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

OFFICE OF PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

December 14, 1999

MEMORANDUM

SUBJECT: UPDATED, REVISED DIMETHOATE. The Updated, Revised HED Chapter of the Reregistration Eligibility Decision Document (RED). PC Code: 035001, Case # 0088.

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TO: Susan Lewis, Chief
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The attached revised review of the Human Health Assessment for the dimethoate RED document (Phase 4) was generated to include new data and reviews, the results of updated modeling and databases, the endpoint reevaluation, and some information provided in the document *Comments on EPA's Dimethoate Draft RED Chapters* (August 20, 1998) submitted by Cheminova Agro A/S in Phase 3 of the Public Participation Process. The Health Effects Division's (HED) revised chapter reflects the Agency's current guidelines concerning the retention of the Food Quality Protection Act (FQPA) factor and the risk assessment, and includes the results of a dietary risk evaluation using United States Department of Agriculture's (USDA) 1989-1992 consumption data and Dietary Exposure Evaluation Model (DEEM) software. This chapter includes a summary of the product and residue chemistry from Bonnie Cropp-Kohlligian,

toxicology review from Byong-Han Chin, occupational exposure from Alan Nielsen, acute DEEM calculations and characterization from Mohsen Sahafeyan, chronic DEEM analysis from Brian Steinwand, drinking water exposures from Jim Wolf [Environmental Fate and Effects Division (EFED)], as well as risk assessment and characterization from Diana Locke.

cc: Margaret Stasikowski
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DIMETHOATE REVISED RISK ASSESSMENT

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DIMETHOATE

Executive Summary

Dimethoate is a general use systemic organophosphate insecticide/acaricide that is used to control a wide variety of target pests including insects and related organisms, mollusks, fouling organisms, and miscellaneous invertebrates. Some examples of the pests that dimethoate is intended to control include aphids, citrus thrips, grasshoppers, leafminers, spider mites, and whiteflies. For reregistration, Cheminova (primary data-submitter) is supporting the use of dimethoate on a variety of foods, feeds, and ornamentals. Manufacturing products contain between 95 and 96% active ingredient. Formulated end-use products are available as emulsifiable concentrates (EC) and wettable powders. However, the wettable powder formulation is being supported during reregistration for use on grapes only. Historically, several other types of formulated products have contained dimethoate, such as dusts, granulars, and a ready-to-use formulation. However, none of these other formulation types are being supported in the reregistration process and are not included in the risk assessment.

Dimethoate is not a restricted use chemical, and based on current labels, products containing dimethoate can be marketed for both residential and occupational uses. The registrants have indicated that they will not support residential use patterns during the reregistration process, and no residential exposure and risk assessment is included in this document. However, residential exposure could occur via agricultural spray drift from the use of dimethoate on fields adjacent to residences. A quantitative exposure and risk assessment for residential exposure via agricultural spray drift has not been completed as part of this risk assessment as the methodology for these assessments is still under development by the Agency.

The toxicity endpoints are based on neurotoxic effects, primarily but not exclusively, cholinesterase inhibition (ChEI) of the red blood cell (RBC), plasma, and brain, as well as absence of pupil response.

An uncertainty factor (UF) of 100 was applied to the doses selected for risk assessment to account for both interspecies extrapolation and intraspecies variability. The Hazard Identification Assessment Review Committee (HIARC) and the FQPA Safety Factor Committee determined that for dimethoate, the 10X factor, used to account for enhanced sensitivity of infants and children (as required by the Food Quality Protection Act), should not be retained.

Tolerances are established for total residues of dimethoate and its oxygen metabolite, omethoate (40 CFR 180.204). The Agency performed an acute dietary analysis (Tier 3) incorporating updated risk assessment guidance and dietary guidelines, a No-Observed-Adverse-Effect-Level (NOAEL) of 2.0 mg/kg/d, a UF of 100, and assumed exposure to ChEI residue levels of dimethoate and its metabolite, omethoate. The acute dietary risk assessment (probabilistic), based on PDP and FDA residue data and the USDA's 1989-1992 Continuing

Survey of Food Intake by Individuals (CSFII) food consumption survey and using an acute Population Adjusted Dose (aPAD = acute RfD ÷ FQPA factor) of 0.02 mg/kg/d, showed that acute dietary exposure to all population subgroups did **not exceed** the aPAD at the 99.9th percentile estimated exposure level **(U.S. population 41% aPAD, children 1-6 years 86% aPAD)**. The crops that appeared to make the most significant contribution to the risk were melons, cabbage (green and red), grapes (fresh, raisins, and juice), apples (juice/cider), blueberries, and turnips (tops and roots). It should be noted however, that tolerance level residues were used in the dietary assessment for melons and cabbage because no monitoring data were available and field trial data were of such a scope and nature that anticipated residue estimates below tolerance levels could not be determined with reasonable confidence.

The chronic dietary analysis was conducted incorporating refinements, including percent crop treated data, processing factors, and some anticipated residues. Based on a limited Tier 2 chronic dietary exposure analysis and using a chronic PAD (cPAD) of 0.0005 mg/kg/d, chronic dietary exposure to all population subgroups did **not exceed** the cPAD (U.S. population 20% cPAD, children 1-6 years 36% cPAD).

In general, estimated drinking water exposures, using surface water and ground water models and some limited monitoring data, indicate that the drinking water contribution to the total dietary burden will not result in total (food + water) dietary risks above the Agency's level of concern (i.e. not > 100% PAD). The Environmental Fate and Effects Division's (EFED) estimated exposure concentrations (EEC) are less than the calculated drinking water levels of comparison (DWLOC) for the majority of uses (application rates less than 4 pounds active ingredient per acre).

Total risks for occupational handlers were assessed using the short-term dermal toxicological endpoint of 10 mg/kg/d (NOAEL based on a dermal study) and inhalation endpoint of 2.0 mg/kg/d (NOAEL based on subchronic oral studies in rats and an acute oral rat study), as well as the intermediate-term endpoint of 3.2 mg/kg/d (LOAEL based on 2 subchronic oral studies in rats) for both dermal and inhalation exposures. A dermal absorption factor of 11% was used for intermediate-term dermal exposure calculations and inhalation exposures are assumed to be 100% absorbed. A margin of exposure (MOE) of 100 was needed for the short-term risks (UF 100 applied) and an MOE of 300 was needed for intermediate-term risks (UF 100 applied + 3X for lack of a NOAEL). A long-term risk assessment was not completed since the Agency believes that dimethoate use patterns do not lend themselves to long-term exposure scenarios.

Short- and intermediate-term handler scenarios in occupational settings were assessed for dermal and inhalation occupational risks at the maximum application rates, as well as proposed reduced rates, for a variety of crops recommended by the available dimethoate labels to bracket risk levels associated with the various use patterns. Most of the handler risk scenarios at the lower application rates are mitigated with additional personal protective equipment (PPE) or engineering controls. At the highest application rates, even with engineering controls, the Agency has risk concerns for the short- and intermediate-term handler scenarios at the 33.2 lb ai/A airblast

application rate (conifer seed nursery), 4.0 lb ai/A aerial application rate (ornamentals) and the 2.0 lb ai/A aerial application rate (grapes). Even with the use of maximum PPE, the Agency also has concerns for handlers using a high-pressure handwand sprayer on ornamentals at 0.01, 0.06, and 0.1 lb ai/gallon application rates. Risks from exposures from using low-pressure handwands are mitigated with additional PPE. No engineering controls are currently available for these types of application scenarios.

Postapplication occupational exposure is likely following applications of dimethoate to fruit, vegetable, grain, fiber, feed, ornamental, and other crops and sites during typical postapplication activities such as harvesting, scouting, pruning, and transplanting. The results of the risk assessment for postapplication exposures indicate that the location and/or the environmental conditions near the time of application greatly influence the estimated restricted-entry interval (REI). As an example, for sites in Florida and Pennsylvania where non-woody food and feed crops were treated, MOEs exceed 300 by day 1 (ranging from 12 to 24 hours depending on the application rate, the crop, or postapplication activity). In contrast, for sites in California, MOEs do not exceed 300 until day 5 (ranging from 12 hours to 5 days) following application. In greater contrast, for sites in New York and Michigan where woody ornamentals were treated at relatively high application rates (2-4 lb ai/A), MOEs exceed 300 by day 41 (ranging from 18 to 41 days). Whereas, for sites in Washington, MOEs do not exceed 300 until day 60 (ranging from 38 to 60 days) following application. For conifer seed nurseries, for sites in New York and Michigan where coniferous trees were treated at very high application rates (8.3-33.2 lb ai/A), MOEs exceed 300 by day 61 (ranging from 29-61 days). Whereas, for sites in Washington, MOEs do not exceed 300 until day 87 (ranging from 60 to 87 days) following application.

Residential uses are no longer being supported. The potential for other non-occupational exposures to individuals living in or near agricultural areas, e.g. potential exposure from spray drift, where dimethoate is being used were not included in the aggregate risk assessment but will be addressed at a later time when methodologies to perform such assessments are in place.

The acute aggregate risk estimate (food + water) does not exceed the Agency's level of concern (i.e. < 100% aPAD) for most uses. The chronic aggregate risk assessment is also not of concern. Aggregate risks based on higher application rates (4 lbs ai/A or greater) are of concern, though some of them are not being supported under reregistration. The Agency is in the process of formulating guidance for conducting cumulative risk assessment. When the guidance is completed, peer reviewed, and finalized, dimethoate and other organophosphates will be revisited to assess the cumulative effects of exposure to multiple organophosphates.

Physical and Chemical Properties

A. Description of Chemical

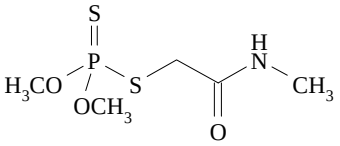
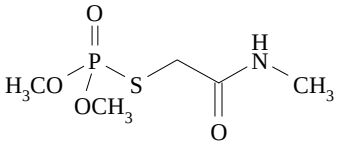
Dimethoate [O,O-dimethyl S-(N-methylcarbamoylmethyl) phosphorodithioate] is a systemic insecticide/acaricide registered for use on various food and feed crops.

Empirical Formula: $C_5H_{12}NO_3PS_2$
Molecular Weight: 229.3
CAS Registry No.: 60-51-5

B. Identification of Active Ingredient

Dimethoate is a white crystalline solid with a mercaptan odor and a melting point of 45-48° C. Dimethoate is soluble in water at 25 g/L at 21 C, is highly soluble in chloroform, methylene chloride, benzene, toluene, alcohols, esters, and ketones, and is only slightly soluble in xylenes, carbon tetrachloride, and aliphatic hydrocarbons. Dimethoate is stable in aqueous solutions at pH 2-7, but hydrolyzes in alkaline media.

Shaughnessy No.: 035001
Chemical structures of Dimethoate and Omethoate

Compound: Chemical name	**Compound**: Chemical name
Dimethoate  *O,O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorodithioate	**Omethoate**  *O,O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorothioate

C. Manufacturing-Use Products

A search of the Reference Files System (REFS) conducted 12/99 identified six dimethoate manufacturing-use products (MPs) registered under Shaughnessy No. 035001. A list of the MPs subject to a reregistration eligibility decision is presented below in Table 1.

TABLE 1

Formulation	EPA Reg. No.	Registrant
98% T	4787-7	Cheminova Agro A/S
96% T	10163-211	Gowan Company
94% T	19713-209	Drexel Chemical Company
82% FI	7969-32	BASF Corporation
96%	34704-788	Platte Chemical Co. Inc.
96%	51036-279	Micro-Flo Company

Hazard Characterization

A. Hazard Profile

The toxicological data base is adequate to support reregistration. However, there are numerous dermal exposure scenarios for which HED has concerns. Based on the inadequacy of the repeated dose 21-day dermal toxicity study and the need to sufficiently characterize dermal toxicity and absorption, the Agency recommended that a 21-day dermal toxicity study be conducted in the rat. This study is still outstanding. In the mean time, a 5-day dermal toxicity study in rats was submitted and judged acceptable for use in short-term occupational exposure assessments (Dimethoate: A Comprehensive Report of the Toxicology Endpoint Selection, Paul Chin, July, 20, 1999).

In summary, dimethoate is moderately (category 2) acutely toxic for oral, and slightly (category 3) toxic for acute dermal toxicity. Dimethoate did not appear to be acutely toxic by the inhalation route (category 4). It is not a skin sensitizer, nor a dermal irritant. An Acute Delayed Neurotoxicity Study in Hens (MRID 42884401) showed that brain ChE was greatly decreased and brain neuropathy target esterase (NTE) was slightly decreased relative to controls, and spinal cord NTE was consistent with control values. The toxicity endpoints selected for the risk assessment are based on neurotoxic effects, primarily but not exclusively, ChEI of the plasma, RBC, and brain, as well as systemic toxicity.

The HED Cancer Peer Review Committee (CARC) classified dimethoate as a Group C carcinogen (possible human carcinogen; final document dated 8/29/91) based on equivocal hemolymphoreticular tumors in male B6C3F1 mice, the compound-related (no dose response) weak effect of combined spleen (hemangioma and hemangiosarcoma), skin (hemangiosarcoma), and lymph (angioma and angiosarcoma) tumors in male Wistar rats, and positive mutagenic activity associated with dimethoate. For the purposes of risk assessment and characterization for dimethoate, the PAD approach, and not a Q_1* approach, was considered more appropriate for quantification of potential human risk for the following reasons: as stated above, the mouse carcinogenicity study showed equivocal hemolymphoreticular tumors, and the rat carcinogenicity study showed a compound-related, weak effect of combined spleen (hemangioma and hemangiosarcoma), skin (hemangiosarcoma), and lymph (angioma and angiosarcoma) tumors, but there was no dose response. In addition, the chronic Reference Dose (RfD) is considered protective enough of any potential cancer risk since the No-Observable-Adverse-Effect-Level (NOAEL) from which it is derived (0.05 mg/kg/d) is at least an order of magnitude lower than the NOAELs or Lowest-Observable-Adverse-Effect-Levels (LOAELs) derived from the systemic effects seen in the rat and mouse carcinogenicity studies. On June 25, 1992, the FIFRA Scientific Advisory Panel (SAP) concurred with the Agency's classification of dimethoate as Group C carcinogen.

1. Acute Toxicity

The following up-dated table summarizes the acute toxicity data for the technical dimethoate.

TABLE 2
ACUTE TOXICITY VALUES - DIMETHOATE TECHNICAL

TEST	RESULTS	TOXICITY CATEGORY
81-1: Oral LD_{50}; Rat; MRID No. 00164219 dimethoate (96-98% technical)	LD_{50}= 387 mg/kg	II
81-2: Dermal LD_{50}; Rabbit; MRID No. 00164220 dimethoate (96-98% technical)	LD_{50} = > 2.0 g/kg	III
81-3: Inhalation LC_{50}; Rat; MRID No. 00060719; dimethoate (95% technical)	LC_{50} > 2 mg/L	IV
81-4: Primary Eye Irritation; Rabbit; MRID No. 00164222; dimethoate (96-98% technical)	Corneal opacities, iritis, and conjunctivitis; reversible within 7 days.	III
81-5: Primary Dermal Irritation; Rabbit; MRID No.:00164221 dimethoate (96-98% technical)	Not a dermal irritant	IV
81-6: Dermal Sensitization; Guinea pig; MRID No. 254924 dimethoate (97.3% technical)	Not a skin sensitizer	N/A
81-7: Acute delayed neurotoxicity study; hens MRID No. 42884401, dimethoate (96.42% a.i.)	No clinical signs of acute delayed neurotoxicity and no compound-related histological changes in nerve tissue.	N/A

81-8: Acute oral neurotoxicity screen study; rats MRID No. 42865102, dimethoate (99.1% a.i.)	Systemic effects NOAEL=20 mg/kg Systemic effects LOAEL=200 mg/kg based on a decrease in body weight. Neurotoxicity toxicity NOAEL =2 mg/kg/d Neurotoxicity toxicity LOAEL=20 mg/kg/d based on an absence of pupil response. At 200 mg/kg the most obvious reactions were tremors, decreased motor activity, decreased body temperature, increased catalepsy time and eleven other parameters which indicated that coordination, sensory and motor systems were affected. These effects were noted immediately following treatment and were reversed by day 7. There were no neuro-histopathological effects in either the central or peripheral nervous systems.	N/A

The acute delayed neurotoxicity study in hens was conducted by oral administration of a single dose of dimethoate (96.42% a.i.) at a dose level of 55 mg/kg to domestic hens. No clinical signs of acute delayed neurotoxicity and no compound-related histological changes in nerve tissue were observed. Brain ChE, and brain and spinal cord neuropathy target esterase (NTE) were measured and showed that brain ChE was greatly decreased and brain NTE was slightly decreased relative to controls, and spinal cord NTE was consistent with control values (MRID No. 42884401).

