

US EPA ARCHIVE DOCUMENT



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

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

DATE: May 17, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessment -- Mesityl Oxide (CAS Reg. No. 141-79-7)

FROM: Pauline Wagner, Chief *Pauline Wagner 5/30/06*
Inert Ingredient Assessment Branch
Registration Division (7505C)

TO: Lois A. Rossi, Director
Registration Division (7505C)

I. FQPA REASSESSMENT ACTION

Action: Reassessment of one inert exemption from the requirement of a tolerance. The reassessment decision is to maintain the inert ingredient tolerance exemption "as-is."

Chemical: Mesityl Oxide

CFR: 40 CFR part 180.920

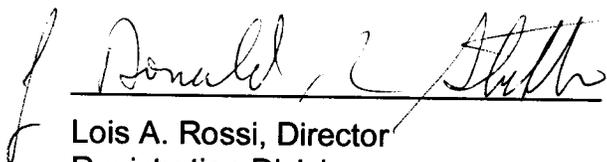
CAS Registry Number and Name: CAS Reg. No. 141-79-7; CAS Name: 3-Penten-2-one, 4-methyl- (8CI, 9CI)

Use Summary: Mesityl oxide is a volatile, flammable unsaturated ketone that is used as a solvent and cosolvent in a variety of pesticide products including those for agricultural, garden, and health service use. It is used as a solvent for synthetic fibers and rubbers, oils, gums, resins, carburetor cleaners, lacquers, varnishes, inks and stains, as well as a synthetic food flavoring. In addition, the chemical has been found in gasoline exhaust. It is also used as a chemical intermediate in the production of methyl isobutyl ketone (MIBK). Mesityl oxide has been reported to occur naturally in foods and has been detected in fruits, spices, vegetables, cocoa, coffee, and tea.

List Reclassification Determination: The current List Classification for mesityl oxide is 2. Because EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to mesityl oxide used as inert ingredients in pesticide formulations, the List Classification for mesityl oxide will change from List 2 to List 4B.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the one exemption from the requirement of a tolerance for the inert ingredient mesityl oxide (CAS Reg. No. 141-79-7) and with the List reclassification determination(s), as described above. I consider the one exemption established in 40 CFR part 180.920 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

5/30/06

Date:

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD



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

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

May 17, 2006

MEMORANDUM

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

FROM: Karen Angulo *Kara Angulo*
Inert Ingredient Assessment Branch (IIAB)
Registration Division (7505C)

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

Background

Attached is the science assessment for mesityl oxide. Mesityl oxide has one exemption from the requirement of a tolerance under 40 CFR 180.920 when used as an inert ingredient (solvent/cosolvent) in pesticide formulations applied to growing crops only. This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, environmental fate, and ecotoxicity of mesityl oxide. The purpose of this document is to reassess the one existing exemption from the requirement of a tolerance for residues of mesityl oxide when used as an inert ingredient (solvent/cosolvent) in pesticide formulations as required under the Food Quality Protection Act (FQPA).

Executive Summary

This report evaluates mesityl oxide, a pesticide inert ingredient for which one exemption from the requirement of tolerance exists when used as a solvent/cosolvent in pesticide formulations applied to growing crops only under 40 CFR 180.920. The tolerance exemption significantly limits use of the chemical to before the edible parts of plant begin to form, and livestock cannot graze on treated crops within 48 hours after application of the pesticide product.

Mesityl oxide is a volatile, flammable unsaturated ketone that is used as a solvent and cosolvent in a variety of pesticide products including those for agricultural, garden, and health service use. It is used as a solvent for synthetic fibers and rubbers, oils, gums, resins, carburetor

cleaners, lacquers, varnishes, inks and stains. In addition, the chemical has been found in gasoline exhaust. It is also used as a chemical intermediate in the production of methyl isobutyl ketone (MIBK).

Sufficient toxicity data and information are available to assess the hazard of mesityl oxide. This hazard assessment was developed using information from various sources, including the Organization for Economic Cooperation and Development (OECD) High Production Volume Chemicals Program. A qualitative assessment for all pathways of human exposure is appropriate given the minimal human health concerns associated with the low levels of exposure expected from the use of mesityl oxide as an inert ingredient in pesticide formulations.

