.

Dermal

A two-year study was conducted by administering JP-5 by dermal application to groups of 49 or 50 male and 50 female B6C3F₁ mice at doses of 0, 250, or 500 mg/kg in an acetone vehicle with a dose volume of 0.1 mL. There was a marked increase in the incidence of chronic dermatitis in both the low and high dose groups (NTP, 1986).

Inhalation

No chronic inhalation toxicity studies on kerosene were identified.

Neurotoxicity

Oral

No reliable oral neurotoxicity studies on kerosene were identified.

Dermal

No histopathological changes were noted in the nervous system of mice following dermal application of 2,000 to 8,000 mg/kg/day of JP-5 for 13 weeks or of dermal application of 250 and 500 mg/kg day of JP-5 for 103 weeks (NTP, 1986).

Inhalation

No histopathological changes were noted in the nervous systems of rats or dogs exposed up to 100 mg/m³ deodorized kerosene for 13 weeks (Carpenter *et al*, 1975, 1976 as cited in ATSDR, 1998). No significant clinical signs except for an increased incidence of fighting were evident in mice exposed continuously to airborne JP-8 at up to 1000 mg/m³ for 90 days (Mattie *et al*, 1991 as cited in ATSDR, 1998).

Mutagenicity

Standard Ames assays on two kerosene samples produced negative results with and without activation (API, 1977, 1978, 1979a as cited in API, 2005). Modified Ames assays on four kerosenes produced negative results (with and without activation) except for one positive assay that occurred with activation (Blackburn *et al*, 1986, CONCAWE 1991 as cited in API 1998). A number of mouse lymphoma assays produced a mixture of negative and positive results (API, 1977, 1979a, 1984b, 1985c as cited in API, 2005). A sister chromatid exchange assay on hydrodesulfurized kerosene was negative with and without activation (API, 1988a as cited in API, 2005).

Bone marrow cytogenetic tests on kerosene with Sprague-Dawley rats were negative (API, 1977, 1979a, 1984b, 1985d as cited in API 2005). A sister chromatid exchange assay on kerosene produced negative results in female mice and a positive response in male mice (API 1988b as cited in API, 2005). A dominant lethal assay of kerosene produced negative results (API, 1973 as cited in API, 2005).

Carcinogenicity

Oral

No oral carcinogenicity studies on kerosene were identified.

Dermal

A two-year study of the administration of JP-5 navy fuel by dermal application to groups of 49 or 50 male and 50 female B6C3F₁ mice at doses of 0, 250, or 500 mg/kg

in an acetone vehicle with a dose volume of 0.1 ml. Under the conditions of this 2-year dermal study, JP-5 at doses of 250 and 500 mg/kg provided no evidence of carcinogenicity for male and female B6C3F₁ mice (NTP, 1986). Other studies of dermal carcinogenicity for kerosene and related materials have shown some positive results (API, 1989 as cited in ATSDR 1998) but studies indicate that kerosene is a mouse skin tumor promoter rather than initiator and that this promotion required prolonged dermal irritation (Nessel *et al*, 1999 as cited in API, 2005). The National Academy of Science (NAS) toxicological assessment of JP-8 concluded that “[T]he carcinogenicity data available on mixtures similar to JP-8 (such as other jet fuels and middle distillates) indicate that most of these materials induce skin tumors in mice when topically applied in excessive amounts and under conditions of excessive skin irritation” (NAS, 2003).

Inhalation

No inhalation carcinogenicity studies on kerosene were identified.

Developmental and Reproductive Toxicity

Oral

Significant decreases in fetal body weight compared to controls were found after pregnant rats were treated orally during gestational days 6-15 with 1,500 mg/kg JP-8. These changes in fetal body weight were found in conjunction with significant decreases in maternal body weight gain at 1,000 mg/kg and in adjusted maternal body weight at 1,500 mg/kg. The NOAEL for maternal body weight changes was 500 mg/kg/day. The developmental NOAEL was 500 mg/kg/day. No other maternal or fetal signs of toxicity were observed at doses up to 2,000 mg/kg/day JP-8 (Cooper and Mattie, 1996 as cited in ATSDR, 1998).

Dermal

No dermal developmental or reproductive studies on kerosene were identified. There were no pathological changes in the reproductive organs of mice following chronic and/or intermediate dermal exposures to JP-5 (NTP, 1986).

Inhalation

No inhalation developmental or reproductive studies on kerosene were identified.