An acute oral neurotoxicity screen study in rats was conducted with four groups of Sprague-Dawley rats dosed at control, 2, 20, or 200 mg/kg of dimethoate (99.1% a.i.) in water by gavage. The animals were assessed for reactions in a functional observational battery (FOB) and motor activity measurements at the peak effect time of 2 hours post dosing and on days 7 and 14. The LOAEL for systemic effects was 200 mg/kg and the NOAEL was 20 mg/kg based upon decreased body weight. The LOAEL for neurotoxicity was 20 mg/kg based on an absence of pupil response (cholinergic response, lack of accommodation) and the NOAEL was 2 mg/kg. At 200 mg/kg the most notable responses were tremors, decreased motor activity, decreased body temperature (4.4^{o} C both sexes) and increased catalepsy time, as well as eleven other parameters which indicated that coordination and, sensory and motor systems were affected. These effects were noted immediately following treatment and were reversed by day 7. There were no neurohistopathological effects in either the central or peripheral nervous systems (MRID No. 42865102).

A nonguideline acute dietary neurotoxicity study in rats (MRID 44818901) was submitted and reviewed (11/99). There are several deficiencies in the study and, the Agency concluded that the study was inappropriate for acute dietary exposure toxicity testing and that the variability of the data made the results invalid. The FIFRA Science Advisory Panel was consulted about the study design and supports the Agency's conclusions.

In a recently submitted, nonguideline, 5-day dermal toxicity study (MRID 44818902) dimethoate 4E (43.5% a.i.) was administered topically to the clipped dorsal region (intact skin) of Sprague Dawley [Crl:CD VAF/Plus] rats (16/sex/dose). Animals received daily dose of 0, 5, 10, 20, 40, or 100 mg a.i./kg/day) for 6 hours per day for 5 days. Plasma, red blood cell, cortex, hippocampus, and striatum cholinesterase determinations were performed on days 3 and 5 (at termination). None of the animals died during the study. Treatment and dose related effects on dermal reactions (desquamation) were found in males only. Other treatment related clinical signs of toxicity observed were ptosis (males) and excessive lacrimation (females). Tremors, shallow breathing, pale eyes, and exophthalmus were observed in the highest dose females (100 mg/kg/d) only. No treatment related effects on FOB measurements were noted during the study. In males, there was a statistical significant reduction ($p < 0.05$ or 0.01) in red blood cell (33-50% inhibition relative to controls), hippocampus (31%), striatum (22-23%) and cortex (20-30%) cholinesterase activity in 100 mg/kg/d group (days 3 or 5). In females treated at 20 mg/kg/d (days 3 or 5), there was a statistical significant reduction ($p < 0.05$ or 0.01)in plasma (33%), red blood cell (35%), and cortex (21%) cholinesterase activity. In females treated at 40 or 100 mg/kg/d (days 3 or 5), there was a statistical significant reduction ($p < 0.05$ or 0.01) in plasma (33-50%), red blood cell (50-75%), hippocampus (38-48%), striatum (40-46%) and cortex (21-51%) cholinesterase activity. The LOAEL for ChE inhibition was 100 mg a.i./kg/day for males and 20 mg a.i./kg/day for females based on statistically significant inhibition of red blood cell cholinesterase and brain cholinesterase activity. The NOAEL was 40 mg/kg/d for males and 10 mg/kg/d for females.

2. Subchronic Toxicity

In a 1959 subchronic study, rats were treated with dimethoate (95% technical) in the diet for 13 weeks at doses of 0, 2, 8, 32, or 400 ppm (equivalent to an intake of 0.1, 0.4, 1.6, and 20 mg/kg/d, respectively). This study also included an additional segment where rats were dosed at 50 ppm (2.5 mg/kg/d) for four weeks, sacrificed and plasma, RBC and brain ChE measurements were taken. The NOAEL was 50 ppm and the systemic LOAEL was 400 ppm based on decreased growth and food consumption and increased kidney and liver weight ratios. The ChE activity NOAEL was 1.6 mg/kg/d and the ChE activity LOAEL was 2.5 mg/kg/d based on the depression of plasma, red blood cell and brain ChE (MRID No. 0051675 and 0077532).

Dogs were treated with dimethoate (95% technical) in the diet for 13 weeks at doses of 0, 2, 10, 50 or 1500-3000 ppm (equivalent to an intake of 0.05, 0.25, 1.25 and 37.5-75 mg/kg/d, respectively). The systemic NOAEL was 1.25 mg/kg/d and the systemic LOAEL was 37.5 mg/kg/d based on tremors and decreased food consumption in females. The ChE activity NOAEL was 0.05 mg/kg/d and the ChE activity LOAEL was 0.25 mg/kg/d based on the dose related depression of red blood cell ChE at 0.25 mg/kg and above (MRID No. 0051676).

In a subchronic neurotoxicity study, male and female Sprague-Dawley rats were treated with dimethoate (99.1% a.i.) in the diet at doses of 1, 50 or 125 ppm (0.06, 3.22 and 8.13 mg/kg/d for males and 0.08, 3.78 and 9.88 mg/kg/d for females, respectively) for 13 weeks. Dimethoate treatment did not result in differences between the control and treated animals in the

FOB or in the locomotor activity evaluations. The NOAEL was 0.06 mg/kg/d and the LOAEL was 3.22 mg/kg/d based on reduction of plasma (24-48%) and red blood cell (34-60%) ChE activity at mid and high dose levels and brain ChE activity (12-20%) at the high dose level. The reductions in olfactory and cortex ChE activity in the high dose males were 12-18% (MRID No. 43128201).

In a repeated dose 21-day dermal toxicity study, dimethoate technical (97.3% a.i.) was administered topically to the clipped dorsal region (intact skin) of New Zealand white rabbits (6/sex/dose) at daily dose levels of 0, 100, 300 or 1000 mg/kg/d for 6 hours per day for 3 weeks. There were no deaths, clinical signs or any treatment-related effects observed. The NOAEL for dermal irritation and for systemic toxicity is 1000 mg/kg/d, the highest dose tested and no LOAEL could be determined. The test substance was dosed at the limit dose of 1000 mg/kg required by the guideline requirement 82-2. This study was classified as unacceptable by the HED-RfD/Peer Review Committee on January 17, 1997. The Committee cited several technical deficiencies in the conduct of the study including: 1) choice of animal species; the rabbit is an inappropriate model for testing this particular chemical, and 2) choice of solvent; the paraffin oil used as a solvent in this study, is inappropriate because it impaired dermal penetration. The Committee concluded that, these deficiencies compromised the results of this study and therefore, the dermal toxicity of dimethoate was significantly underestimated (MRID 470201-046). It should be noted that though rabbits are frequently the species of choice for dermal toxicity studies, rats are preferred for organophosphate compounds because the rabbit has a number of unique physiological and biochemical characteristics which can lead to a potentially dangerous underestimation of the dermal toxicity of a chemical. This is particularly true of organophosphate cholinesterase inhibitors which require biological activation to the oxone. The rabbit possesses a high concentration of blood arylesterases which detoxify such compounds before they can be activated in the liver making the rabbit uniquely insensitive to them. Dermal rabbit studies can be expected to underestimate the toxicity of such compounds by 10 to 30 fold.

3. Chronic Toxicity and Carcinogenicity

A one year feeding study was conducted using groups of beagle dogs (6/sex/dose) treated with dimethoate (96.44% a.i.) in the diet at doses of 0, 5, 20 or 125 ppm (equivalent to 0, 0.18, 0.70 and 4.18 mg/kg/d in males and 0, 0.19, 0.76 and 4.31 mg/kg/d in females). The LOAEL for systemic toxicity was 5 ppm based on decreased liver weights in females and the presence of a brown, granular pigment in the liver of both sexes. No NOAEL could be established. The ChE activity LOAEL was 0.18 mg/kg/d based on a reduction in brain ChE (7% $p<0.05$ males; 10% $p<0.05$ females). No NOAEL could be established. In addition, red blood cell ChE was decreased in both sexes in the 0.70 and 4.18 mg/kg/d groups and plasma ChE was decreased in both sexes in the 4.18 mg/kg/d group (MRID No. 41939801, 42192301).

In a chronic/carcinogenicity feeding study, Wistar rats (65/sex/group) were fed diets containing 0, 5, 25, or 100 ppm dimethoate (0, 0.25, 1.25 or 5 mg/kg/d) for 2 years. An additional 20 animals/sex were given 1 ppm (0.05 mg/kg/d) in order to determine a NOAEL for

ChE inhibition. The NOAEL for systemic toxicity was 1.25 mg/kg/d and the LOAEL was 5 mg/kg/d based on increased mortality (females), decreased body weight gain (males), anemia (males) and increased leukocytes (males and females). The ChE activity NOAEL was 0.05 mg/kg/d and the LOAEL was 0.25 mg/kg/d based on brain and red blood cell ChE inhibition. Administration of dimethoate was associated with dose related trends for:

(i) spleen hemangiosarcoma;
(ii) combined spleen hemangioma and hemangiosarcoma, and;
(iii) combined spleen hemangioma, hemangiosarcoma and skin hemangiosarcoma.

Furthermore, there were significant differences in pair-wise comparisons between controls and the low dose (0.25 mg/kg) or high dose (5 mg/kg) for spleen (hemangioma/ hemangiosarcoma) and in the combined tumors of spleen and skin hemangiosarcoma and lymph angioma/angiosarcoma. Although there was no dose response, there were significant pair-wise comparisons at the low and high doses for all tumors combined. The HED Peer Review Committee agreed that despite no dose response, these tumors were compound related but that the tumor incidences did not indicate much more than a weak effect (MRID # 00164177).

In a chronic/carcinogenicity feeding study, B6C3F1 mice (60/sex/group) were fed diets containing 0, 25, 100 or 200 ppm dimethoate (0, 3.75, 15 and 30 mg/kg/d) for 78 weeks. Ten animals of the 60 per sex were used as satellite animals and were sacrificed at 52 weeks. The NOAEL/LOAEL for the systemic toxicity were less than 3.75 mg/kg/d (the lowest dose tested) based on:

(i) the increased incidence of hepatic vacuolation in females at all levels;
(ii) decrease in the relative weights of brain, heart, kidney, and spleen in all treated animals;
(iii) decrease in the absolute and relative weight of the ovaries in all treated animals, and;
(iv) a significant decrease in body weight gain in all males and in high dose females (during the first five weeks of the study).

Absolute liver weights were significantly increased in both sexes of the mid and high dose groups, while relative liver weights were significantly decreased in mid and high dose females. The ChE activity NOAEL/LOAEL were less than 3.75 mg/kg/d based on significant depression ($p<0.01$) of plasma and RBC ChE activities at all dosage levels. Brain ChE was not measured. Administration of dimethoate in the males was associated with a significant dose related increase in:

(i) combined lung adenoma and/or adenocarcinoma;
(ii) for lymphoma, and;
(iii) for the combined group of lymphoma, reticular sarcoma, and leukemia.

A significant difference in the pair-wise comparison of control and the highest dose level

(30 mg/kg/d) was found for the combined tumor group of lymphoma, reticular sarcoma, and leukemia. The HED Peer Review Committee agreed that the increased incidence for the combined tumors compared to concurrent controls appeared to be compound-related, but could only classify this incidence as equivocal. Administration of dimethoate in females was associated with a significant dose related increase in liver carcinoma and for combined liver adenoma and/or carcinoma. However, the Committee agreed that not much weight should be put on the combined tumor incidence in female mice because there were no significant pair-wise comparisons. There also was no evidence of precursor lesions to carcinogenicity (MRID # 00163800; Accession # 265362-265364).

The dosing was adequate in both the rat and the mouse studies for the assessment of the carcinogenic potential of dimethoate. The Committee has classified dimethoate as a Group C carcinogen (possible human carcinogen; final document dated 8/29/91) based on equivocal hemolymphoreticular tumors in male B6C3F1 mice, the compound-related, weak effect (no dose response) of combined spleen (hemangioma and hemangiosarcoma), skin (hemangiosarcoma) and lymph (angioma and angiosarcoma) tumors in male Wistar rats, and positive mutagenic activity associated with dimethoate. It is for this reason that an RfD approach, and not a Q_1* approach, is considered more appropriate for quantification of potential human risk.

4. Developmental Toxicity

Groups of 25 pregnant CrL: COBS CD (SD) BR strain rats were given daily doses of dimethoate (97.3% a.i.) by oral gavage at 0, 3, 6 or 18 mg/kg body weight on gestation days 6 through 15, inclusive. The NOAEL for maternal toxicity was 6 mg/kg/d and the LOAEL was 18 mg/kg/d based on body weight decrement. The NOAEL for developmental toxicity $\geq$ 18 mg/kg/d, the highest dose level tested and a LOAEL was not established (MRID # 00141142 & 00150130).

Groups of 16 pregnant New Zealand White rabbits were given daily doses of dimethoate (97.3% a.i.) by oral gavage at 0, 10, 20, or 40 mg/kg body weight on gestation days 7 through 19, inclusive. The NOAEL for maternal toxicity was 10 mg/kg/d and the LOAEL was 20 mg/kg/d based on reduced body weight gain at the mid- and high-dose levels, and tremors and unsteady gait at the high-dose level. The NOAEL for developmental toxicity was 20 mg/kg/d and the LOAEL was 40 mg/kg/d based on a significant reduction in fetal weight (MRID No.: 00159759 & 00159760).

5. Reproductive Toxicity

A reproductive toxicity study was conducted in which Crl:CD BR rats were fed dimethoate in the diet at dosage levels of 0, 1, 15 or 65 ppm. The NOAEL for parental systemic toxicity was considered to be 1 ppm (0.08 mg/kg/d in males and 0.09 mg/kg/d in females) and the LOAEL for was considered to be 15 ppm (1.2 mg/kg/d in males and 1.3 mg/kg/d in females) based on decreased plasma, erythrocyte and brain cholinesterase activity in both sexes and all

generations. There was no effect on premating body weight gain or food consumption for any sex and generation. The reproductive toxicity NOAEL/LOAEL of 1.25 and @ 6.5 mg/kg/d, respectively are based upon slight, but dose-related decreases in the number of live pups at birth and pup weight at birth in the F1a and F2b pups, and decreased fertility for the F1a & b and F2a & b matings. Startle reflex occurred at an increased age in F1 and F2 pups (MRID No.42251501).

6. Mutagenicity

In the Ames test, dimethoate was not mutagenic when tested in S. typhimurium strains TA1535, 1537, 98 and 100 at non-cytotoxic doses (MRID # 00063996).

Equivocal results were obtained from a Chinese hamster ovary (CHO)/HPRT gene mutation assay. In this assay, dimethoate was tested at 0, 1000, 1500, 2000, 2700 or 2500 μg/ml. A statistically significant increase in mutation frequency was observed at 2700 (with and without S-9 activation) and 3500 µg/ml (without S-9 activation). Because some of the results were not reproducible, it could not be determined if increases were biologically significant or were due to inherent technical problems with the assay (Accession # 256594).

Dimethoate was not mutagenic in a dominant lethal assay. In this assay, dimethoate was administered orally by gavage at 5, 10 or 20 mg/kg to 5 male mice/group for 5 consecutive days. Dimethoate did not elicit a dominant lethal effect in the offspring of male mice which were sequentially mated (2 females/mating) for 8 weeks (Accession # 259921).

Dimethoate was not mutagenic in a cytogenetic assay in bone marrow of rat. Dimethoate at intraperitoneal doses of 15, 75, or 150 mg/kg, a clastogenic response was not observed in bone marrow of male or female rats harvested 6, 16 and 24 hours after treatment (Accession # 259921).

Dimethoate was not mutagenic in a mouse micronucleus assay. Dimethoate did not induce any significant increase in the number of PCE (polychromatic erythrocytes) containing micronuclei from animals (5/sex/group) administered single or multiple intraperitoneal doses of 55 mg/kg (Accession # 257603).

Dimethoate was positive for inducing unscheduled DNA synthesis (UDS) in rat hepatocytes. Dimethoate at the highest dose tested (763.33 ug/ml) and 229.0 ug/ml caused an increase in grain counts (i.e. evidence of UDS) in autoradiographically treated slide cultures. Dimethoate was cytotoxic at concentrations of 763.33 ug/ml and above (MRID # 43151801).

Dimethoate was positive in a dose-related trend for inducing UDS in rat hepatocyte cultures exposed to doses from 23 to 2290 μg/ml as measured by uptake of radio-thymidine by liquid scintillation counting. Dimethoate was cytotoxic at concentrations of 2290 μg/ml (MRID # 43151801, 43151802).

Dimethoate was negative for inducing unscheduled DNA synthesis (UDS) in hepatocyte cultures from rats (males only). In this study dimethoate was administered by oral gavage at dose levels up to a clinically toxic dose of 200 mg/kg. However, the Agency classified this study as unacceptable since no evidence was available to assure transport of the test article to the target tissue (hepatocyte) (MRID 42082001).

7. Metabolism

Groups of male and female Wistar rats were dosed with ^{14}C-dimethoate (labeled in the O-methyl groups) at a single oral dose (10 or 100 mg/kg), an intravenous dose (10 mg/kg) or 14-day repeated oral doses of dimethoate at 10 mg/kg followed by a single oral dose of ^{14}C-dimethoate at 10 mg/kg. Dimethoate was rapidly absorbed, metabolized, and eliminated in rats for all dosing regimens. There were no remarkable sex-, dose- or treatment-related differences in the absorption, distribution, and elimination of dimethoate in rats. Total recovery of radioactivity ranged between 91% and 97% of the administered dose for all tested groups within 5 days after dosing. Most of the radioactivity (85-91% of the dose) was excreted in the urine. A small amount of radioactivity was found in feces (1-2% of the dose), in the tissues and remaining carcass (1-2%), and in the expired air as carbon dioxide (2-3%). ^{14}C-concentrations in all tissues was less than 7 ppm after a single oral dose at 100 mg/kg and less than 0.3 ppm after a single or multiple oral doses at 10 mg/kg (14-daily dose) and an intravenous dose at 10 mg/kg.