Mesityl oxide has been shown to be a mild to severe skin and eye irritant, as well as a strong skin sensitizer. Nasal, respiratory tract and eye irritation are likely following long or repeated exposure to mesityl oxide with effects on the blood, kidneys, liver, and lungs occurring at higher concentrations. With the exception of reduced number of litters, no other reproductive or developmental effects are reported. All of these effects occurred at concentrations higher than expected from mesityl oxide's use as an inert ingredient in pesticide products. Mesityl oxide is also negative for genotoxicity and is not expected to be carcinogenic. In addition, no neurotoxicity has been observed with the exception of transient reversible effects.

Mesityl oxide has been reported to occur naturally in foods and has been detected in fruits, spices, vegetables, cocoa, coffee, and tea, and it is also used as a synthetic flavoring agent. As an inert ingredient in pesticide products, the current tolerance exemption strictly limits the use of mesityl oxide to applications before the edible parts of a plant begin to form, and livestock are not to be grazed in treated areas within 48 hours after application. It is highly volatile and biodegrades rapidly in the environment. Considering the use limitation for mesityl oxide and its physical chemical properties, dietary (food and drinking water) and residential exposures are not expected to occur at levels of concern from the use of mesityl oxide as an inert ingredient in pesticide products. Mesityl oxide is not toxic to aquatic or terrestrial organisms. It is also not persistent in the environment and bioconcentration in aquatic organisms is not anticipated.

Taking into consideration all available information on mesityl oxide, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to mesityl oxide when considering exposure through food commodities and all other non-occupational sources for which there is reliable information. Therefore, it is recommended that the one exemption from the requirement of a tolerance established for residues of mesityl oxide when used on growing crops can be considered reassessed as safe under section 408(q) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Introduction

This report provides a qualitative assessment for mesityl oxide, a pesticide inert ingredient for which one exemption from the requirement of tolerance exists when used in pesticide formulations applied to growing crops only under 40 CFR 180.920.

II. Use Information

A. Pesticide Uses

Mesityl oxide is used as a solvent and cosolvent in a variety of pesticide products including those for agricultural and home garden use. The one tolerance exemption for this chemical is presented below in Table 1.

Table 1. Pesticide Uses

CFR Citation				CAS Reg. No. CAS Name
40 CFR §	Inert Ingredients	Limits	Uses	
180.920*	Mesityl Oxide	Not for use after edible parts of plant begin to form. Do not graze livestock in treated areas within 48 hours after application.	Solvent, cosolvent	141-79-7 3-Penten-2-one, 4-methyl- (8CI, 9CI)

*Residues listed in 40 CFR 180.920 are exempt 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 growing crops only.

B. Other Uses

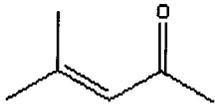
Mesityl oxide is used as a solvent for synthetic fibers and rubbers, oils, gums, resins, carburetor cleaners, lacquers, varnishes, inks and stains. It is also used as a chemical intermediate in the production of methyl isobutyl ketone (MIBK) and as a component of paint removers. The chemical has been shown to occur at a concentration of up to 1.5 ppm in gasoline exhaust.

Mesityl oxide has been reported to occur naturally in foods and has been detected in fruits, spices, vegetables, cocoa, coffee, and tea. Mesityl oxide is also used as a synthetic flavoring agent. It is included in the food additive database maintained by the U.S. Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSCAN) under an ongoing program known as the Priority-based Assessment of Food Additives (PAFA). The more than 3,000 substances included in the database comprise an inventory referred to as "*Everything*" Added to Food in the United States (EAFUS). The list of substances contains ingredients directly added to food that FDA has either approved as food additives or listed or affirmed as Generally Recognized as Safe (GRAS).

III. Physical and Chemical Properties

Physical and chemical characteristics of mesityl oxide, along with its structure and nomenclature, are found in Table 2.

Table 2. Physical and Chemical Properties of Mesityl Oxide

Parameter	Value	Reference
Structure		ChemFinder
CAS Number	141-79-7	HSDB
Molecular Formula	C ₆ H ₁₀ O	HSDB
Molecular Weight	98.14	HSDB
Synonyms	4-Methyl-3-penten-2-one; Isobutenyl methyl ketone; Isopropylidene acetone; and Methyl isobutenyl ketone	Haz-Map ChemFinder
Odor	Peppermint, honey	HSDB
Physical State	Colorless to light yellow oily liquid	HSDB
Melting Point	-52.9°C	HSDB
Boiling Point	130°C @ 760 mm Hg	HSDB
Water Solubility	29,000 ppm	HSDB
Other Solubility	Miscible with most organic liquids	HSDB
Vapor Density	3.4 (air = 1)	HSDB
Vapor Pressure	8.7 mm Hg @ 20°C	HSDB
Log K _{ow} / K _{ow}	1.39 (Hansch) / 24.5	HSDB
K _{oc}	15.3*	HSDB
Henry's Law Constant	3.67 x 10 ⁻⁵ atm-m ³ /mole @ 20°C*	HSDB
Specific Gravity	0.8592 @ 15°C	HSDB
Relative Evaporation Rate	8.4 (ether = 1)	HSDB
Viscosity	0.0060 Poise @ 20°C	HSDB