C. Mode of Action, Metabolism, and Pharmacokinetics

Limited animal data indicate that kerosene is absorbed and distributed to various tissues. Kerosene, labeled with ³H-toluene or ¹⁴C-hexadecane, was given to tracheotomized baboons. Radioactivity was recovered from the brain, lung, liver,

spleen, heart, and kidney after 6 hours, however, the amounts absorbed and distributed were minimal (Mann *et al*, 1977 as cited in ATSDR, 1998).

D. Special Considerations for Infants and Children

The database for kerosene is sufficient for assessing the potential developmental effects from exposure to this substance. In a developmental toxicity study with mice, there was no incidence of developmental toxicity in the absence of maternal toxicity. No quantitative or qualitative susceptibility was observed from the available developmental toxicity study in mice. Therefore, there is no concern at this time for increased sensitivity to infants and children from kerosene. For the same reason, a safety factor analysis has not been used to assess the risk and, therefore, the additional tenfold safety factor for the protection of infants and children is also unnecessary.

E. Environmental Fate Characterization and Drinking Water Considerations

Kerosene is a complex mixture of various hydrocarbon fractions, and as such its transport and transformation in the environment is dependent on the environmental fate of the individual hydrocarbons that comprise it. In general, environmental releases of kerosene will predominantly result in partitioning to air, given the volatility of the individual hydrocarbon compounds that make up kerosene. In the air phase, photodegradation will be rapid.

Atmospheric oxidation rates and half-lives were calculated for the low and high end of the range of molecular weight constituents of kerosenes (e.g., C₉ and C₁₆ hydrocarbon structures). Atmospheric oxidation potential (AOP) half-life estimates for these compounds ranged from 0.2 to 1.5 days (API, 2005).

The minor fractions of kerosene that may partition to soil and water would likely undergo biodegradation. The API HPV Test Plan submission for the Kerosene/Jet Fuel Category included biodegradation data (judged to be adequate by EPA) which concluded that "kerosenes are inherently biodegradable, with a generally high degree of complete biodegradation" (API, 2005).

Based on the use of kerosene as a solvent in pesticide formulations applied to animals, and the environmental fate characteristics of kerosene as described above, concentrations of kerosene in drinking water resulting from such use would be negligible.

VI. Exposure Assessment

Based on the volatility of kerosene, dietary exposures to kerosene are unlikely to occur as the result of the use of kerosene as an inert ingredient in pesticide formulations applied to animals (livestock).

Residential exposure (via the dermal and inhalation routes) to kerosene as a result of its use as an inert ingredient in pesticide formulations applied to animals (livestock) is unlikely as livestock treatment is performed in agricultural settings. There are no other pesticide products registered for residential uses that contain kerosene as an inert ingredient.

VII. Aggregate Exposures

In examining aggregate exposure, the Federal Food, Drug, and Cosmetic Act (FFCDA) section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other nonoccupational 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).

For kerosene, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is conducted since exposure via these pathways is unlikely and is far less than any of the no-observed-adverse-effect levels seen in a number of toxicity studies in animals, including repeated dose studies, developmental toxicity studies, chronic toxicity studies and carcinogenicity studies.

VIII. Cumulative Exposure

Section 408(b)(2)(D)(v) of 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."

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 kerosene and any other substances, and kerosene does not appear to produce toxic metabolites produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that kerosene has a common mechanism of toxicity with other substances. For information regarding EPA'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/>.

IX. Human Health Risk Characterization

Kerosene is a Toxicity Category III substance for acute oral, dermal, and inhalation toxicity and eye irritation and a Toxicity Category II substance for skin irritation. Kerosene is not a skin sensitizer. Repeat dosing studies (oral, dermal) typically resulted in irritation and compensating responses to the irritation (oral NOAEL

750 mg/kg/day, dermal NOAEL >165 mg/kg/day. A 28-day rat inhalation toxicity study with kerosene resulted in no treatment-related effects to rats exposed to a nominal concentration of 25mg/m³ kerosene. A 90 day mouse inhalation study with JP-5 resulted in hepatocellular fatty changes and vacuolization being observed at dose levels of 150 mg/M³. A NOAEL was not reported. *In vivo* and *in vitro* genotoxicity studies with kerosene resulted in primarily negative results. dermal carcinogenicity study (2-year) of JP-5 at doses of 250 and 500 mg/kg/day provided no evidence of carcinogenicity for male and female B6C3F₁ mice.