Most (83-91%) of the administered dose in urine samples from orally or intravenously dosed rats were identified by HPLC analysis followed by confirmation by mass spectrometry. Four metabolites identified were as follows:

Ref II (Omethoate, 1-6% of dose),
Ref XVI (Dimethylthiophosphoric acid, 4-11% of dose),
Ref XV (Dimethyldithiophosphate, 20-30% of dose), and
Ref III (Dimethoate carboxylic acid, 29-46% of dose).

There were no qualitative or quantitative differences in the metabolite profiles for dose level and sex of rats after oral or intravenous administration of ^{14}C-dimethoate. Five radioactive components were not identified but no component in the urine samples represented more than 7% of the dose. Unchanged parent in the urine samples represented 0.4-2% of the dose. Biliary excretion of radioactivity by bile-cannulated rats accounted for 4-5% of the dose 2 days after a single oral administration of ^{14}C-dimethoate at 10 or 100 mg/kg. The metabolic pathway consisted of hydrolytic and oxidative pathways. The hydrolytic pathway (major) involves cleavage of the C-N bond to yield dimethoate carboxylic acid that was subsequently metabolized to dimethyldithiophosphate, dimethylthiophosphoric acid and dimethylphosphoric acid. The minor metabolic pathway involves oxidation of dimethoate to its oxone analogue, omethoate, that was subsequently metabolized to dimethylthiophosphoric acid and dimethylphosphoric acid. Loss of the methoxy groups of the parent to yield carbon dioxide is a minor metabolic pathway.

B. Endpoint Selection

1. Acute Dietary (one day)

A weight-of-the-evidence analysis of the toxicity database showed that a NOAEL = 2 mg/kg/d is appropriate for the timeframe of an acute dietary endpoint based on a number of studies, several of which included measurements for ChEI (HIARC meeting 06/29/99).

In an acute neurotoxicity study (MRID 42865102), four groups of Sprague-Dawley Crl:CD^{R}BR strain rats (Charles River, Portage Michigan) were dosed as control, 2, 20 or 200 mg/kg of dimethoate in water by gavage and assessed for reactions in functional observational battery (FOB) assessments and motor activity measurements at the predetermined estimated peak effect time of 2 hours post dosing and on days 7 and 14. The LOAEL for systemic effects was 200 mg/kg and the NOAEL was 20 mg/kg based on a decrease in body weight. Neurotoxicity was characterized as behavioral reactions at the initial observation only. At 20 mg/kg the critical effect was an absence of pupil response (an autonomic domain response with 5/12 males and 6 or 12 females affected vs only 1 or 2 in the controls; cholinergic response). At 200 mg/kg the most obvious reactions were tremors (all animals affected, none in other groups), decreased motor activity (total: 40% males, 54% females and ambulatory: 56% both sexes), decreased body temperature (about 4.4 degrees both sexes), increased catalepsy time (0.6 seconds in males and 3.6 seconds in females) and eleven other parameters which indicated that coordination, sensory and motor systems were affected. These effects were noted immediately following treatment and were reversed by day 7 but based on cage side observations some symptoms persisted for up to day 5. There were no neurohistopathological effects in either the central or peripheral nervous systems. **The LOAEL for neurotoxicity was 20 mg/kg based on lack of pupil response (blocked accommodation; cholinergic response) and the NOAEL was 2 mg/kg.**

In a 90-day subchronic feeding study (MRID 00051675 & 00077532), rats were dosed with 0, 2, 8, 32, 400 ppm (0, 0.1, 0.4, 1.6, 20 mg/kg/bw) of dimethoate in the diet for 13 weeks. Plasma and red blood cell (RBC) ChE measurements were made at pre-exposure and weeks 1, 2, 6, 10, and 13 of exposure. At sacrifice brain cholinesterase was also measured. Plasma, RBC, and brain ChE levels did not differ significantly from controls at any time period. **Thus for the one week time period, the NOAEL is 32 ppm (1.6 mg/kg/d).** This study also included an additional segment where rats were dosed at 50 ppm (2.5 mg/kg/d) for four weeks, sacrificed and plasma, RBC and brain ChE measurements were taken. At the four week time period all three compartments were depressed from controls (plasma 80%, RBC 56% and brain 36% for males).

In a 90-day subchronic neurotoxicity study (MRID 43128201), rats were dosed at 0, 1, 50, 125 ppm (0, 0.06, 3.2, 8 mg/kg/bw) in the diet for 13 weeks. Plasma and RBC ChE measurements were made at pre-exposure, and weeks 3, 7, and 13 of exposure. At sacrifice brain ChE was also measured. **At the three week time point (earliest measurement) the NOAEL for ChEI was 50 ppm (3.2 mg/kg/d) based on statistically significant plasma ChEI at 125 ppm (8 mg/kg/d).** At 50 ppm (3.2 mg/kg/d) the plasma ChE measurement was minimally

depressed (19%), not statistically significant and there was no inhibition of RBC ChE. Given the fact that in the previously described study, the LOAEL for plasma, RBC, and brain ChEI at four weeks was 50 ppm (2.5 mg/kg/bw), the time dependency of this dose level vis-a-vis an effect level appears to be between three and four weeks for repeated dose studies.

These two studies, taken together, lend support to the choice of the acute neurotoxicity study for the acute dietary endpoint. Although there were no ChE measurements in the acute study, the levels at which no observable adverse effects were seen, 1.6 mg/kg and 3.2 mg/kg, occurred in the two subchronic studies at weeks 1 and 3, respectively,

The dose and endpoint for establishing the acute RfD is the NOAEL = 2 mg/kg based on the lack of pupil response (in the acute neurotoxicity study) and the NOAEL of 1.6 mg/kg and the 3.2 mg/kg in the 90-day feeding and the 90-day neurotoxicity study, respectively.

$$\textbf{Acute RfD} = \frac{\textbf{2.0 mg/kg}}{\textbf{100 (UF)}} = \textbf{0.02 mg/kg}$$

* UF 100 = 10x for inter-species extrapolation and 10x for intra-species variation

The acute neurotoxicity study is appropriate for use in establishing the acute dietary RfD since the effects are a result of a single exposure to dimethoate. Although cholinesterase activities were not measured in this study, the endpoint selected (absent pupillary response) is indicative of cholinergic toxicity. This endpoint is supported by two subchronic studies (discussed above), both of which had interim ChE measurements. The NOAEL of 2 mg/kg established in the acute neurotoxicity study is supported by the NOAELs established in the 90 day studies: In the 1959 study, the NOAEL was 32 ppm (1.6 mg/kg) for lack of ChEI at the 1-week measurement and in the 1994 neurotoxicity study, the NOAEL was also 50 ppm (3.2 mg/kg) for lack of ChEI at the 3-week measurement. Thus, the lack of ChEI in these studies increases confidence that the use of the NOAEL of 2 mg/kg reported in the acute study will not underestimate the toxicity of dimethoate in acute dietary assessments. It was presumed that ChEI would not have occurred at the 2 mg/kg (NOAEL) dose in this study since no ChEI was seen after repeated dosing (i.e., at 1 week and also at 3-weeks) in the subchronic studies.

2. Chronic Dietary

In a chronic/carcinogenicity feeding study (MRID 00265610), Wistar rats (65/sex/group) were fed diets containing 0, 5, 25 or 100 ppm dimethoate (equivalent to 0, 0.25, 1.25 or 5 mg/kg/d) for 2 years. An additional 20 animals/sex were given 1 ppm (0.05 mg/kg/d) in order to determine a NOAEL for ChEI. For systemic toxicity, the NOAEL was 1.25 mg/kg/d and the LOAEL was 5 mg/kg/d based on increased mortality (females), decreased body weight gain (males), anemia (males) and increased leukocytes (males and females). For ChEI, the NOAEL was 0.05 mg/kg/d and the LOAEL was 0.25 mg/kg/d based on RBC and brain inhibition.

The dose and endpoint for establishing the RfD is a NOAEL = 0.05 mg/kg based on RBC and brain ChEI at 0.25 mg/kg (LOAEL).

$$\textbf{Chronic RfD -} \quad \frac{\textbf{0.05 mg/kg}}{\textbf{100 (UF)}} \quad \textbf{= 0.0005 mg/kg}$$

3. Occupational Endpoints

i) Dermal absorption

Dermal absorption of dimethoate was 7.6-8.2%, 7.9-8.5%, and 9-11% of the administered dose from rats 1, 2, and 5 days after dermal treatment at 10 mg/kg, respectively. At 100 mg/kg, dermal absorption was 1-2% of the dose from rats 1, 2, and 5 days after dermal treatment. In terms of weight equivalent of dimethoate absorbed, dermal absorption was approximately 1 mg/kg at each dose level (MRID No. 43964001). Dermal absorption was not measured 8 or 10 hours post treatment. Therefore, the Committee **recommended the use of the highest percent dermal absorption value (11%)** measured 5 days after treatment at the low dose.

A dermal absorption factor is required ONLY for the Intermediate-Term risk assessment. A dermal absorption factor is NOT required for Short-Term risk assessment since a dermal NOAEL was selected for this exposure period.

ii) Short-term dermal exposure (1-7 days)

In a 5-day dermal toxicity study (MRID 44818902), dimethoate 4E (43.5% a.i.) was administered topically to the clipped dorsal region (intact skin) of Sprague Dawley [Crl:CD VAF/Plus] rats (16/sex/dose). Animals received daily dose of 0, 5, 10, 20, 40, or 100 mg a.i./kg/day) for 6 hours per day for 5 days. Plasma, RBC, and brain (cortex, hippocampus, and striatum) ChE determinations were performed on days 3 and 5 (at termination). None of the animals died during the study. Treatment and dose related effects on dermal reactions (desquamation) were found in males only. Other treatment related clinical signs of toxicity observed were ptosis (males) and excessive lacrimation (females). Tremors, shallow breathing, pale eyes, and exophthalmus were observed in the highest dose females (100 mg/kg/d) only. No treatment related effects on FOB measurements were noted during the study. In males, there was a statistically significant reduction ($p < 0.05$ or 0.01) in red blood cell (33-50% inhibition relative to controls), hippocampus (31%), striatum (22-23%) and cortex (20-30%) ChE activity in the100 mg/kg/d group (days 3 or 5). In females treated at 20 mg/kg/d (days 3 or 5), there was a statistically significant reduction ($p < 0.05$ or 0.01) in plasma (33%), RBC (35%), and cortex (21%) ChE activity. In females treated at 40 or 100 mg/kg/d (days 3 or 5), there was a statistically significant reduction ($p < 0.05$ or 0.01) in plasma (33-50%), RBC (50-75%), hippocampus (38-48%), striatum (40-46%) and cortex (21-51%) ChE activity.

The LOAEL for ChEI was 100 mg a.i./kg/day for males and 20 mg a.i./kg/day for females

based on statistically significant inhibition of RBC ChE and brain ChE activity. The NOAEL was 40 mg/kg/d for males and 10 mg/kg/d for females. **The dose and endpoint selected is NOAEL = 10 mg/kg based on statistically significant inhibition of plasma, RBC and brain ChE activity in female rats at 20 mg/kg (LOAEL).**

The dose, endpoint and study are appropriate for the route (dermal) and exposure period (1-7 days) of concern. Although a 21-day dermal toxicity study in rabbits (MRID 00159759) is available in the data base, it was not used because the rabbits are not the appropriate species since they may under estimate the toxicity of this class of chemicals (organophosphates) and also the vehicle used (i.e, paraffin) was not appropriate (TES Document 013180).

iii) Intermediate-term dermal exposure (7 days to several months)

In a 90-day subchronic feeding study (MRID 00051675 & 00077532), rats were dosed with 0, 2, 8, 32, or 400 ppm (0, 0.1, 0.4, 1.6, 20 mg/kg/bw) of dimethoate in the diet for 13 weeks. Plasma and RBC ChE measurements (titrimetric method) were made at pre-exposure and weeks 1, 2, 6, 10, and 13 of exposure. At sacrifice brain ChE was also measured. Plasma, RBC, and brain ChE levels did not differ significantly from controls at any time period. This study also included an additional group where rats were dosed at 50 ppm (2.5 mg/kg/bw) for four weeks, sacrificed and plasma, RBC and brain ChE measurements were taken. At the four week time period all three compartments were depressed from controls (plasma 80%, RBC 56% and brain 36% for males).

In a 90-day subchronic neurotoxicity study (MRID 43128201), Sprague-Dawley rats (10/sex/dose) received dietary administration of dimethoate (99.1%) at dosed at 0, 1, 50, or 125 ppm (0, 0.06, 3.22 or 8.13 mg/kg/d in males and 0, 0.08, 3.78 or 9.88 mg/kg/d in females, respectively) in the diet for 13 weeks. Plasma and RBC ChE measurements were made at pre-exposure, and weeks 3, 7, and 13 of exposure. At sacrifice brain ChE was also measured. At 50 ppm (3.22 mg/kg/d) at the three week measurement plasma ChE was minimally depressed (19%), not statistically significant and there was no inhibition of RBC ChE. At the 7-week measurement statistically significant inhibition of plasma (25%) and RBC (48%) in males and RBC (35%) in females were observed.

The dose and endpoint selected is LOAEL = 50 ppm (3.2 mg/kg/d) based on the ChEI seen at 4 weeks in the 1959 study and at 7 weeks in the 1994 study at this dose (i.e., combined results of the two studies). The oral LOAEL was selected for this exposure scenario for the following reasons: 1) a 21-day dermal toxicity study is not available in the database; 2) the 5-day dermal toxicity study used for the Short-Term exposure is not adequate since the treatment period (5 days) will underestimate the risk for the exposure period of concern (up to but no more than 30 days); 3) based on the results of the two subchronic studies, the true NOAEL lies somewhere between 32 ppm at the 1 week measurement, when no ChEI was observed, and 50 ppm at the 3 week measurement, when minimal, not statistically significant ChEI was observed; 4) the higher confidence in the LOAEL of 50 ppm (3.2 mg/kg/d) from the 1994 study at 4 weeks; and 5) the

concern for the occurrence of statistically significant ChEI at approximately 3-4 weeks which is the exposure period of concern (exposure up to 30 days).

Since a LOAEL is used, a **MOE of 300** is required for this exposure scenario. Since an oral value was selected, the 11% dermal absorption factor should be used for risk assessment. In the document *Comments on EPA's Dimethoate Draft RED Chapters* (August 20, 1998), Cheminova has indicated that it has conducted a 28-Day dermal toxicity rat study which measures ChE activity (Submission date of the completed study TBD).

iv) Long-term dermal exposure (several months to lifetime)

The current use pattern does not indicate the potential for long term dermal exposure.

v) Inhalation exposure (short- and intermediate-term)

At the July 8, 1999 meeting, the HIARC recommended the use of the oral NOAEL of 2.0 mg/kg for short-term and the oral LOAEL of 3.2 mg/kg/d for the intermediate-term inhalation exposure risk assessments. Since an oral dose is used, risk assessment followed a route-to route extrapolation. The inhalation exposure component (i.e. µg a.i /day), using 100% absorption rate (default value), and application rate were converted to an **equivalent oral dose** (mg/kg/d). The equivalent oral dose was then compared to the oral values shown below to calculate the MOE's.

Short-term:	NOAEL 2 mg/kg/d	Acute Neurotoxicity-Rat
Intermediate-term	LOAEL 3.2 mg/kg/d	90-Day Neurotoxicity-Rat

TABLE 3

DIMETHOATE ENDPOINTS				
Exposure Duration	**Exposure Route**	**Endpoint**		**Comments**
		Dose	**Effect**	
Acute - PAD	Dietary	aPAD = 0.02 mg/kg/d	Lack of pupil response and lack of cholinesterase inhibition (ChEI) at 1 & 3 week measurements	NOAEL = 2.0 mg/kg. Based on absence of pupillary response (LOAEL=20 mg/kg), which is indicative of ChEI, in rat acute neurotox study. Supported by NOAEL =1.6 mg/kg/d at 1 week in rat 90-d feeding study. No ChEI until 4 wks at 2.5 mg/kg/d. Also by NOAEL=3.2 mg/kg/d for lack of ChEI at 3 wks in 90-d rat neurotox study. LOAEL=8 mg/kg/d. Uncertainty factor (UF) of 100 applied for intra & inter species differences. FQPA factor not retained.
Chronic - PAD	Dietary	cPAD = 0.0005 mg/kg/d	ChEI of brain & RBC	NOAEL = 0.05 mg/kg/d. LOAEL of 0.25 mg/kg/d for brain and RBC ChEI in both sexes. 2-Yr chronic feeding study in rats. UF of 100 applied for intra & inter species differences. FQPA factor not retained.
Short-term (1-7 days) Occupational	Dermal	Dermal NOAEL = 10 mg/kg/d	ChEI of plasma, RBC & brain	NOAEL=10 mg/kg/d. LOAEL=20 mg/kg/d for ChEI of plasma, RBC, & brain in 5-day rat dermal study. UF of 100 applied for intra & inter species differences.
Intermediate-term (7 - 180 days) Occupational	Dermal	Oral LOAEL = 3.2 mg/kg/d	ChEI of plasma, RBC, & brain	LOAEL = 3.2 mg/kg/d based on the ChEI of plasma, RBC, & brain seen at 4 weeks (50 ppm) in 90-d rat feeding study and at 7 weeks (50 ppm) in 90-d rat neurotox study at this dose (i.e., combined results of the two studies). The dermal absorption factor of 11% was used in assessing the risks since this endpoint is derived from an oral study. UF of 300 applied for intra & inter species differences, & use of a LOAEL.
Short-term Occupational	Inhalation	Oral NOAEL = 2.0 mg/kg/d	Lack of pupil response and inhibition of plasma ChEI	Same NOAEL used for aPAD. 100% absorption is assumed. UF of 100 applied for intra & inter species differences.
Intermediate-term Occupational	Inhalation	Oral LOAEL = 3.2 mg/kg/d	ChEI of plasma, RBC, & brain	Same LOAEL as intermediate-term dermal. 100% absorption would be assumed. UF of 300 applied for intra & inter species differences, & use of LOAEL.