*Estimated

IV. Hazard Assessment

A. Hazard Profile

This hazard assessment of mesityl oxide was developed using the Screening Information Data Set (SIDS) on mesityl oxide, which was prepared by EPA and submitted to OECD under the SIDS High Production Volume Chemicals Program. Based on the data submitted, the SIDS Initial Assessment Profile (SIAP) for this submission concludes that mesityl oxide is “currently considered of low priority for further work” (OECD SIAP, 1997). Other sources of information used in this assessment include journal articles, the U.S. Registry of Toxic Effects of Chemical Substances

(RTECS), the Hazardous Substances Data Bank (HSDB), and information from EPA's Toxics program (OPPT).

B. Toxicological Data

Acute Toxicity:

Available acute toxicological information indicates the low toxicity of mesityl oxide. The OECD SIAP qualitatively states that mesityl oxide is "slightly toxic by the oral, inhalation and dermal route of acute toxicity," However, mesityl oxide has also been shown to be a skin and eye irritant, as well as a strong skin sensitizer. The results of acute toxicity studies are summarized in the following table:

Table 3. Summary of Acute Toxicity Data for Mesityl Oxide

Study Type (Species)	Toxicity Value	Reference
Oral LD ₅₀ (rat, mouse, rabbit, guinea pig)	Rat: LD ₅₀ = 1120 mg/kg Mouse: LD ₅₀ = 923 mg/kg Rabbit: LD ₅₀ = 1000 mg/kg Guinea Pig: LD ₅₀ = 800 mg/kg (Toxicity Category III)	Topping, et al., 2001
Inhalation LC ₅₀ (rat)	LC ₅₀ = 1000 ppm or 4 mg/L (Toxicity Category III)	HSDB
Dermal LD ₅₀ (rabbit)	LD ₅₀ = 5.99 mL/kg	Topping, et al., 2001
Dermal irritation (rabbit)	Mild skin irritation at 430 mg	RTECS, 2004
Dermal sensitization (guinea pig)	Strong sensitizer	Ciba Geigy, 1987
Eye irritation (rabbit)	Severe eye irritation at 20 mg	RTECS, 2004

Subchronic Toxicity:

In a repeat dose inhalation study, groups of 10 male Wistar rats and 10 guinea pigs of both sexes were exposed to mesityl oxide at concentrations of 0, 50, 100, 250 or 500 ppm (equivalent to 0, 0.2, 0.4, and 1.0 mg/L) for 8 hr/day, 5 days/week for 6 weeks (Smyth et al., 1942). The 500 ppm group was terminated after 10 days due to high mortality (65 percent). Observations were recorded on the growth, blood count, urine, and microscopic pathology. Effects were seen at all concentrations except 50 ppm. Chronic conjunctivitis and nasal irritation were observed at 250 and 500 ppm. Poor growth was observed in animals exposed to 250 ppm. No blood cell changes were noted at any concentration. Animals exposed to 250 and 500 ppm had mild albuminuria. In addition, exposure to mesityl oxide resulted in vascular congestion, primarily in the kidneys. The liver and lungs were affected to a lesser degree. Liver pathology was observed in 2 of 16, 2 of 4, and 3 of 5 animals exposed to 100, 250 and 500 ppm, respectively. Kidney pathology was observed in 5 of 16 animals exposed to 100 ppm and was observed in all of the animals exposed to 250 and 500 ppm. Mortality only occurred at 500 ppm, with a death rate of 65 percent. Death was attributed to mesityl oxide's narcotic action.

Several studies cited in Patty's Industrial Hygiene and Toxicology also examined the inhalation toxicity of mesityl oxide (Clayton and Clayton, 1982). Exposure of mice to concentrations of 6,000-24,000 ppm (24 mg/L – 96 mg/L) mesityl oxide resulted in ocular and nasal irritation, labored breathing, convulsions, narcosis, vasodilation, cyanosis, and death. Rats exposed to 300 ppm for 2 hr/day for 30 days showed leucocytosis and hypertrophy of the liver, kidney, and spleen. Exposure of rabbits to 25 ppm (0.1 mg/L or 100 mg/m³) 4hr/day for 189 days produced anemia and leucopenia.