No quantitative or qualitative effects were observed in the fetuses from an oral developmental rat toxicity study. Decreases in fetal body weight were observed at 1,500 mg/kg/day JP-8 whereas decreases in maternal body weight gain were observed at 1,000 mg/kg/day. The NOAEL for maternal and developmental effects was 500 mg/kg.

In general, environmental releases of kerosene will predominantly result in partitioning to air, given the volatility of the individual hydrocarbon compounds that make up kerosene. In the air phase, photodegradation will be rapid, and for those fractions of kerosene that will partition to soil and water, biodegradation will occur.

Based upon limited use pattern of products containing kerosene (i.e., livestock use), as well as the volatility and biodegradation of kerosene, the use of kerosene as inert ingredient in pesticide products applied to animals is not expected to result in human exposure above any dose level that would produce an adverse effect.

Taking into consideration all available information on kerosene, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to kerosene when used as an inert ingredient in pesticide products when considering dietary (food and drinking water) exposure and all non-occupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the exemption from the requirement of a tolerance established for residues of kerosene can be considered reassessed as safe under section 408(q) of FFDCA.

X. Ecotoxicity and Ecological Risk Characterization

The following evaluation of existing data relative to kerosene toxicity to fish, aquatic invertebrates, and algae was provided in the API HPV Test Plan submission for the Kerosene/Jet Fuel Category (API, 2005):

Data for one category member (kerosene, hydrodesulfurized, CAS no. 64742-81-0) and two surrogate (non-HPV) kerosene streams are available. Both surrogate streams -- Sweetened Kerosene, CAS no. 91770-15-9 and Hydrocracked Heavy Naphtha, CAS no. 101316-80-7 -- are included in the CONCAWE (1995) dossier on kerosenes and jet fuels, and were assessed for ecotoxicity by Exxon (1995a-e), while the category member was tested by both Exxon (1995f-h) and Shell (1995a-c). Robust summaries for the surrogate and category member studies are included in the Robust Summary, Appendix D. All studies used exposures to water accommodated fractions (WAFs) of the process streams. Each of the different streams exhibited

similar toxicity to rainbow trout (*Oncorhynchus mykiss*, 96-hour EL50 values of 18 - 25 mg/L); likewise, toxicity to the alga *Selenastrum capricornutum*, with 96-hour growth rate EL50 values of 5.0 - 6.2 mg/L and biomass inhibition EL50 values of 5.9 - 11 mg/L, did not vary greatly among the streams. There was considerable variation in the measured toxicity of the category member (CAS no. 64742-81-0) to daphnids (*Daphnia magna*) when evaluated in different tests; in the test using daily renewal of freshly-prepared WAF (Exxon 1995g), the 48-hr EL50 was estimated at 1.4 mg/L, while in the test where solution was not renewed (Shell, 1995b) it was estimated at between 40 and 89 mg/L. In spite of daily renewal, a sample of kerosene (CAS no. 91770-15-9) exhibited considerably less toxicity than the hydrodesulfurized and hydrocracked materials tested in the same laboratory (Exxon 1995b), indicating the difference in that measurement is due to the nature of the sample rather than variations in the testing approach.

Two additional studies using the WAF methodology, summarized by CONCAWE (1995), indicate greater sensitivity of a marine amphipod (*Chaetogammarus marinus*) with an EL50 of 1.4 mg/L, than of the zebrafish (*Brachydanio rerio*), EL50 13.5 mg/L, to cracked kerosene (CAS no. 68477-39-4). These results are consistent with those summarized above and indicate measurable, moderate aquatic toxicity of kerosenes over a range of CAS numbers.

There is considerable data regarding toxicity of jet fuels to aquatic organisms, as summarized by CONCAWE (1995). Many of the studies used a water-soluble fraction, in which the aqueous fraction of a single loading rate of hydrocarbon, after equilibration, is diluted to varying percentages (expressed as either percent WSF or mg/L corresponding to the dilution) and used for exposure. This approach can provide an indication of the relative toxicity of different insoluble products or the relative sensitivity of different organisms to a single test material, but is not useful for quantifying the amount of the material that must be added to a given volume of aqueous medium to produce the effect. In general these studies indicate similar results to those obtained using the WAF methodology, with generally similar toxicity among different jet fuel products for a given species or taxonomic group.