C. Classification of Carcinogenic Potential

The Cancer Peer Review Committee has classified dimethoate as a **Group C** carcinogen (possible human carcinogen);based on equivocal hemolymphoreticular tumors in male B6C3F1 mice, the compound-related (no dose response) weak effect of combined spleen (hemangioma and hemangiosarcoma), skin (hemangiosarcoma), and lymph (angioma and angiosarcoma) tumors in male Wistar rats, and positive mutagenic activity associated with dimethoate (CPRC Document

dated 8/29/91).

D. FQPA Considerations

The HIARC and the FQPA Safety Factor Committee determined that for dimethoate, the 10X factor, used to account for enhanced sensitivity of infants and children (as required by the Food Quality Protection Act), should be removed. This conclusion was based on the developmental and reproductive toxicity studies in the toxicology database for dimethoate in which there does not appear to be any special sensitivity for pre- or post-natal effects. In addition, the HIARC determined that, based on a weight-of-the-evidence review of the available data, a developmental neurotoxicity study with dimethoate in rats is not required at this time.

1. Neurotoxicity

In an acute delayed neurotoxicity study, no delayed neurotoxicity was seen in hens given a single oral dose (via gelatin capsule) of dimethoate at 50 mg/kg (MRID No. 42884401) The Committee noted that this study did not assess for the potential of dimethoate to inhibit neurotoxic esterase (NTE) in hens.

The acute neurotoxicity study is described in Section II. A. Acute Dietary. No treatment-related neuropathological effects were observed. The NOAEL was 2 mg/kg based on a absence of pupil response at 20 mg/kg (MRID No. 42865102).

In the subchronic neurotoxicity study, male and female Sprague-Dawley rats received diets containing dimethoate (99.1% a.i.) in the diet at doses of 1, 50, and 125 ppm (0.06, 3.22 and 8.13 mg/kg/d for males and 0.08, 3.78, and 9.88 mg/kg/d for females, respectively) for 13 weeks. Dimethoate treatment did not result in differences between the control and treated animals in the functional observational battery or in the locomotor activity evaluations. The NOAEL was 1 ppm and the LOAEL was 50 ppm based on reduction of in plasma (24-48%) and red blood cell (RBC) (34-60%) ChE activity at mid and high dose levels and brain ChE activity (12-20%) at the high dose level. The reductions in olfactory and cortex ChE activity in the high dose males were 12-18% (MRID No. 43128201).

2. Developmental Toxicity

The developmental toxicity studies in rats and rabbits showed no evidence of additional sensitivity to young rats or rabbits following pre- or postnatal exposure to dimethoate and comparable NOAELs were established for adults and offspring.

In a developmental toxicity study pregnant Crl:COBS-CD(SD) rats received oral doses of dimethoate (97.3%) at doses of 0, 3, 6 or 8 mg/kg/d during gestation days 6 through 15. For maternal toxicity, the NOAEL was 6 mg/kg/d and the LOAEL was 18 mg/kg/d based on body weight decrement. For developmental toxicity, the NOAEL was 18 mg/kg/d (HDT); a LOAEL

was not established. There was no evidence of developmental toxicity (MRID No. 00141142, 00150130).

In a developmental toxicity study, pregnant New Zealand White rabbits were given single oral dose of dimethoate (97.3%) at 0, 10, 20, or 40 mg/kg/d during gestation days 7 through 19. For maternal toxicity, the NOAEL was 10 mg/kg/d and the LOAEL was 20 mg/kg/d based on decreased body weigh gain. For developmental toxicity, the NOAEL was 20 mg/kg/d and the LOAEL was 40 mg/kg/d based on decreased fetal body weight. There was no evidence of developmental toxicity (MRID No.00149126).

3. Reproductive Toxicity

In a two-generation reproduction study, Crl:CD BR rats were fed diets containing dimethoate (96.4%) at 0, 1, 15 or 65 ppm (0, 0.08, 1.2 or 5.46 mg/kg/d in males and 0.09, 1.3 or 6.04 mg/kg/d in females). There was no increased sensitivity to pups over the adults. For parental/systemic toxicity, the NOAEL was 0.08 mg/kg/d and the LOAEL was 1.2 mg/kg/d based on cholinesterase inhibition in both sexes in all generation. For reproductive toxicity, the NOAEL was 1.29 mg/kg/d) and the LOAEL was 5.46 mg/kg/d based on decreases in the number of live pups, pup body weights, and fertility in the F1a, F1b, F2a and F2b matings (MRID No. 42251501).

4. Determination of Susceptibility

Prenatal developmental toxicity studies in rats and rabbits provided no indication of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to dimethoate. There was no indication of increased susceptibility in the offspring as compared to parental animals in the 2-generation reproduction study.

5. Determination of Need for Developmental Neurotoxicity Study

There are sufficient data available to adequately assess the potential for toxicity to young animals following pre-and/or post-natal exposure to dimethoate. These include acceptable developmental toxicity studies in rats and rabbits, as well as, a 2-generation reproduction study in rats. In addition, no treatment-related neuropathology was seen after acute and subchronic exposure to rats. Additionally, there was no evidence of abnormalities to the fetus to the fetal nervous system in the pre- and post-natal studies. Based on the weight-of-evidence, the HIARC determined that a developmental neurotoxicity study in rats is not required for dimethoate. However, based on a recent change in Agency policy that will require developmental neurotoxicity studies on all neurotoxic pesticides (Data call-in FR42945, August 6, 1999), case-by-case consideration will determine how this change will affect dimethoate data requirements.

Exposure Characterization

A. Dietary Exposure

1. Food Exposure

Adequate plant and animal metabolism data are available except that additional characterization/identification of radioactive residues in milk is needed for confirmatory purposes. Adequate methods are available for data collection and tolerance enforcement. Radiovalidation data from the livestock metabolism studies remain outstanding and are considered confirmatory. Adequate magnitude of residue data are available for commodities used for human consumption except the processed commodities of apples and safflower. Meat, milk, poultry, and egg storage stability data and test sample storage interval/condition information to support available animal magnitude of the residue data remain outstanding and are considered confirmatory. [Note: Metabolism data concerning the characterization/identification of radioactive residues in milk, and radiovalidation data from the livestock metabolism studies, have been submitted and are under review. A safflower processing study has also been submitted and is under review.]

i) Directions for use

The Agency has determined that the following food/feed uses for dimethoate are subject to reregistration: alfalfa (grown for hay, forage, and seed), apples, asparagus, beans, broccoli, Brussels sprouts, cabbage, cauliflower, celery, cherries, grapefruit, lemons, oranges, tangerines, collards, corn (field and pop), cotton, endive (escarole), grapes, grass grown for seed, kale, lentils, lettuce (head and leaf), melons (including watermelon), mustard greens, pears, peas, pecans, peppers, potatoes, safflower, grain sorghum, soybeans, spinach, Swiss chard, tomatoes, turnips, and wheat. The use of dimethoate in animal premise treatments in the form of 1% or 2% sprays is also subject to reregistration. An import tolerance on blueberries exists.

A summary of the food/feed use patterns (except blueberries and animal premise treatments) subject to reregistration for dimethoate is provided in the table below. The conclusions listed in Appendix A regarding the reregistration eligibility of dimethoate food/feed uses are predicated on these use patterns. When end-use product DCIs are developed (e.g., at issuance of the RED), the Registration Division (RD) should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the food/feed use patterns specified in the table below.

The Agency notes that Cheminova Agro A/S has submitted the majority of the residue chemistry data in support of the reregistration of dimethoate and that the food/feed use patterns that they will support, according to a letter to the Agency dated 5/21/97, are consistent with the food/feed use patterns considered by the Agency (see table below) with the exceptions of cherries and citrus fruits (grapefruit, lemons, oranges, and tangerines). The Agency understands that Cheminova Agro A/S will not support the following uses of dimethoate: (i) alfalfa grown for seed,

(ii) asparagus, (iii) cowpeas, (iv) Brussels sprouts, (v) grass grown for seed, and (vi) the use of dimethoate as an animal premise treatment. The Agency also understands that Cheminova Agro A/S will not support the currently established import tolerance for dimethoate residues of concern in/on blueberries, the SLN registration for the use of dimethoate on pop corn in Texas (TX93002100), and the SLN registration for the use of dimethoate on pecans in Georgia (GA82000100).

TABLE 4
FOOD/FEED USE PATTERNS SUBJECT TO REREGISTRATION

[Note: Although an import tolerance for dimethoate residues of concern in/on blueberries exits, use information on blueberries is not included in the table below. Use information on dimethoate as 1% or 2% premise treatment sprays is also not included]

Crop Group *Application Site* Application Type Application Equipment	Maximum Single Application Rate	Maximum Number of Applications	Minimum Retreatment Interval	Minimum Pre-harvest Interval
Brassica Leafy Vegetables				
Broccoli Broadcast application Ground and aerial equipment	0.5 lb ai/A	6	7-days	7-days
Cabbage Broadcast application Ground and aerial equipment	0.5 lb ai/A	3	7-days	7-days
Cauliflower Broadcast application Ground and aerial equipment	0.5 lb ai/A	6	7-days	7-days
Collards Broadcast application Ground and aerial equipment	0.26 lb ai/A	4	7-days	14-days
Kale Broadcast application Ground and aerial equipment	0.26 lb ai/A	2	15-days	14-days
Mustard Greens Broadcast application Ground and aerial equipment	0.26 lb ai/A	2	9-days	14-days
Brussels Sprouts [1] Broadcast application Ground and aerial equipment	1 lb ai/A	6	--	10-days
Cereal Grains				

Crop Group *Application Site* Application Type Application Equipment	Maximum Single Application Rate	Maximum Number of Applications	Minimum Retreatment Interval	Minimum Pre-harvest Interval
Field corn Broadcast application Ground and aerial equipment	0.5 lb ai/A	3	7-days	A 28-day PHI for grain and a 14-day PHI for forage.
Pop Corn [2] Broadcast application Ground and aerial equipment	0.5 lb ai/A [TX93002100]	3	--	14-days
Grain Sorghum Broadcast application Ground and aerial equipment	0.5 lb ai/A	3	7-days	28-days
Wheat Broadcast application Ground and aerial equipment	0.67 lb ai/A	2	5-days	60-days
Citrus Fruits [3]				
Grapefruit Broadcast application Ground and aerial equipment	2 lb ai/A	2	--	15-days
Lemons Broadcast application Ground and aerial equipment	2 lb ai/A	2	--	15-days
Oranges Broadcast application Ground and aerial equipment	2 lb ai/A	2	--	15-days
Tangerines Broadcast application Ground and aerial equipment	2 lb ai/A	2	--	15-days
Cucurbits				
Melons Broadcast application Ground and aerial equipment	0.5 lb ai/A	2	7-days	3-days
Watermelons Broadcast application Ground and aerial equipment	0.5 lb ai/A	2	7-days	3-days
Fruiting Vegetables				

Crop Group *Application Site* Application Type Application Equipment	Maximum Single Application Rate	Maximum Number of Applications	Minimum Retreatment Interval	Minimum Pre-harvest Interval
Peppers Broadcast application Ground and aerial equipment	0.33 lb ai/A	1	n/a	0-days
Tomatoes Broadcast application Ground and aerial equipment	0.5 lb ai/A	2	6-days	7-days
Legumes				
Peas Broadcast application Ground and aerial equipment	0.17 lb ai/A	1	n/a	0-day
Beans Broadcast application Ground and aerial equipment	0.5 lb ai/A	2	7-days	0-day
Lentils Broadcast application Ground and aerial equipment	0.5 lb ai/A	2	7-days	0-day
Soybeans Broadcast application Ground and aerial equipment	0.5 lb ai/A	2	7-days	21-days
Leafy Vegetables				
Head lettuce Broadcast application Ground and aerial equipment	0.26 lb ai/A	3	5-days	7-days
Leaf lettuce Broadcast application Ground and aerial equipment	0.26 lb ai/A	4	5-days	14-days
Endive (escarole) Broadcast application Ground and aerial equipment	0.26 lb ai/A	3	5-days	14-days
Spinach Broadcast application Ground and aerial equipment	0.26 lb ai/A	2	10-days	14-days

Crop Group *Application Site* Application Type Application Equipment	Maximum Single Application Rate	Maximum Number of Applications	Minimum Retreatment Interval	Minimum Pre-harvest Interval
Swiss Chard Broadcast application Ground and aerial equipment	0.26 lb ai/A	3	5-days	14-days
Celery Broadcast application Ground and aerial equipment	0.5 lb ai/A	6	7-days	7-days
Non-Grass Animal Feeds				
Alfalfa Broadcast application Ground and aerial equipment	0.5 lb ai/A	1	n/a	10-days
Alfalfa grown for seed [1] Broadcast application Ground and aerial equipment	0.5 lb ai/A	1	n/a	10-days
Pome Fruits				
Apples Broadcast application Ground and aerial equipment	0.5 lb ai/A	3	7-days	35-days
Pears Broadcast application Ground and aerial equipment	0.5 lb ai/A	3	7-days	28-days
Roots and Tubers				
Potatoes Broadcast application Ground and aerial equipment	0.5 lb ai/A	2	7-days	0-days
Turnips [4] Broadcast application Ground and aerial equipment	0.26 lb ai/A	3	7-days	14-days
Other Crops				
Asparagus [1] Post harvest application Ground and aerial equipment	0.5 lb ai/A	5	7-days	180-days
Cherries [5] Broadcast application Ground and aerial equipment	2 lb ai/A	1	n/a	21-days

Crop Group *Application Site* Application Type Application Equipment	Maximum Single Application Rate	Maximum Number of Applications	Minimum Retreatment Interval	Minimum Pre-harvest Interval
Cotton Broadcast application Ground and aerial equipment	0.5 lb ai/A	2	14-days	14-days
Grapes Broadcast application Ground and aerial equipment	2 lb ai/A	1	n/a	28-days
Grass grown for seed [1,6] Broadcast application Ground and aerial equipment	0.5 lb ai/A	3	28-days	21-days
Pecans Broadcast application Ground and aerial equipment	0.34 lb ai/A	1	n/a	21-days
	0.66 lb ai/A [GA82000100] [7]	2	--	21-days
Safflower Broadcast application Ground and aerial equipment	0.5 lb ai/A	2	14-days	14-days

1.According to a letter to the Agency dated 5/21/97, Cheminova Agro A/S is not supporting the use of dimethoate on this crop under reregistration.

2.Based on the Special Local Needs (SLN) registration that exists for the use of dimethoate on pop corn in Texas (TX93002100).

3.Cheminova Agro A/S has indicated that they wish to support a lower single application rate for dimethoate on grapefruit, lemons, oranges, and tangerines (0.5 lb ai/A); however, no data are available which adequately depict residues likely to remain in/on grapefruit, lemons, oranges, and tangerines resulting from the use of dimethoate at the lower single application rate.

4.This use is supported by Cheminova and IR-4 at the same use rate.

5.Numerous SLN registrations exist for the use of dimethoate on cherries at the maximum use rate indicated. Cheminova Agro A/S has indicated that they wish to support a lower single application rate (0.33 lb ai/A); however, no data are available which adequately depict residues likely to remain in/on cherries resulting from the use of dimethoate at the lower single application rate.

6.This use is supported by IR-4.

7.Based on the SLN registration that exists for the use of dimethoate on pecans in Georgia (GA82000100). According to a letter to the Agency dated 5/21/97, Cheminova Agro A/S is not supporting this SLN registration.
The Agency has determined that available field trial data are adequate to support this SLN registration (memo by E.