Neurotoxicity:

The OECD SIAP states that other than transient reversible effects observed in a 49-day inhalation study in rats at concentrations up to 302 ppm (1212 mg/m³ or 1.2 mg/L), that can be attributed to the irritative nature of mesityl oxide, no neurotoxicity has been observed (OECD SIAP, 1997). In this combined repeat dose and reproductive/developmental study, which is discussed in more detail below (see reproductive/developmental toxicity), male and female rats were exposed to mesityl oxide at concentrations of 0, 31, 103, or 302 ppm (or 0, 0.12, 0.4, or 1.2 mg/L) (Bernard and Faber, 1992). During exposure, effects included a transient reduction in activity at 103 (Day 0 only) and 302 ppm (Days 0-13) and partially closed eyes at 302 ppm (Days 0-3). These clinical signs were indicative of the irritative nature of mesityl oxide. Reduced activity was not observed at 31 ppm.

Genotoxicity:

Mesityl oxide has tested negative for genotoxicity in both *in vivo* and *in vitro* tests. The OECD SIAP states that Ames and mouse micronucleus screens were negative (OECD SIAP, 1997). Two studies were obtained from the TSCA Test Submission Database (U.S. EPA, 2005). An *in vitro* reverse mutation test was conducted using *Salmonella typhimurim* strains at 100-5000 µg/plate of mesityl oxide. Mesityl oxide was negative for genotoxicity, both with and without metabolic activation. In an *in vivo*, mammalian bone marrow micronucleus assay, male and female mice were parenterally exposed to 170, 340, or 680 mg/kg of mesityl oxide. Bone marrow depression was observed at 72 hours in high dose males, but not in females.

Carcinogenicity:

Data are not available to evaluate the carcinogenicity of mesityl oxide. Based on its negative genotoxic activity, mesityl oxide is not expected to be carcinogenic.

Reproductive/Developmental Toxicity:

The inhalation toxicity of mesityl oxide was studied in a combined repeat concentration and reproductive/developmental toxicity screening test in the rat (Bernard and Faber, 1992). In this study, male and female rats were exposed to 31, 103, or 302 ppm (or 0, 0.12, 0.4, or 1.2 mg/L) of mesityl oxide during pre-mating (14 days), mating (1-14 days), gestation (21-22 days), and early lactation (4 days). The animals were

exposed 6 hours/day, 7 days/week for a total of 36 to 49 exposures for female rats and 49 exposures for male rats.

Exposure to mesityl oxide resulted in a concentration-dependent reduction in food consumption, body weight, and body weight gain; clinical abnormalities (porphyrin nasal discharge and sialorrhea); and nasal passage pathology (sero-cellular exudates). Fourteen days of exposure to 302 ppm of mesityl oxide reduced the number of litters produced by the mating pairs. Reproductive performance of male rats exposed to 302 ppm for 42 days and bred to unexposed females was comparable to control values. The number of litters produced by mating pairs exposed to 103 or 31 ppm of mesityl oxide was unaffected by treatment. A single male pup from a low-exposure litter was born with physical deformities including a cleft lip, cleft palate, anophthalmia, and petechial bruises. However, the study authors concluded that these developmental abnormalities were not treatment-related. Thus, the lowest-observable-adverse-effect-level (LOAEL) for systemic toxicity is 31 ppm for males and females based on effects on food consumption, body weights, body weight gain, and nasal passage histopathology. The reproductive/developmental LOAEL is 302 ppm, based on decreased number of litters. The NOAEL is 103 ppm.

C. Metabolism and Pharmacokinetics

Limited information is available to assess the metabolism and pharmacokinetics of mesityl oxide. Patty's Toxicology states that "[i]nformation on the metabolism of [mesityl oxide] is fragmentary. It has been reported that metabolism occurs through formation of a glucuronide" (Bingham et al., 2001). Mesityl oxide is readily absorbed through intact skin. While absorbed mesityl oxide is reduced in the body to an appreciable extent, repeated exposure of animals to non-lethal concentrations suggests that mesityl oxide is probably not rapidly eliminated. After frequent exposures, blood concentrations can reach anesthetic levels (HSDB, 2005).