Based on the mammalian toxicity data, and the use pattern of pesticide products containing kerosene, there are minimal environmental risk concerns for nontarget terrestrial organisms.

REFERENCES:

API (American Petroleum Institute). 2005. Kerosene/Jet Fuel Test Plans and Robust Summary. Petroleum HPV Testing Group, American Petroleum Institute. December 15, 2005 Submission under the High Production Volume Test Challenge Program. <http://www.epa.gov/oppt/chemrtk/kerjetfc/c15020tl.pdf>

ATSDR (Agency for Toxic Substances and Disease Registry). 1998. Toxicological Profile for Jet Fuels JP-5 and JP-8 CAS Reg. No. 8008-20-6. August 1998. <http://www.atsdr.cdc.gov/toxprofiles/tp121.html#bookmark04>

CAS (Chemical Abstracts Service). 2006. STN on the Web. <http://stnweb.cas.org/> Last updated: July 1, 2006.

ChemIDPlus. 2004. ChemIDPlus. National Library of Medicine. National Institutes of Health. <http://chem.sis.nlm.nih.gov/chemidplus/> Last Updated: September 9, 2004.

EPA (U.S. Environmental Protection Agency). 2000. Estimation Programs Interface (EPI) Suite™, Version 3.12. U.S. Environmental Protection Agency, Washington, DC

NAS (National Academies of Science). 2003. Toxicologic Assessment of Jet-Propulsion Fuel 8. Subcommittee on Jet-Propulsion Fuel 8. Committee on Toxicology. Board on Environmental Studies and Toxicology. National Academies Press. Washington, D.C. <http://darwin.nap.edu/books/0309087155/html/R1.html>

NTP (National Toxicology Program). 1986. Toxicology and Carcinogenesis Studies of Marine Diesel Fuel (NO CAS) and JP-5 Navy Fuel (CAS No. 8008-20-6) in B6C3F1 Mice (Dermal Studies). National Toxicology Program Technical Report 310. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health. http://ntp.niehs.nih.gov/ntp/htdocs/LT_rpts/tr310.pdf

Inoue, H., Yamamoto, T., Shoji, A., Watari, N., Hirouchi, Y., Enomoto, M., and Morita, K. 1999a. Oral Chronic Toxicity and Carcinogenicity Test of Polyoxyethylene (10) Nonylphenol ether (NP-10) in Female F344 Rats, *The Journal of Toxicological Science*, 24 suppl 167-193

Inoue, H., Yamamoto, T., Shoji, A., Watari, N., Hirouchi, Y., Enomoto, M., and Morita, K. 1999b. Oral Chronic Toxicity and Carcinogenicity Test of Polyoxyethylene (10) Nonylphenol ether (NP-10) in Female B6C3F1 Mice, *The Journal of Toxicological Science*, 24 suppl 149-166

Lonza Incorporated (Lonza). 1996. Untitled Submissions under TSCA Section 8(d) With Cover Letters. Doc. Nos. 86970000016, 86970000018, 86970000019, and 86970000021 Dated October 14, 1996

Meyer, O., Andersen, P.H., Hansen, E.V. and Larsen, J.C. 1988. Teratogenicity and *in Vitro* Mutagenicity Studies on Nonoxynol-9 and -30. *Pharmacology & Toxicology* 62, 236-238)

Smyth, H.F. and Calandra, J.C. 1969. Toxicologic Studies of Alkylphenol Polyoxyethylene Surfactants, *Toxicology and Applied Pharmacology* 14 315-334

Union Carbide Corporation (Union Carbide) 1999. Support: Final Report Developmental Toxicity Evaluation of Tergitol NP-4 Surfactant Administered by Gavage to CD(Sprague-Dawley) Rats, With Cover Letter Submission under TSCA Section 8(e). Doc. No. 89990000183 Dated April 23, 1999

US Department of Agriculture (USDA). 2003. Human and Ecological Risk Assessment of Nonylphenol Polyethoxylate-based Surfactants in Forest Service Herbicide

Applications, USDA Forest Service

<http://www.fs.fed.us/r5/spf/publications/pesticide/npe-ra-final.pdf>

US Environmental Protection Agency (EPA). 2005. Aquatic Life Ambient Water Quality Criteria – Nonylphenol—Final. Office of Water. EPA-822-R-05-005.

<http://www.epa.gov/ost/criteria/nonylphenol/final-doc.pdf>