Zager dated 1/5/82).

ii) Plant metabolism

The qualitative nature of the residue in plants is adequately understood. Dimethoate is readily taken up and translocated by plants, and is metabolized by hydrolytic and oxidative processes. The residues to be regulated in plants are dimethoate and its oxygen analog, omethoate. The current tolerance expression for plant commodities is adequate.

iii) Animal metabolism

The qualitative nature of dimethoate residue in eggs, poultry tissues and ruminant tissue is adequately understood. However, the nature of the residue in milk remains inadequately understood. Additional characterization and identification of radioactive residues in milk samples collected from the submitted ruminant metabolism study is required for confirmatory purposes. [Note: These data have been submitted and are under review.] The available animal metabolism data indicate that metabolism occurs via conversion of dimethoate to omethoate, followed by cleavage of the P-S bond resulting in phosphorylation of natural products. The established tolerances for dimethoate residues in animal commodities are currently expressed in terms of the total residues of dimethoate and its oxygen analog, omethoate. The adequacy of the current tolerance expression for animal commodities will be reevaluated once the requested milk data are reviewed.

iv) Residue analytical method - plants and animals

Adequate methods are available for data collection and tolerance enforcement. The Pesticide Analytical Manual (PAM) Vol. II lists three GLC methods (Methods A, B, and C) using flame photometric detection, and a colorimetric procedure (Method D) for analysis of residues of dimethoate and its oxygen analog in/on plant and animal commodities. A second colorimetric procedure (Method E) is listed for the determination of residues of dimethoate *per se*. The limits of detection for the GLC methods vary from 0.001 ppm for residues in milk to 0.05 ppm for residues in forage and straw. A TLC method is also listed (Method I) for determination of residues of dimethoate and its oxygen analog in/on plant commodities.

Radiovalidation data from the livestock metabolism studies remain outstanding and are considered confirmatory. [Note: These data have been submitted and are under review.]

The 1/94 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that residues of dimethoate and omethoate are completely recovered (>80%) by Multiresidue Method Section 302 (Luke Method; Protocol D) but are not recovered by Multiresidue Method Sections 303 (Mills, Onley, Gaither Method; Protocol E, nonfatty) and 304 (Mills fatty food method; Protocol E, fatty).

v) Storage stability

Raw Agricultural Commodities

Storage stability data have been submitted for cottonseed (representative of oilseeds), oranges (representative of fruits and fruiting vegetables), potatoes (representative of root crops), sorghum grain (representative of non-oily grains), and sorghum forage (representative of leafy vegetables) indicating that fortified residues of dimethoate and its oxygen analog, omethoate in/on these commodities are reasonably stable under frozen storage conditions for ~27 months. Additional storage stability data indicate that residues of dimethoate *per se* are stable during frozen storage for up to 12 months in/on lettuce and for up to 6 months in/on apples.

No additional dimethoate storage stability data are required to support available dimethoate field trial and processing data.

Processed Commodities

No dimethoate storage stability data have been submitted indicating the stability of dimethoate residues of concern in processed commodities. However, storage stability data for processed commodities are not required to support available citrus, field corn, cottonseed, grape, potato, tomato and wheat processing studies based on the relative stability of Dimethoate residues of concern demonstrated by available raw agricultural commodity (RAC) storage stability data and in consideration of the relatively short frozen storage intervals of test samples from these processing studies. (Note: Soybean field trial data were used to satisfy soybean processing data requirements.)

New apple and safflower processing studies are required. When these new studies are conducted, they should include supporting concurrent storage stability data.

Animal Commodities

No dimethoate storage stability data have been submitted indicating the stability of dimethoate residues of concern in meat, milk, poultry, and eggs. These data remain outstanding and are considered confirmatory.

Test sample storage intervals/conditions information is required to validate existing livestock magnitude of the residue data. This information is not currently available for the livestock magnitude of the residue data submitted for dimethoate tolerance reassessments. This information is vital to conducting dimethoate tolerance reassessments. In addition, since meat, milk, poultry, and eggs exposure estimates are based on magnitude of the residue data, test sample storage information from these studies would dramatically increase our confidence with respect to exposure estimates for these commodities. This information remains outstanding and is considered confirmatory. The registrant has provided some test sample information to support poultry magnitude of the residue data (MRID 44382501), which are under review.

vi) Magnitude of the residue - potable water, irrigated crops, fish

Dimethoate is not registered for direct use on potable water or aquatic food and feed crops. Therefore, no residue chemistry data are required under these guidelines.

vii) Magnitude of the residue - food handling

Dimethoate is not registered for food contact use inside food-handling establishments. Therefore, no residue chemistry data are required under this guideline.

viii) Magnitude of the residue - meat, milk, poultry & eggs

The reregistration requirements for magnitude of the residue in meat, milk, poultry and eggs have been fulfilled except for metabolism data which were outstanding on milk. These data have recently been submitted and when the review is completed the available magnitude of the residue data for milk will be reevaluated and tolerance revisions may be required.

ix) Magnitude of the residue - crop field trials

The reregistration requirements for the magnitude of the residue in/on plants have been fulfilled for the following raw agricultural commodities (RACs): alfalfa forage; alfalfa hay; apples; asparagus; beans (dried and succulent); blueberries; broccoli; Brussels sprouts; cabbage; cauliflower; celery; cherries; collards; corn (field) stover; corn (pop) stover (translated from field corn data); corn (field) forage; corn (field) grain; corn (pop) grain (translated from field corn data); cottonseed; endive; grapefruit; grapes; kale; lemons; lentils; lettuce (leaf and head); melons; mustard greens; oranges; pears; peas (dried and succulent); pea vines; pea hay; pecans; peppers; potatoes; safflower seed; sorghum forage; sorghum stover; sorghum grain; soybean forage; soybean hay; soybeans; spinach; Swiss chard; tangerines; tomatoes; turnip roots; turnip tops; wheat forage; wheat grain; wheat hay; and wheat straw. The available field trial data for these RACs have been reevaluated for purposes of tolerance reassessment. Overall, acceptable field trials were performed representing the maximum registered use patterns and conditions under which the pesticide could be applied. The geographic representation for each commodity is generally adequate, and a sufficient number of trials reflecting representative formulation classes were conducted. Refer to "Tolerance Reassessment Summary" section for recommendations and adjustments with respect to established tolerance levels.

Dimethoate is no longer registered for use on tobacco. Hence, previously required magnitude of residue data on tobacco are no longer needed.

HED has recommended in favor of a waiver from the requirement to provide data for corn (field), soybeans, sorghum, and wheat aspirated grain dust fractions based on the currently registered uses of dimethoate on these crops and because residues are not expected to concentrate on the surface of RACs as dimethoate is a systemic insecticide.

The reregistration requirements for the magnitude of residue in plants have not been fulfilled for bean forage and bean hay. The deficiencies for the commodities of beans can be resolved by either label amendments and appropriate tolerance proposals based on available data or the submission of new magnitude of the residue data to support the currently registered use rate.

The reregistration requirements for the magnitude of residue in plants have been fulfilled for pea vines and pea hay. The registrant must either petition the Agency for the establishment of tolerances for the total residues of dimethoate and omethoate in/on pea vines and pea hay or amend product labels to restrict the use of dimethoate to peas (not including field peas).

Magnitude of residue data on alfalfa seed are required to support the use of dimethoate on alfalfa grown for seed.

Magnitude of residue data on grass seed, forage and hay are required to support registrations in Oregon (including SLN OR85004400) for uses of dimethoate on grass grown for seed. Data are required depicting residues in/on grass forage and hay regrowth after seed harvest reflecting the maximum use rate permitted for use of dimethoate on grass grown for seed. [Note: These data have been submitted and are under review.]

As a result of changes in the Livestock Feeds Table (Table 1, July 1996), magnitude of residue data are currently required by the Agency for cotton gin byproducts.

x) Magnitude of the residue - processed food/feed

Acceptable processing studies have been submitted for corn (field), cottonseed, grapes, oranges, potatoes, tomatoes, and wheat. The processing data from these studies do not indicate a need to establish food/feed additive tolerances for the combined residues of dimethoate and omethoate in the processed commodities of corn (field), cottonseed, grapes oranges, potatoes, tomatoes and wheat under 40 CFR 186.2100. The data indicate that the establishment of a tolerance listed under 40 CFR 180.204(a) is required for dried citrus pulp.

The requirement for a soybean processing study was waived based on nondetectable residues in/on the RAC following treatment at 5x.

Data depicting Dimethoate residues of concern in grape juice were not submitted. However, since residues in grape pomace (wet and dry) were approximately equal to residues in grapes and the theoretical concentration factor for grape juice is 1.2x, concentration of residues in grape juice is not expected.

A safflower processing study has been submitted and is under review. A new apple processing study is required for confirmatory purposes.

xi) Reduction of the residues - anticipated residues

No data/information were submitted nor are they required.

xii) Confined/field rotational crops

The reregistration requirements for confined/field rotational crop studies are fulfilled. The available confined rotational crop data indicate that dimethoate residues of concern do not accumulate at levels above 0.01 ppm in rotational crops at 30-day plantback intervals. Limited field rotational crop studies are not required, and plantback restrictions are not required for dimethoate EPs.

2. Drinking Water Exposure

The Agency does not have concerns for dietary exposures from drinking water resulting from all but one use, since the estimates derived from conservative models are below the Agency's level of concern. EFED's screening-level assessments with the GENEEC and SCI-GROW models use the highest labeled application rate for a pesticide to provide high-end estimates in surface and ground water. The high application rates associated with the seed orchard use, do result in potentially high drinking water exposures that exceed the Agency's level of concern. Any application rates of 4 pounds active ingredient per acre or higher result in drinking water levels of concern. The discussion that follows concerns the agricultural uses of dimethoate and not the seed orchard use.

Even with the refinements provided in the PRZMS/EXAMS model, the surface water estimates are still considered screening level and protective. In the case of dimethoate, the model estimates indicated low drinking water exposures for all the crops assessed; broccoli, citrus, corn, and cotton. The modeled (Tier 2) acute surface water concentrations are based on several fruit/vegetable scenarios that range from 7.97 μg/L for corn (application rate of 0.5 lbs ai/A for 3 applications and a 7 day interval to 9.76 μg/L for citrus (application rate 0.5 lbs ai/A for 2 applications and a 15 day interval) to 15.14 μg/L for broccoli (application rate 0.5 lbs ai/A for 6 applications and a 7 day interval) up to 22.83 μg/L for cotton (application rate 0.5 lbs ai/A for 2 applications and a 14 day interval). Limited available monitoring data, which were not available at the time of the initial dietary risk assessment (01/98), indicate water levels below EFED's modeling estimates (2.0 μg/L). HED considers the drinking water risk assessment using the estimates from models protective of any potential exposures to dimethoate from water.

Considering the modeled concentrations, the rate of microbial degradation, and the available monitoring data, the dimethoate parent is not expected to exceed 2.0 μg/L (closer to 1.0 μg/L by EFED's estimates) for any appreciable length of time. **No assessment for the degradates was made by EFED due to lack of data.**

The modeled (Tier 2) chronic surface water concentrations are based on the same fruit/vegetable scenarios, but are a one year mean, and range from 0.598 μg/L for citrus to 0.720 μg/L for corn to 1.042 μg/L for cotton up to 1.263 μg/L for broccoli.

It is uncertain whether exposures from ground water would pose a risk concern without any targeted monitoring studies. The highly conservative modeled ground water concentration of 0.002 μg/L from the acute SCI-GROW model is the estimated concentration for both the acute and chronic ground water drinking water estimates. However, EFED believes it is very unlikely that any ground water exposures would be as high as 0.002 μg/L, based on fate information.

B. Non-dietary Exposure

1. Summary of Use Patterns and Formulations

Dimethoate is an organophosphate insecticide/acaricide/miticide that is used to control a wide variety of target pests including insects and related organisms, mollusks, fouling organisms and miscellaneous invertebrates. Some examples of the pests that dimethoate is intended to control include aphids, citrus thrips, grasshoppers, leafminers, spider mites, and whiteflies. Dimethoate currently has 106 active registrations, 61 of these registrations have been granted under Section 24 of FIFRA. Manufacturing products contain between 95 and 96% active ingredient. Formulated end-use products include: emulsifiable concentrates that range in concentration from 8-57% dimethoate, and several wettable powder products that each contain 25% dimethoate. Historically, several other types of formulated products have contained dimethoate, such as dusts and granulars, and a ready-to-use formulation that contains 30.5% dimethoate. It is the understanding of EPA, however, that none of these other formulation types are being supported in the reregistration process. This summary is based on the *Label Use Information System (LUIS)* report for dimethoate and a review of the dimethoate file (November, 1997) in the *Reference Files System.*

Based on the available information, currently products containing dimethoate are intended for both the residential and occupational markets. However, since the registrants have indicated that they will not support residential use patterns during the reregistration process, no residential exposure and risk assessment is included in this document.

An analysis of the current labeling and available use information was completed (e.g., LUIS). In addition, information was received from one of the main registrants about use patterns likely to be supported for reregistration. The information indicates that dimethoate currently is available in a wettable powder formulation for a variety of uses; however this formulation type will be supported during reregistration for use only on grapes. The information from the registrant also indicates that dimethoate currently is available in a ready-to-use formulation; however this formulation type will not be supported during reregistration.

The information indicates that dimethoate can potentially be used on the following sites and that these sites definitely are being supported during reregistration:

- *Food/Feed/Fiber Crops*: broccoli, Brussels sprouts, cabbage, grass, asparagus, cauliflower, collards, kale, mustard greens, corn, sorghum, wheat, grapefruit, lemons, oranges, tangerines, melons, watermelons, peppers, tomatoes, peas, beans (excluding cowpeas), lentils, soybeans, celery, endive (escarole), head and leaf lettuce, spinach, Swiss chard, alfalfa, pears, apples, potatoes, turnips, grapes, cherries, pecans, cotton, and safflower. *Ornamental Crops:* arborvitae, azalea, birch, boxwood, camellia, carnation, cedar, Christmas trees, citrus trees (non-bearing nursery stock), cypress, daylilies, Douglas fir, Elaeagnus, elm, Euonymous, Ficus nitida, gardenia, gerbera, gladiolus, hemlock, holly (American, English) iris, juniper, oak, pine, pinyon pine, poinsettia, pyracantha, roses, taxus

(yew), viburnum.

The information indicates that dimethoate currently can be potentially used on the following sites; however these uses may not be supported during reregistration:

- *Ornamental Uses:* hackberry, honeysuckle
- *Forestry Uses*
- *Uses on non-crop land adjacent to vineyards:* currently registered only in California
- *Uses in and around Residences or Recreation Areas:* including households/domestic dwellings, pet living and sleeping quarters,
- *Uses in and around Animal/Livestock Quarters*
- *Uses on Meat or Dairy Animals*
- *Uses in Outdoor Commercial/Institutional/Industrial Premises:* including loading docks, and warehouses
- *Uses on Outdoor Refuse or Solid Waste:* including refuse areas, manure piles, and garbage dumps
- *Uses for Sewage Systems*

The information indicates that dimethoate currently can be potentially used with the following equipment; however these uses may not be supported during reregistration:

- *Chemigation*
- *High Pressure Handwand*
- *Sprinkler Can*
- *Ultra Low Volume Aerial*: less than two gallons of finished spray per acre

In addition to reviewing and summarizing the use information available from within the agency (e.g., LUIS and labels), EPA also reviewed the following two documents that document the use patterns for Dimethoate:

- *Dimethoate Use Information:* Authored by Blane Dahl of Jellinek, Schwartz, and Connolly (5/21/97); and
- *Dimethoate Usage Report:* Authored by P. Leanne Pruett (5/30/96).

These documents were essentially found to agree with the information that serves as the basis for the handler exposure/risk assessment presented in this document. Much of the unique information included in these documents was not required for the handler exposure assessment.

2. Handler Exposure

i) Handler exposure scenarios and assumptions

EPA has determined that exposure to pesticide handlers is likely during the use of dimethoate in occupational settings. The anticipated use patterns and current labeling indicate 16 major occupational exposure scenarios based on the types of equipment that potentially can be used to make dimethoate applications. These 16 scenarios serve as the basis for the quantitative exposure/risk assessment developed for handlers in the occupational setting. These include the following:

(1a) mixing/loading liquids for aerial application or chemigation (if retained);
(1b) mixing/loading liquids for groundboom application;
(1c) mixing/loading liquids for airblast sprayer application;
(2a) mixing/loading wettable powders for aerial application or chemigation (if retained);
(2b) mixing/loading wettable powders for groundboom application;
(2c) mixing/loading wettable powders for airblast sprayer application;
(2d) mixing/loading wettable powders for non-cropland adjacent to vineyards (if retained);
(3) applying sprays with aircraft;
(4) applying sprays with helicopter;
(5) applying sprays using a groundboom sprayer;
(6) applying liquids using a paintbrush;
(7) applying sprays using an airblast sprayer;
(8) applying ready-to-use liquids;
(9) applying sprays to non-cropland adjacent to vineyards;
(10) mixing/loading/applying sprays using soil injection;
(11) mixing/loading/applying sprays using a backpack;
(12) mixing/loading/applying sprays using a low pressure hand wand;
(13) mixing/loading/applying sprays using a high pressure hand wand;
(14) mixing/loading/applying sprays using a sprinkler can;
(15) mixing/loading/applying sprays using a soil drench device; and
(16) flagging during aerial application.

The following assumptions and factors were used in order to complete this exposure assessment:

- Average body weight of an adult handler is 70 kg. This body weight is used in the short-term and intermediate-term assessments, since the endpoints of concern are not gender-specific (i.e., the cholinesterase inhibition could be assumed to occur in males or females).

- The number of acres treated or volume of spray solution applied per day are specific to each equipment type addressed in the exposure assessment and are representative of the amount that can be treated/applied in a single 8 hour workday for each exposure scenario.