D. Special Considerations for Infants and Children

Only one reproductive and developmental study is available for mesityl oxide. However, with the exception of a reduced number of litters from the available inhalation reproduction study, no other reproductive or developmental effects in animals have been located in the literature. The reproductive/developmental LOAEL is 302 ppm, based on decreased number of litters, and the NOAEL is 103 ppm. There is no quantitative susceptibility for mesityl oxide because the parental LOAEL was 31 ppm, the lowest dose tested. Based on this information there is no concern, at this time, for increased sensitivity to infants and children to mesityl oxide when used as an inert ingredient in pesticide formulations. For the same reason, a safety factor analysis has not been used to assess risk and, therefore, the additional tenfold safety factor for the protection of infants and children is also unnecessary.

V. Environmental Fate Characterization and Drinking Water Considerations

Mesityl oxide is not expected to be persistent in the environment. When released to the environment, mesityl oxide is expected to partition partially into the vapor-phase. Vapor-phase mesityl oxide is rapidly degraded with photochemically formed hydroxyl radicals (estimated half-life of 4.8 hours in air) and through direct photolysis (experimental half-life and rate constant of 76.8 hours and 8.75×10^{-3} /hour, respectively).

In addition, mesityl oxide is expected to biodegrade significantly. Mesityl oxide can also be expected to evaporate from dry soil based on an estimated vapor pressure of 8.7 mm Hg at 20°C. Volatilization from water is expected to occur rapidly based on a relatively low estimated Henry's Law constant of 3.67×10^{-5} atm-m³/mole at 20°C, and half-lives of 12.2 and 1.1 days from a model environmental pond and a model river (one meter deep), respectively. In addition, the estimated K_{oc} of 15.3 and estimated BCF of 1.9 indicate that adsorption to sediment and bioconcentration in aquatic organisms are not significant. However, considering its potential to evaporate rapidly from dry soil, to volatilize relatively rapidly from surface water, and to biodegrade, mesityl oxide is not expected to be present in drinking water sources at high concentrations as a result of its use as an inert ingredient in pesticide formulations.

VI. Exposure Assessment

Mesityl oxide is used in the manufacture of resins, stain removers, carburetor cleaners, paint and varnish removers, and inks. In addition, mesityl oxide has been reported to occur naturally in foods and has been detected in fruits, spices, vegetables, cocoa, coffee, and tea. It is included in the food additive database maintained by the FDA.

Mesityl oxide is used as a solvent and cosolvent in pesticide products, including those for agricultural, garden, and health service use. The current tolerance exemption strictly limits the use of mesityl oxide to applications before the edible parts of a plant begin to form, and livestock are not to be grazed in treated areas within 48 hours after application of the pesticide product. The first use limitation reduces the number of applications that can occur, and, therefore, reduces the likelihood of residues on food. In addition, mesityl oxide's physical-chemical properties and the fate of the chemical in the environment also limit the likelihood of residues on food; it rapidly volatilizes when released, rapidly biodegrades in the environment, and bioaccumulation is not expected. Considering its physical-chemical and fate properties and the significant limitation on the use in pesticide products, mesityl oxide is not expected to contribute significantly to drinking water. Therefore, dietary exposures of concern from food and drinking water are not likely from the use of mesityl oxide in pesticide formulations. While dermal and inhalation from residential uses are possible, the significant use limitations of the current tolerance exemption greatly reduce the potential for exposures of concern.

VII. Aggregate Exposures

In examining aggregate exposure, the FFDCA 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 mesityl oxide, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the lack of human health concerns associated with the low levels of exposure to this chemical when used as an inert ingredient in pesticide formulations.

VIII. Cumulative Exposure

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether mesityl oxide 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 mesityl oxide and any other substances and, this material does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that mesityl oxide 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

Mesityl oxide is used as a solvent and cosolvent in pesticide products, including agricultural and home garden use. The use of mesityl oxide in pesticide products as an inert ingredient is strictly limited to before the edible parts of plant begin to form, and livestock cannot graze on treated crops within 48 hours after application.

Available toxicological data indicate the low acute toxicity of mesityl oxide. Subchronic and chronic toxicity studies indicate that nasal, respiratory tract and eye irritation are likely following long or repeated exposure to mesityl oxide. Effects on the blood, kidneys, liver, and lungs have occurred following exposure to high concentrations. With the exception of reduced number of litters, no other reproductive or developmental effects are reported. All of these effects occur at concentrations higher than expected from mesityl oxide's use as an inert ingredient in pesticide products. Data are not available to evaluate carcinogenicity, but based on its negative genotoxic activity, mesityl oxide is not expected to be carcinogenic.