- Daily areas and volumes (as appropriate) to be treated in each occupational exposure scenario include: 350 acres for aerial and chemigation applications; 80 acres for groundboom applications in an agricultural setting; 40 acres for airblast applications in an agricultural setting; 20 acres for airblast/mistblower applications in conifer seed nurseries; 10 acres for right-of-way applications; 2 gallons for paint-on agents; 1000 gallons for high pressure handwand applications; 40 gallons for backpack sprayers; and 40 gallons for low pressure handwands. No data or volumes were estimated for the ready-to-use product, soil drench method, soil injection method, or sprinkler can method because scenario-specific exposure data are not available and use information describing these techniques in sufficient detail were not available.

- The following are the maximum use rates being supported for reregistration by at least one registrant. (Note: since other registrants, including IR-4 and States may support other crops (i.e., Brussels sprouts), higher use rates, and other formulations and equipment, the risk assessment also contains the current formulations, equipment types, and use rates.)

  -- At 8.3 - 33.2 lb/A emulsifiable concentrate: conifer seed nursery
  -- At 2.0 lb/A wettable powder formulation: grapes
  -- At 1.0 lb/A emulsifiable concentrate formulation: citrus (soil drench)
  -- At 0.67 lb/A emulsifiable concentrate formulation: wheat
  -- At 0.5 lb/A emulsifiable concentrate formulation: broccoli, cabbage, cauliflower, field corn, sorghum, citrus (foliar applications), melons, watermelons, tomatoes, beans (excluding cowpeas), lentils, soybeans, celery, alfalfa, pears, apples, potatoes, cotton, and safflower
  -- At 0.33 lb/A emulsifiable concentrate formulation: peppers, cherries, and pecans
  -- At 0.25 lb/A emulsifiable concentrate formulation: collards, kale, mustard greens, endive (escarole), head lettuce, leaf lettuce, spinach, Swiss chard, and turnips
  -- At 0.16 lb/A emulsifiable concentrate formulation: peas

- Calculations are completed at the maximum application rates for a variety of crops recommended by the available dimethoate labels to bracket risk levels associated with the various use patterns.

- Due to a lack of scenario-specific data, EPA calculates unit exposure values using generic protection factors that are applied to represent various risk mitigation options (i.e., the use of personal protective equipment (PPE) and engineering controls). PPE protection factors include those representing double layers of clothing (50%), chemical-resistant gloves (90%), and respiratory protection (80 to 90% depending upon mitigation selected). Engineering controls are generally assigned a protection factor of 90% or higher.

Engineering controls may include closed mixing/loading systems and enclosed cabs/cockpits.

ii) Handler exposure assessment

The following document, evaluating handler exposures in various ground and aerial application scenarios, was submitted in support of the reregistration of dimethoate:

- *Preliminary Analysis of Human Exposure to Dimethoate:* EPA MRID NR409494-01; Authored by P.R. Datta; Report Issue Date 7/14/78.

This document included calculations that addressed the dermal and inhalation exposure routes for occupational handlers of dimethoate. However, the document did not contain any chemical-specific data generated under FIFRA data requirements/guidelines in support of the reregistration of dimethoate. The *Pesticide Handlers Exposure Database (PHED)* was not utilized as a source for any surrogate data in this registrant-submitted assessment because it was completed prior to the existence of PHED. The authors selected the following two literature references to serve as the basis for this assessment:

- *Exposures to Pesticides in Agriculture, A Survey of Spraymen Using Dimethoate in the Sudan:* Copplestone JF, Fakhri ZI, Miles JW, Mitchell CA, Ostman Y, and Wolfe HR; Bull. World Health 54:217-223, 1976.

- *Parathion Exposures in Agricultural Spray Pilots and Ground Crews:* Gordon M, Cohen B, Richter E, Luria M, and Schoenberg J; Environ. Med. & Physiol. May 8-11, pages 17-19, 1978.

The registrant-submitted assessment addressed a variety of dimethoate exposure scenarios based on uses ranging from typical agricultural crops (e.g., citrus, grapes, corn, pecans, tobacco, apples and cotton) to uses in livestock facilities, veterinary offices, forestry, and in commercial ornamental propagation.

At this time, the registrant submission is unacceptable for incorporation into the handler exposure assessment completed by EPA because the data upon which it is based were not generated in accordance with FIFRA requirements (e.g., *Good Laboratory Practices* and the *Pesticide Assessment Guidelines)*. Additionally, EPA uses PHED as a primary source of surrogate exposure data because the data contained in the system have undergone an extensive quality control/quality assurance review process as has the system itself (i.e., values calculated using PHED can be considered reliable based on the data included in the system).

As no acceptable chemical-specific handler exposure data were submitted in support of the reregistration of dimethoate, an exposure assessment for each use scenario was developed, using surrogate values calculated using the *Pesticide Handlers Exposure Database (V 1.1).* PHED data were used to complete an assessment only for those scenarios where the surrogate data were

deemed appropriate. PHED was designed by a task force consisting of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a generic database containing measured exposure data for workers involved in the handling or application of pesticides in the field (i.e., currently contains data for over 2000 monitored exposure events). The basic assumption underlying the system is that exposure to pesticide handlers can be calculated using the monitored data as exposure is primarily a function of the physical parameters of the handling and application process (e.g., packaging type, application method, and clothing scenario). PHED also contains algorithms that allow the user to complete surrogate task-based exposure assessments beginning with one of the four main data files contained in the system (i.e., mixer/loader, applicator, flagger, and mixer/loader/applicator).

Users can select data from each major PHED file and construct exposure scenarios that are representative of the use of the chemical. However, to add consistency to the risk assessment process, the EPA in conjunction with the PHED task force has evaluated all data within the system and developed a surrogate exposure table that contains a series of standard unit exposure values for various occupational exposure scenarios (*PHED Surrogate Exposure Guide of May, 1997*). These standard unit exposure values are the basis for this assessment. The standard exposure values (i.e., the unit exposure values included in the exposure and risk assessment tables) are based on the "best fit" values calculated by PHED. PHED calculates "best fit" exposure values by assessing the distributions of exposures for each body part included in datasets selected for the assessment (e.g., chest or forearm) and then calculates a composite exposure value representing the entire body. PHED categorizes distributions as normal, lognormal, or in an "other" category. Generally, most data contained in PHED are lognormally distributed or fall into the PHED "other" distribution category. If the distribution is lognormal, the geometric mean for the distribution is used in the calculation of the "best fit" exposure value. If the data are an "other" distribution, the median value of the dataset is used in the calculation of the "best fit" exposure value. As a result, the surrogate unit exposure values that serve as the basis for this assessment generally range from the geometric mean to the median of the selected dataset.

Occupational handler exposure assessments are completed by the EPA using a baseline exposure scenario and, if required, increasing levels of risk mitigation (PPE and engineering controls) to achieve an appropriate margin of exposure or cancer risk. The baseline clothing/PPE ensemble for occupational exposure scenarios is generally an individual wearing long pants, a long-sleeved shirt, no chemical-resistant gloves (there are exceptions pertaining to the use of gloves and these are noted), and no respirator.

The exposure/risk assessment that has been completed for the occupational handler scenarios is presented in Appendices D through F. Occupational handler scenarios were assessed using the short- and intermediate-term endpoints deemed appropriate for dermal exposure. The short-term dermal endpoint is a NOAEL of 10 mg/kg/d based on a 5-day dermal study. No dermal absorption adjustment is required since the endpoint is based on a dermal study. The short-term inhalation endpoint is a NOAEL of 2 mg/kg/d based on an oral acute neurotoxicity and two 90-day oral subchronic studies. Absorption is assumed to be 100 percent. The Uncertainty

Factor for both short-term endpoints is 100; 10X for intraspecies variability and 10X for interspecies extrapolation.

The intermediate-term dermal endpoint is an LOAEL of 3.2 mg/kg/d based on an oral subchronic neurotoxicity study in rats and a subchronic oral study. Dermal absorption is assumed to be 11% for the purposes of risk assessment. The intermediate-term inhalation endpoint is an LOAEL of 3.2 kg/kg/day based on two 90-day oral subchronic rat studies. Absorption is assumed to be 100 percent. The Uncertainty Factor for both intermediate-term endpoints is 300; 10X for intraspecies variability, 10X for interspecies extrapolation and 3X for the use of an LOAEL rather than a NOAEL.

EPA anticipates that occupational dimethoate exposures will only occur in a short-term or intermediate-term pattern. EPA anticipates that occupational exposures will not be long-term or chronic because EPA defines long-term or chronic exposures as use of the chemical more than several months a year and it is anticipated that dimethoate, as with other typical pesticide compounds, will not be used that frequently.

The calculation of baseline total daily dose levels (mg/kg/d) that include dermal and inhalation exposures are presented in Appendix D for all occupational handler exposure scenarios. The total daily dose levels presented in Appendix D were then used to calculate *Margins of Exposure (MOEs)* for baseline attire using the short and intermediate-term toxicological endpoints (Appendix D). In Appendix E, MOEs were calculated, when necessary, using personal protective equipment in addition to baseline attire. In Appendix F, MOEs were calculated, when necessary, using engineering controls. Appendix H summarizes the caveats and parameters specific to the surrogate data used for each exposure scenario and corresponding exposure/risk assessment. These caveats include the source of the data and an assessment of the overall quality of the data. The assessment of data quality is based on the number of observations and the available quality control data. The quality control data are assessed based on a grading criteria established by the PHED task force. Additionally, it should be noted that all calculations were completed based on current EPA policies pertaining to the completion of occupational exposure/risk assessments (e.g., rounding and acceptable data sources).

iii) Calculating dose from dermal and inhalation exposure

The methods used to calculate daily dose (mg/kg/d) resulting from dermal and inhalation exposures to dimethoate handlers are presented below.

Daily dermal dose is calculated using the following formula [Note: The same formula is applied regardless of the risk mitigation level. Only the unit exposure levels vary with different levels of risk mitigation.]:

$$D_{\text{Daily Dermal}} = (UE \times AR \times A \times (DA/100))/(BW)$$

Where:

$D_{daily\ Dermal}$	=	Daily absorbed dose (mg ai/kg/day) resulting from dermal exposure;
UE	=	Unit exposure (mg/lb ai handled) excerpted from PHED surrogate exposure table;
AR	=	Application rate (lb ai/acre) excerpted from available use information/labels, when certain hand devices were used (lb ai/acre) is replaced with (lb ai/gal);
A	=	Acres treated (acres/day) based on the amount that can be applied in a single day based on the application equipment type, when certain hand devices were used, (A/day) is replaced with (gal/day);
DA	=	Dermal absorption factor (%), if appropriate; and
BW	=	Body weight (kg) based on the body weight of an average adult human.

[Note: The product (UE x AR x A) is presented as the interim *Daily Dermal Exposure* (mg/day) value in Appendix D.]

Daily inhalation dose is calculated using the following formula [Note: The same formula is applied regardless of the risk mitigation level. Only the unit exposure levels vary with different levels of risk mitigation.]:

$$D_{Daily\ Inhalation} = (UE \times (1\ mg/1000\ \mu g) \times AR \times A \times (IA/100))/(BW)$$

Where:

$D_{daily\ Inhalation}$	=	Daily absorbed dose (mg ai/kg/day) resulting from inhalation exposure;
UE	=	Unit exposure (mg/lb ai handled) excerpted from PHED surrogate exposure table, calculated using a standard inhalation rate of 29 liters/minute;
AR	=	Application rate (lb ai/acre) excerpted from available use information/labels, when certain hand devices were used (lb ai/acre) is replaced with (lb ai/gal);
A	=	Acres treated (acres/day) based on the amount that can be applied in a single day based on the application equipment type, when certain hand devices were used, (A/day) is replaced with (gal/day);
IA	=	Inhalation absorption (%); and
BW	=	Body weight (kg) based on the body weight of an average adult human.

3. Postapplication Exposures

i) Postapplication exposure scenarios and assumptions

EPA has determined that postapplication exposure is likely following applications of dimethoate to fruit, vegetable, grain, fiber, feed, conifer seed nursery, and ornamental crops as well as other sites during typical postapplication activities such as harvesting, scouting, pruning, and transplanting. The postapplication risk is based on the intermediate-term dermal toxicity endpoint only, since EPA estimates postapplication exposures to workers and crop advisors may exceed 7 days per year. For this risk assessment, the Agency is characterizing risk to (1) postapplication workers by the required duration of the restricted-entry interval (REI), and (2) crops advisors/scouts by the duration of the postapplication period during which personal protective equipment must be used.

Postapplication risks are mitigated for workers using a restricted-entry interval (REI). In general, the REI is established based on the number of days following application that must elapse before the pesticide residues dissipate to a level where estimated worker MOE's equal or exceed 300 while wearing baseline attire (i.e., long-sleeve shirt, long pants, shoes, and socks). Under the Worker Protection Standard for Agricultural Pesticides (WPS) -- 40 CFR Part 170, entry to perform routine hand labor tasks is prohibited during the REI and personal protective equipment can not be considered as a risk reduction measure in establishing the REI. Postapplication risks are mitigated for crop advisors/scouts using entry restrictions, not restricted-entry intervals. Since under the Worker Protection Standard for Agricultural Pesticides -- 40 CFR Part 170, crop advisors/scouts are defined as handlers, the Agency can permit such persons to enter treated areas to perform scouting tasks, provided they are using required personal protective equipment. In general, the entry restriction is established based on the number of days following application that must elapse before the pesticide residues dissipate to a level where estimated scout/crop advisor MOE's equal or exceed 300 while wearing baseline attire (i.e., long-sleeve shirt, long pants, shoes, and socks).

For the purpose of conducting this assessment, indicator crop groups/activities, and assumptions regarding application rates and dermal transfer coefficients for these crop groups were selected that are likely to be representative of postapplication exposures to dimethoate. Transfer coefficients (Tc) are used to relate the DFR values to activity patterns (e.g., harvesting, scouting, irrigating) to estimate potential human exposure. All postapplication activities are assessed in this RED using surrogate transfer coefficient values to estimate potential exposure levels for all crops to determine the number of days following application when target MOEs (i.e., 300) are reached, since no dermal exposure levels were monitored concurrently with the DFR levels in registrant submitted studies. The transfer coefficients used are listed in the policy issued by the Science Advisory Council for Exposure. The results of this assessment are provided in the *Risk from Postapplication Exposure* section below. Since a multitude of crops are treated with dimethoate, it is necessary to assess the exposure potential resulting from a variety of crop types and postapplication activities. These surrogate transfer coefficients are believed to represent a reasonable and reliable estimate of potential postapplication exposures. The following is a

summary of transfer coefficients and use rates by crop used in the postapplication assessment:

0.16 lb ai/A (Medium potential for dermal transfer) Peas: harvest (*hand*), stake/tie, scout, irrigate: With transfer coefficient of 4,000.

0.25 lb ai/A (Low potential for dermal transfer) collards, kale, mustard greens, celery, endive, escarole, head lettuce, leaf lettuce, spinach, Swiss chard, turnips: harvest (*hand*) with transfer coefficient of 2,500; scout, irrigate with transfer coefficient of 1,000.

0.33 lb/A (Medium potential for dermal transfer) peppers: harvest (*hand*), stake/tie, scout, irrigate with transfer coefficient of 4,000.

(Tree Fruit/Nut) cherries, pecans: all activities, e.g., harvest (*hand*), prune, prop, summer shake, rake, pole and pickup (*nuts*) with transfer coefficient of 10,000.

0.5 lb ai/A (Low potential for dermal transfer) broccoli, Brussels sprouts, cabbage, cauliflower, celery, alfalfa, sorghum: harvest (*hand*) with transfer coefficient of 2,500; scout, irrigate with transfer coefficient of 1,000.

(Medium potential for dermal transfer) melons, watermelons, lentils, soybeans: harvest (*hand*), stake/tie, scout, irrigate with transfer coefficient of 4,000.

(High potential for dermal transfer) field corn, tomatoes, beans (excluding cowpeas): harvest (*hand*) with transfer coefficient of 10,000; stake/tie, scout, irrigate with transfer coefficient of 4,000.

(Tree fruit) citrus (foliar applications), pears, apples: all activities, e.g., harvest (*hand*), prune, prop, summer shake, rake, pole and pickup (*nuts*) with transfer coefficient of 10,000.

(Tubers) potatoes: dig/harvest by hand with transfer coefficient of 10,000; sort, pack with transfer coefficient of 2,500.

Cotton, safflower: early season scouting with transfer coefficient of 1,000; late season scouting with transfer coefficient of 4,000.

0.67 lb ai/A (Low potential for dermal transfer) wheat: harvest with transfer coefficient of 2,500; scout, irrigate with transfer coefficient of 1,000.

2.0 lb ai/A Grapes: harvest, hand girdle, cane, tie, prune, thin, tip with transfer coefficient of 15,000.

Herbaceous and woody ornamentals: cut/harvest, prune with transfer coefficient of 10,000; and irrigate with a transfer coefficient of 4,000.

4.0 lb ai/A Herbaceous and woody ornamentals: cut/harvest, prune with transfer coefficient of 10,000, and irrigate with a transfer coefficient of 4,000.

8.3 lb ai/A
33.2 lb ai/A Coniferous trees in nurseries grown for seed cone production: harvest with transfer coefficients of 5,000-10,000. (No transfer coefficient data are currently available for this use pattern, however, EPA believes they would fall within this range.)

ii) Data sources and assumptions for scenarios considered

Postapplication exposure data were required for dimethoate during the DCI in support of the reregistration process, since, at that time, one or more toxicological criteria had been triggered. The following postapplication studies dislodgeable foliar residue (DFR) studies were submitted by the registrant:

- *A Study to Determine the Degradation of Dimethoate and Dimethoxon Grape Foliage Treated With Cygon Systemic 25W for Grape Insect Control:* American Cyanamid Company Experiment No. 60903-71-B4-R (Cyanamid Report No. 72-000015); Issue Date 5/25/72; Author: R. Little.

In this study, the dissipation of dimethoate and dimethoxon (a.k.a. omethoate) from treated grape leaves was quantified after a seasonal application schedule. Two areas of a vineyard containing Thompson seedless grapes were treated in Reedley, California during the growing season of 1971. Two application schedules were followed, one at each site. In the first schedule, four applications were completed at weekly intervals while the second schedule involved three applications at 14 day intervals. Residue levels were monitored using two techniques that include a total residue extraction using methylene chloride and a dislodging procedure using an aqueous saline solution. Whole-leaf samples were collected. Surface areas were calculated on a per sample basis using a plot of the surface area to weight ratio of the grape leaves picked from the same vineyard. According to the report, "the calculated half-lives for the total residues of dimethoate and omethoate in the methylene chloride and saline phases were 2.1 and 1.5 days, respectively."

A review of this study was completed which can be identified by the following information:

- *Data Evaluation Record for Case GS0088/Chemical 035001, Dimethoate:* Authored by Peg Perreault of Dynamac, Inc./ Rockville, Maryland; Approved by Jim Adams of the Occupational and Residential Exposure Branch 10/5/87.

Based on historical standards, the study was deemed to be "scientifically sound" and was found as a source of "supplemental information towards the registration of dimethoate." One should consider, however, that during the review process several inadequacies were identified including: methylene chloride and saline were used for the dislodging process; the control samples were

apparently contaminated with dimethoate residues; and no meteorological data were provided in the report. It should be noted that these deficiencies would not be considered acceptable by current data evaluation standards. This study should not be considered as an acceptable source of information for use in the dimethoate reregistration process.

- *MRID # 446903-02. Bookbinder, M.G. Dissipation of Dislodgeable Foliar Residues of Dimethoate (O,O-dimethyl S-[N-[methylcarbamoyl]methyl] phosphorodithioate) and its Metabolite Omethoate (O,O-dimethyl S-[2-(methylamino)-2-oxoethyl] phorphorothioate) after Application of CLEAN CROP® DIMETHOATE 400 Insecticide to Tomato Plants. October, 1998.*

The study was conducted in three geographical locations: near Porterville in Tulare County, California; near Hobe Sound, Martin County, Florida; and near Germansville in Lehigh County, Pennsylvania. According to the 1998 Agricultural Statistics Handbook (NASS, USDA), as cited in the study report, the test states and adjacent states produced 78 percent of the 1997 U.S. tomato acreage. At each of the test sites, two plots were established. One plot, located upwind from the other, was left untreated and served as a control. The other plot was divided into 3 subplots. Sampling rows were selected to minimize edge effects and spray overlap. During the field trial, test plots were maintained according to normal regional practice for tomato culture. The test plots received 2 applications, 7 or 8 days apart, of CLEAN CROP® DIMETHOATE 400 insecticide. As prescribed on the label, the dimethoate was formulated as a 42.9 percent emulsifiable concentrate containing 4 lbs active ingredient (ai) per gallon. The dimethoate was applied at the maximum registered application rate for tomatoes of 0.5 lb ai/acre, using CO_2 powered backpack boom equipment at the Florida site, and tractor-mounted PTO-powered groundboom equipment at the California and Pennsylvania sites. The California test plots received furrow irrigation totaling 22 inches during the trial period, but no rainfall. The Florida sites received drip irrigation totaling 2.16 inches and rain on days 4, 11, 12, and 13 after the second application. No irrigation was applied to the Pennsylvania site, but rain was recorded on days 3, 4, 5, 6, 10, 11, 12, and 14 after the second application -- with a one-day high rainfall event of 2.2 inches on day 6 after the second application. Tomato DFR leaf-punch samples of approximately 400 cm^2 of surface (two-sided) were collected using a 1-inch diameter Birkestrand leaf punch sampler plots prior to each application, as soon as the spray had dried (Day 0), and on days 1, 2, 3, 5, 7, 10, 14, 21, 28, and 35 after the second application. Samples collected after 14 days after the second application were not analyzed, because residues had dropped to below the limit of quantification (LOQ) by that time. In summary, the study completed in support of the regulatory requirements for dimethoate mostly met the criteria contained in Subdivision K of the Pesticide Assessment Guidelines. The following major issue was noted: residue values were calculated even for samples with concentrations below the LOQ, which may have affected the half life calculations.

- *MRID # 446903-01. Bookbinder, M. G. Dissipation of Dislodgeable Foliar Residues of Dimethoate (O,O-dimethyl S-[N-[methylcarbamoyl]methyl] phosphorodithioate) and its Metabolite Omethoate (O,O-dimethyl S-[2-(methylamino)-2-oxoethyl] phorphorothioate) after Application of CLEAN CROP® DIMETHOATE 400 Insecticide to Leaf Lettuce.*

October, 1998.

The study was conducted in three geographical locations: near Porterville in Tulare County, California; near Hobe Sound in Martin County, Florida; and near Germansville in Lehigh County, Pennsylvania. According to the 1998 Agricultural Statistics Handbook (NASS, USDA), as cited in the study report, the test states and adjacent states produced 100 percent of the 1997 U.S. leaf lettuce crop. At each of the test sites, two plots were established. One plot was left untreated and served as a control. The other plot was divided into 3 subplots for leaf disc collection. Sampling rows were selected to minimize edge effects and spray overlap. The test plots received 2 applications, 7 or 8 days apart, of CLEAN CROP® DIMETHOATE 400 insecticide. The dimethoate was formulated as a 42.9 percent emulsifiable concentrate containing 4 lbs active ingredient (ai) per gallon. The dimethoate was applied at the maximum registered application rate of 0.25 lb ai/acre, using CO_2 powered backpack boom equipment at the Florida site, and tractor-mounted PTO-powered groundboom equipment at the California and Pennsylvania sites. Application equipment was calibrated prior to application. Leaf disk samples of approximately 400 cm^2 of surface (two-sided) were collected from both the control and test plots prior to each application, as soon as the spray had dried (Day 0), and on 1, 2, 3, 5, 7, 10, 14, 21, 28, and 35 days after the second application. Samples collected subsequent to 14 days after the second application were not analyzed, because residues had dropped to below the limit of quantification (LOQ) by that time. Daily rainfall data were obtained onsite. Rainfall at the Florida and Pennsylvania sites during the sampling period totaled approximately 160 and 130% respectively of the 10 year regional precipitation avenge for the trial period. The California site received no rainfall during the study period. In summary, this DFR study completed in support of the regulatory requirements for Dimethoate met most of the criteria contained in Subdivision K of the Pesticide Assessment Guidelines. In addition, some discrepancy and minor issues were noted in this review.

- *MRID # 448276-01. Prochaska, Lee M. Dissipation of Dimethoate and its Metabolite Omethoate Dislodgeable Foliar Residues on Apples Treated with CLEAN CROP® DIMETHOATE 400 - Phase I: Field Investigation and Phase 2: Analytical. May 4, 1999.*

Clean Crop® Dimethoate 400 was applied using airblast sprayers twice during the growing season in August to apple trees in three locations. An application rate of 1.0 lb. active ingredient/ Acre (a.i./A) was employed. Application equipment was calibrated prior to application. Foliage samples were collected as soon as sprays had dried (e.g., no later than 4 hours post-application), 12 hours, 1, 2, 3, 5, 7, 10, 14, 21, 28, and 35 days after the last application. The first study site was in Ottawa County, near Marne, Michigan; the second was in upstate New York, in Wayne County near Alton, NY; and the third site was in the Washington State central valley, in Grant County, near Ephrata, WA. In 1997, the top three U.S. apple-producing states were Washington, Michigan, and New York; these states together produced 69 percent of the total U.S. crop (USDA, Agricultural Statistics, 1997). Historical meteorological conditions at the three sites seem to indicate nearly normal conditions in these areas at the time of the study. There was no rainfall within 24 hours before or after application. Irrigation was applied to the plots in Washington State on the fifth day after application. Cheminova analyzed

the dissipation data using a nonlinear regression fit to a first order decay equation. Combined dimethoate and omethoate were reanalyzed using linear regression of log transformed data. Residues were still detectable 35 days after the application at all locations. The study met most of the requirements of the Environmental Protection Agency's (US-EPA) OPPTS Series 875, Occupational and Residential Exposure Test Guidelines, Group B: Postapplication Exposure Monitoring Test Guidelines. The major deviation was that the study was conducted using an application rate of 1.0 lb ai/acre as opposed to the label specified maximum application rate of 0.5 lb ai/acre.

- *MRID No. 447882-01. Prochaska, Lee M. Dissipation of Dimethoate and its Metabolite Omethoate Dislodgeable Foliar Residues on Grapes Treated with Clean Crop® Dimethoate 400, Phase I Field Investigation & Phase II Analytical,*

The study was conducted in three geographical locations: in the California Central Valley, near Porterville, in Tulare County; in upstate New York, near Dundee, in Yates County; and in the Washington State central valley, 8 miles south of Quincy, in Grant County. At each of the test sites, two plots were established. One plot was left untreated and served as a control. The other plot was divided into 3 subplots for leaf disc collection. Sampling rows were selected to minimize edge effects and spray overlap. Clean Crop® Dimethoate 400 was applied to the vineyards twice during the growing season from a few days to a month after "veraison," which is the point at which the grape enters the ripening period (i.e., "green" to mature fruit). Both applications were applied at 1 lb ai/A, not the label permitted maximum rate of 2 lbs ai/A. Airblast sprayers were used at all test sites. No rain events are noted in California; irrigation occurred three times (4 inches each time); these did not coincide with pesticide applications. In New York, there were 16 rain events; these did not coincide with pesticide applications. In Washington, there were 10 rain events and two irrigation events; these did not coincide with pesticide applications. Foliage samples were collected as soon as sprays had dried (e.g., no later than 4 hours post-application), 12 hours, 1, 2, 3, 5, 7, 10, 14, 21, 28, and 35 days after the last application. When dimethoate and omethoate dislodgeable foliar residues were combined, levels were detectable through day 35 at the WA and CA sites. Combined levels had fallen to < LOQ after day 14 at the NY site. Using linear regression - Microsoft EXCEL 97® combined dimethoate and omethoate DFR half-lives were: California - 4.7 days (R^2 = 0.84); Washington State - 4.92 days (R^2 = 0.86); and New York - 1.55 days (R^2 = 0.94). Cheminova estimates for dimethoate half-lives were: California - 0.4 days (R^2 = 0.98); Washington State - 1.33 days (R^2 = 0.97); and New York - 0.85 days (R^2 = 0.97). Cheminova estimates for omethoate half-lives were: California - 10.8 days (R^2 = 0.92); Washington State - 18.2 days (R^2 = 0.93); and New York - 5.3 days (R^2 = 0.93). This study met most of the OPPTS Series 875 Group B Occupational and Residential Exposure Test Guidelines. The most important deviation was that the study was not conducted at the maximum application rate.

iii) Postapplication exposures for other crops

EPA had no dimethoate-specific data for the crops other than lettuce, grapes, tomatoes,

grapes, and apples. Therefore, a surrogate postapplication exposure risk assessment was conducted for the other crops using one of the four studies submitted.

The apple data were used in the postapplication assessment for all tree fruit and nut crops, conifer seed nurseries, and woody ornamentals.

The grape data were used in the postapplication assessment just for grapes.

The lettuce data (MRID 446903-01) were used for crops with an application rate of 0.25 lb ai/acre and less, since the data represent DFR levels obtained at an application rate of 0.25 lb ai/acre. For applications to peas, the predicted DFR levels ($\mu g/cm^2$) based on the slope and intercept were normalized (see equation in Exposure and Risk Calculation section below) to account for a potential decrease in residues when dimethoate is applied at the application rate of 0.16 lb ai/acre. These data were used to assess postapplication risks (see Appendix G-3) from contact with:

- peas at an application rate of 0.16 lb ai/acre and assessed for hand harvesting, staking/ tying, scouting, irrigating (transfer coefficient = 4,000);

- collards, kale, mustard greens, endive, escarole, head lettuce, leaf lettuce, spinach, Swiss chard, and turnips at an application rate of 0.25 lb ai/acre and assessed for hand harvesting (transfer coefficient = 2,500) and scouting or irrigating (transfer coefficient = 1,000).

The tomato data (MRID446903-02) were used for crops with an application rate ranging from 0.33 lb ai/acre and higher (except tree and woody crops), since the data represent non-woody plants and DFR levels were obtained at an application rate of 0.5 lb ai/acre. For applications other than at the 0.5 lb ai/acre rate, the predicted DFR levels ($\mu g/cm^2$) based on the slope and intercept were then normalized to account for a potential increase/decrease in residues when dimethoate is applied at application rates ranging from 0.33 lb ai/acre to 4 lb ai/acre (e.g., DFR levels were multiplied by two to approximate the residues at 1.0 lb ai/acre). These data were used to assess postapplication risks (see Appendix G-4) from contact with:

- peppers at an application rate of 0.33 lb ai/acre and assessed for hand harvesting, staking/tying, scouting, irrigating (transfer coefficient = 4,000);

- broccoli, Brussels sprouts, cabbage, cauliflower, celery, alfalfa, and sorghum at an application rate of 0.5 lb ai/acre and assessed for hand harvesting (transfer coefficient = 2,500) and scouting or irrigating (transfer coefficient = 1,000);

- melons, watermelons, lentils, soybeans at an application rate of 0.5 lb ai/acre and assessed for hand harvesting, staking/tying, scouting, irrigating (transfer coefficient = 4,000);

- field corn, tomatoes, beans (excluding cowpeas) at an application rate of 0.5 lb ai/acre and assessed for hand harvesting (transfer coefficient = 10,000) and staking/tying, scouting,

irrigating (transfer coefficient 4,000);

- potatoes at an application rate of 0.5 lb ai/acre and assessed for hand digging/harvesting (transfer coefficient = 10,000) and sorting, packing (transfer coefficient = 2,500);

- cotton, safflower at an application rate of 0.5 lb ai/acre and assessed for hoeing/late season scouting (transfer coefficient = 4,000) and early season scouting (transfer coefficient = 1,000);

- wheat at an application rate of 0.67 lb ai/acre and assessed for harvesting (transfer coefficient = 2,500) and scouting, irrigating (transfer coefficient = 1,000); and

- herbaceous ornamentals at an application rate of 2.0 and 4.0 lb ai/acre and assessed for cutting/harvesting, pruning (transfer coefficient = 10,000) and irrigating (transfer coefficient = 4,000).

The grape data were used in the postapplication assessment for just grape crops (see Appendix G-5). The grape data (MRID 447882-01) represent DFR levels obtained at an application rate of 1.0 lb ai/acre. The predicted DFR levels ($\mu g/cm^2$) based on the slope and intercept were then normalized to account for a potential increase in residues when dimethoate is applied at the application rate of 2.0 lb ai/acre.

The apple data were used in the postapplication assessment for all tree fruit and nut crops, conifer seed nurseries, and woody ornamentals. The apple data (MRID 448276-01) represent DFR levels obtained at an application rate of 1.0 lb ai/acre. The predicted DFR levels ($\mu g/cm^2$) based on the slope and intercept were then normalized to account for a potential increase in residues when dimethoate is applied at the application rate of 2.0, 4.0. 8.3, and 33.2 lb ai/acre, and for potential decrease in residues when dimethoate is applied at the application rate of 0.33 lb ai/acre and 0.5 lb ai/acre. These data were used to assess postapplication risks (see Appendix G-6) from contact with:

- cherries, pecans at an application rate of 0.33 lb ai/acre and assessed for hand harvesting, pruning, propping, harvesting nuts by shaking, raking, poling, and pickup, and all other activities (transfer coefficient = 10,000);

- citrus (tree fruit-foliar applications), pears, apples at an application rate of 0.5 lb ai/acre and assessed for hand harvesting, pruning, propping, harvesting nuts by shaking, raking, poling, and pickup, and all other activities (transfer coefficient = 10,000);

- woody ornamentals at an application rate of 2.0 and 4.0 lb ai/acre and assessed for cutting/harvesting, pruning (transfer coefficient = 10,000) and irrigating (transfer coefficient = 4,000);

- coniferous trees grown for seed cone production in nurseries at an application rate of 8.3

and 33.2 lb ai/acre and assessed for hand harvesting seed cones (transfer coefficient = 5,000 - 10,000). (There are no transfer coefficient data currently available for this use pattern, however, EPA believes they would be within this range).