Dietary (food and drinking water) and residential (dermal and inhalation) exposures of concern are not anticipated from the use of mesityl oxide in pesticide products due to the inert ingredient's physical-chemical and environmental fate properties, as well as the strict use limitations which significantly reduce the number of applications (can be applied only before the

edible parts of plants are formed). In addition, mesityl oxide has been reported to occur naturally in foods and has been detected in fruits, spices, vegetables, cocoa, coffee, and tea.

Taking into consideration all available information on mesityl oxide, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to mesityl oxide when considering dietary exposure (through food commodities and drinking water) and all other non-occupational sources for which there is reliable information. Therefore, it is recommended that the one exemption from the requirement of a tolerance established for residues of mesityl oxide when used on growing crops under 40 CFR 180.920 can be considered reassessed as safe under section 408(q) of the FFDCA.

X. Ecotoxicity and Ecological Risk Characterization

Limited data are available to qualitatively evaluate the effects of mesityl oxide on aquatic and terrestrial animals. Available information indicates low toxicity to aquatic and terrestrial organisms. The OECD-SIAP states that mesityl oxide exhibits low toxicity to aquatic invertebrates, relatively low toxicity to freshwater vertebrates, and low toxicity to a variety of bacterial species (OESD SIAP, 1997). It is also not expected to be chronically toxic. In addition, the chemical has been shown to be stimulating to the germination of two species of terrestrial plants.

Mesityl oxide is not expected to be persistent in the environment. It is highly volatile when released and is expected to biodegrade readily. Adsorption to soil/sediment and bioconcentration in aquatic organisms are not expected to be significant. Therefore, no long-term environmental impacts are expected to occur from the use of mesityl oxide as an inert ingredient in pesticide formulations.

REFERENCES:

Bernard, L.G. and W.D. Faber 1992. Combined Repeated Dose and Reproductive/Developmental Toxicity Screening Test in the Rat. Ketones Panel – Chemical Manufacturers Association, Report No. HAEL: 91-0033. Submitted to EPA/OTS September 2, 1992.

Bingham, E., B. Cohrssen, and C. Powell. (eds.) 2001. Patty's Toxicology: Volume 6. John Wiley Sons, New York.

ChemFinder. 2006. ChemFinder Database. Cambridge Soft Corporation, Cambridge MA. <http://chemfinder.cambridgesoft.com>

Ciba-Geigy. 1987. Skin Sensitization Test in the Guinea Pig with TK 11831-1. Final Report. April 21, 1987. Submitted to EPA/OTS May 26, 1992.

Clayton G. D and F.E Clayton. (eds.) 1982. Patty's Industrial Hygiene and Toxicology: Vol. 2A, 2B, 2C. John Wiley Sons, New York.

Haz-Map. 2005. Occupational Health and Toxicity Database. U.S. National Library of Medicine, National Institutes of Health, Bethesda, MD. <http://hazmap.nlm.nih.gov>

HSDB (Hazardous Substances Data Bank). 2004/2005. U.S. National Library of Medicine, National Institutes of Health, Bethesda, MD. Searched through TOXNET. <http://toxnet.nlm.nih.gov/>.

OECD SIAP. 1997. SIDS Initial Assessment Profile (SIAP) for Mesityl Oxide. Summary of SIDS Submission to the Organization for Economic Cooperation and Development (OECD) High Production Volume Chemicals Program. June, 1997. <http://cs3-hq.oecd.org/scripts/hpv/>.

RTECS. 2004. Registry of Toxic Effects of Chemical Substances. Portions copyright, U.S. Government, by and through MDL Information Systems, Inc. Searched through DIALOG, File 336: RTECS.

Smyth, H.F., Jr., J. Seaton and L. Fischer. 1942. Response of Guinea pigs and Rats to Repeated Inhalation of Vapors of Mesityl Oxide and Isophorone. *Journal of Industrial Hygiene and Toxicology*. 24:46-50.

Topping, D.C., D.A. Morgott, and J.L. Donoghue. 2001. Ketones of six to thirteen carbons. In: *Patty's Toxicology*, fifth edition, vol. 6. (E. Bingham, B. Cohrssen, and C.H. Powell, eds.)

U.S. EPA. 2005. TSCA – Results of Chemical Testing Summary Table. <http://www.epa.gov/opptintr/chemtest/sumindex.htm>.

U.S. Food and Drug Administration (FDA). 2005. Everything Added to Food in the United States Database. <http://www.cfsan.fda.gov/~dms/eafus.html>.