4. Residential

Residential uses are no longer being supported. However, based on available information, HED remains concerned about residential risks from dimethoate spray drift. The potential for these **non-occupational exposures to individuals living in or near agricultural areas**, e.g. potential exposure from spray drift, where dimethoate is being used were not assessed but will be addressed at a later time when methodologies to perform such assessments are in place.

Risk Assessment/Characterization

Risk is a function of exposure multiplied by hazard (Risk = Exposure x Hazard). Exposure may be measured or modeled, depending on the available data. Ideally the exposure data would be chemical specific occupational or residential monitoring data, at the tap drinking water data, and close to the plate food residue data on all crops. In the absence of an ideal data set, surrogate data, and other factors are incorporated into the exposure assessments (dietary and non-dietary) to present a reasonable exposure picture based on the best available data. The hazard portion of the risk equation has several layers of safety built into it to provide a cushion between exposure and the dose at which adverse effects were seen in an animal study. Generally, endpoints are based on the dose at which **no** observable adverse effect is seen in an animal study. This is the No Observable Adverse Effect Level (NOAEL). The Lowest Observable Adverse Effect Level (LOAEL) is the next highest dose in an animal study, up from the NOAEL, at which the adverse effect of concern is seen. Levels of ChE inhibition which are of concern to the Agency do not always manifest themselves in clinical signs. In humans, the initial signs of organophosphate poisoning are headache, hypersecretion, muscle twitching, nausea, and diarrhea. Many of these symptoms are often confused with flu-like symptoms. Since the toxicity studies used for endpoint selection are conducted in animals, and there are differences between individual humans, additional uncertainty factors for inter- and intra-species variability are integrated into the hazard portion of the risk equation. Since the passage of the FQPA, an additional layer of protection is factored in (when appropriate) to provide an even greater safety cushion between exposure and toxic effects for particularly sensitive populations. It is in this light that expressions of risk (risk numbers) should be viewed with an understanding that they are not portrayals of imminent toxic effects to humans but as a measure of the distance between potential exposure and possible toxic effects.

In accordance with current HED policy (effective 03/11/99) the acute and chronic dietary endpoints are expressed as acute Population Adjusted Dose (aPAD) and chronic PAD (cPAD), and no longer as an adjusted Reference Dose (RfD).

$$\text{RfD} = \frac{\text{acute or chronic NOAEL}}{\text{Uncertainty Factor (UF)}}$$

Generally, an UF of 100 is applied for intra- and inter-species differences.

$$\text{PAD} = \frac{\text{acute or chronic RfD}}{\text{FQPA factor}}$$

The use of the PAD will apply whether the FQPA factor is retained (10x or 3x) or not (1x). When a PAD is used, such as in the dietary assessment, the risk is expressed as a percentage of the PAD which is equal to the measured exposure divided by the PAD and then multiplied by 100 or:

$$\text{Risk (\% PAD)} = \frac{\text{Exposure}}{\text{PAD}} \times 100$$

Occupational, residential (when applicable), and the aggregate risk (when appropriate) will still be expressed as the Margin of Exposure (MOE).

$$\text{MOE} = \frac{\text{NOAEL}}{\text{Exposure}}$$

Current HED policy requires that FQPA safety factors be retained for dietary and non-occupational exposures, when appropriate, not occupational exposures. Therefore, an MOE of $\geq$ 100 is generally needed in the occupational exposure risk assessment. However, in the case of dimethoate, an MOE of 300 is needed for some exposures since a LOAEL was used for the intermediate-term endpoints.

A. Uncertainty Factors

The HIARC and the FQPA Safety Factor Committee determined that for dimethoate, the 10X factor, used to account for enhanced sensitivity of infants and children (as required by the Food Quality Protection Act), should be removed. This conclusion was based on the developmental and reproductive toxicity studies in the toxicology database for dimethoate in which there does not appear to be any special sensitivity for pre- or post-natal effects.

An uncertainty factor (UF) of 100 was applied to the risk assessment to account for both interspecies extrapolation and intraspecies variability. Therefore, an UF of 100 was applied to determine the acute and chronic RfDs and an MOE of $\geq$ 100/300 is needed in the occupational exposure risk assessment. Since the FQPA safety factor was not retained (i.e. 1X), The RfDs and PADs are the same. In the earlier HED Chapter (01/09/98) the acute dietary risk was expressed as a MOE.

B. Dietary Risk

1. Acute Dietary Risk

i) Overview

Tolerances are established for total residues of the insecticide dimethoate and its oxygen analog omethoate (40 CFR 180.204). The EPA had earlier conducted a Tier 1 assessment of the acute dietary risk for dimethoate using the Dietary Risk Evaluation System, DRES, (Brian Steinwand). The MOE values (all below 40) indicated a concern, given that an acceptable MOE is 100 or greater. A limited Tier 2 analysis was conducted in HED to refine the DRES assessment and to try to determine which commodities were significant contributors to exposure. HED was not able to make this determination using DRES system. In addition, rerunning the DRES analysis using anticipated residues (AR) was not expected to significantly further refine the acute

dietary risk. HED, therefore recommended that the registrant(s) conduct an acute probabilistic (Monte Carlo) analysis to address acute dietary concerns. The submission was reviewed (Sahafeyan, M.; DP Barcode: D249135, Jan. 29, 1999) and deemed unacceptable primarily because of the exclusion of some commodities in the assessment which are presently registered and included on the labels. Consequently, an in-house acute probabilistic risk assessment was performed, with the emphasis on the wider use of monitoring data, by utilizing the Agency's own statistical method that would allow estimating the residues on single-serving units of foods from composited monitoring data.

The probabilistic acute dietary exposure risk assessment for dimethoate in foods was conducted using the toxicological end point of NOAEL = 2 mg/kg/d, maximum percent crop treated (%CT), PDP and FDA residue data and the 1989-1992 USDA Continuing Surveys of Food Intake by Individuals (CSFII) database. When appropriate, the newly proposed statistical method was used to convert (decomposite) the PDP and FDA composite residue data to the residues that reflected pesticide concentrations on single-serving units of foods. No truncation was performed on any of the decomposited data in this assessment. When the total number of samples or total number of detected residues in monitoring data for a particular crop was not sufficient, the monitoring data from another crop was translated to the previous crop (Probabilistic Acute Dietary Exposure Estimates for Dimethoate, Mohsen Sahafeyan, August 18, 1999).

The DEEM evaluations were performed with and without cooking factors. The results for both assessments showed estimated dietary exposure for the U.S. population and all its population subgroups are below the level of concern (<100% aPAD). The range of estimated dietary exposure in one assessment (all the crops were included and cooking factors were incorporated) was 41% aPAD for the U.S. population and 86 % aPAD for children 1-6 (population with highest exposure). The range changed when the cooking factors were not incorporated in the assessment, resulting in 49% aPAD and 97% aPAD for U.S. population and children 1-6, respectively.

ii) Residue data

Extensive monitoring data for dimethoate and omethoate from the USDA Pesticide Data Program (PDP) and the FDA Surveillance Monitoring Program are available. The PDP data are generally preferred over FDA data for use in dietary exposure and risk analyses. The USDA PDP was specifically designed for risk assessment; analysts prepare samples in a manner similar to typical consumer practices, such as washing, coring/pitting, and/or peeling. The 20 lb. surveillance samples are collected by FDA for tolerance enforcement purposes, and are not washed or peeled prior to analysis; in addition, FDA samples are collected in the channels of commerce, and often represent "farm gate" residues. The PDP samples are 5 lb. composites collected at large-scale distribution centers, just prior to sale in grocery stores, and are more likely to reflect "dinner plate" residues. In this assessment, monitoring data (versus field trial data) was used as much as possible.

iii) Methodology for combining residues of dimethoate and omethoate

The monitoring programs (PDP and FDA) analyze for dimethoate (parent compound) and omethoate (metabolite) separately. Since the tolerance expression includes both dimethoate and omethoate, the residues of parent and its metabolite were summed for use in the dietary risk assessment. Different scenarios were possible (e.g. a tomato sample may be analyzed for one compound but not for the other or it may have a detected residue for one and not for the other). Procedures in the following table were used in determining the residue values to be inserted in the dietary exposure analyses.

Table 5 - Procedure used for adding dimethoate and omethoate for different scenarios

Dimethoate Value Reported	**Omethoate Value Reported**	**Treatment**
Detect	Detect	Dimethoate detect + Omethoate Detect
Detect	Non-Detect	Dimethoate Detect + ½ LOD for Omethoate for that sample
Non-Detect	Detect	½ LOD for Dimethoate for that sample + Omethoate Detect
Non-Detect	Non-Detect	½ LOD for Dimethoate for that sample + ½ LOD for Omethoate for that sample
Detect	Not analyzed	Detect for Dimethoate + Detect (same value) for Omethoate
Non-Detect	Not analyzed	½ LOD for Dimethoate for that sample + ½ average LOD for Omethoate for that commodity
Not Analyzed	Detect	Detect for Omethoate + Detect (same value) for Dimethoate
Not Analyzed	Non-Detect	½ LOD for Omethoate for that sample + ½ average LOD for Dimethoate for that commodity

iv) Processing factors

Processing studies that were submitted, accepted by the Agency (Bonnie Cropp-Kohlligian, DP Barcode Nos: D205591, D206804, D206555, and D213099, 11/6/95), and used in the acute dietary risk assessment, include citrus (orange juice, dried citrus pulp), field corn, cottonseed, grapes, potatoes, soybeans, tomatoes, and wheat (Probabilistic Acute Dietary Exposure Estimates for Dimethoate, Mohsen Sahafeyan, August 18, 1999).

The Agency identified several studies in the open literature that investigated the effect of kitchen-processing on concentrations of dimethoate residues in foods (Dimethoate: Interim Memorandum on the Effect of Peeling, Washing or Cooking on Concentrations of Dimethoate in Foods, Stephen DeVito, July 2, 1999). Based on the results of these studies, a cooking factor of 0.7 (i.e., 30% reduction of residues by cooking) for any cooked form of vegetables and fruits, and a cooking factor of 0.8 (i.e., 20% reduction of residues by cooking) for any cooked forms of grains were applied in the calculation of the second assessment (Table 6 in the Results section of Sahafeyan memo, August 18, 1999). Since most residue data for vegetables and fruits used in this

assessment were from PDP monitoring data, and these type of data are obtained from washed and peeled (where appropriate) fruits and vegetables, no washing or peeling reduction factors were generally used in this risk assessment. Several other organophosphate pesticides in meat was found, and showed that cooking causes decomposition of the substances tested. Based on the results of this study, a cooking factor of 0.7 (i.e., 30% reduction of residues by cooking) for any cooked form of meat was applied in the calculation of the second assessment.

Table 6

Acute Probabilistic Dietary (food) Risk Assessment						
Population / Sub-population	**95th Percentile**		**99th Percentile**		**99.9th Percentile**	
	Exposure (mg/kg/d)	**%aPAD**	**Exposure (mg/kg/d)**	**%aPAD**	**Exposure (mg/kg/d)**	**%aPAD**
US (all season)	0.000355	1.77	0.003127	15.64	0.008229	41.14
All Infants (<1 yr)	0.000350	1.75	0.001307	6.53	0.006265	31.32
Nursing Infants (<1 yr)	0.000113	0.56	0.000958	4.79	0.004723	23.61
Non-nursing Infants(<1yr)	0.000406	2.03	0.001450	7.25	0.006748	33.74
Children (1-6 yrs)	0.000540	2.70	0.004169	20.85	0.017287	86.43
Children (7-12 yrs)	0.000260	1.30	0.002693	13.47	0.007316	36.58
Females (13+/prg/not nsg)	0.000206	1.03	0.003669	18.34	0.005813	29.07
Females (13+/nursing)	0.000774	3.87	0.003609	18.05	0.004246	21.23
Females (13-19 yrs/np/nn)	0.000163	0.82	0.002613	13.06	0.011232	56.16
Females (20+ yrs/np/nn)	0.000377	1.89	0.003328	16.64	0.007348	36.74
Females (13-50 yrs)	0.000193	0.97	0.002913	14.56	0.008488	42.44
Males (13-19 yrs)	0.000271	1.35	0.002471	12.36	0.005630	28.15
Males (20+ yrs)	0.000326	1.63	0.002922	14.61	0.006078	30.39
Seniors (55+ yrs)	0.001203	6.01	0.003610	18.05	0.007099	35.50
Pacific Region	0.000619	3.10	0.003057	15.28	0.007651	38.26

2. Chronic Dietary Risk

The refined chronic dietary (food sources) analysis (Tier 2) for dimethoate that was originally conducted (HED chapter 01/09/98) using DRES software and was found to be below HED's level of concern (< 100% cPAD). Less than 100% cPAD is required. After the Agency acquired the new DEEM software and more up-to-date consumption data (USDA 1989-1991), the chronic dietary analysis was conducted again (08/06/98, 08/19/98 amendment) incorporating refinements, as before, including %CT data, processing factors, and some anticipated residues. Again, it showed that the chronic dietary risk from the uses recommended through reregistration, is not of concern.

Table 7

CHRONIC DIETARY (FOOD) RISK ANALYSIS		
Population	**Exposure (mg/kg/d)**	**% cPAD**
U.S. Population	0.0001	20
Nursing infants (< 1 yr)	0.000048	10
Non-nursing infants (< 1 yr)	0.000143	29
Females (13+yrs, pregnant)	0.000058	12
Females (13+ yrs, nursing)	0.00015	30
Children (1-6 yrs)	0.000181	36
Children (7-12 yrs)	0.0001	20
Males (13-19 yrs)	0.000067	13
Females (13-19 yrs, np/nn)	0.000056	11
Males (20 + yrs)	0.00009	18
Females (20+ yrs, np/nn)	0.000098	20
Seniors (55+ yrs)	0.000095	19

np = not pregnant, nn = not nursing

C. Drinking Water Risk

Generally, the Agency calculates Drinking Water Levels of Comparison (DWLOC) for comparison to measured or modeled drinking water concentrations for the risk analysis. The DWLOC is the concentration in drinking water, as part of the aggregate exposure, that occupies no more than 100% of the PAD. The dietary exposure and DWLOC together, cannot be greater than 100% of the PAD. Any measured or modeled drinking water estimates that are less than the DWLOC are not of concern.

Acute or chronic DWLOCs ($DWLOC_{acute/chronic}$) were calculated using the following formulae:

$$DWLOC_{acute/chronic}\ (ug/L) = \frac{\text{acute/chronic water exposure (mg/kg/d) x body weight (kg)}}{\text{consumption (L/d) x } 10^{-3}\text{ mg/ug}}$$

acute/chronic water exposure (mg/kg/d) = [PAD - acute/chronic food (mg/kg/d)]

The current Agency default body weight and consumption values are 10 kg and 1 liter/day, respectively, for all infants and children, 70 kg and 2 liters/day for adult males, and 60 kg and 2 liters/day for adult females. These default values and others are presently under review in the Agency. If at a future time the Agency decides to change the default assumptions used, the impact of the changes on the dimethoate risk assessment will be considered.

1. Surface Water Drinking Water Risk

The Agency has calculated drinking water levels of comparison (DWLOCs) for acute and chronic (non-cancer) exposure to dimethoate in surface and ground water for population subgroups; children 1-6 years, infants, females 13+ years not pregnant/not nursing, and the U.S. population/adult males. In the case of females and infants/children, DEEM provides exposure from food for various population subgroups. The **highest exposed** subgroup is chosen for the DWLOC calculation. To calculate the DWLOC for acute or chronic (non-cancer) exposure relative to an acute or chronic toxicity endpoint, the dietary food exposure (from DEEM) was subtracted from the PAD to obtain the exposure to dimethoate in drinking water that would not be of concern.

Taking into account the present uses and uses proposed in this action, the Agency concluded with reasonable certainty that residues of dimethoate in drinking water (when considered along with other sources of exposure for which the Agency has reliable data) would not result in a total dietary risk above the Agency's level of concern.

The Agency bases this determination on a comparison of estimated concentrations of dimethoate in surface waters and ground waters to back-calculated "levels of comparison" for dimethoate in drinking water. The estimates of dimethoate in surface and ground waters are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water, and were supplemented with limited monitoring data.

The seed orchard use is the only exception to the risk finding (below Agency's level of concern). The Agency estimates that the seed orchard use results in potential drinking water risks that are above the Agency's level of concern.

Table 8 Acute Drinking Water Risks Based on Surface Water Exposures

Population	PRZM/ EXAMS (ug/L)	aPAD (mg/kg/d)	Acute Food Exposure (mg/kg/d)	Acute H_2O Exposure (mg/kg/d)	$DWLOC_{acute}$ (ug/L)
U.S. Pop	7.97-22.83	0.02	0.008229	0.011771	412.0
Female 13-19 np/nn	7.97-22.83	0.02	0.011232	0.008768	263.0
Infants <1 yr not nursing	7.97-22.83	0.02	0.006265	0.013735	137.4
Children 1-6	7.97-22.83	0.02	0.017287	0.002713	27.1

Table 9 Chronic Drinking Water Risks Based on Surface Water Exposures

Population	PRZM/ EXAMS (ug/L)	cPAD (mg/kg/d)	Chronic Food Exposure (mg/kg/d)	Chronic H_2O Exposure (mg/kg/d)	$DWLOC_{chronic}$ (ug/L)
U.S. Pop	0.6-1.26	0.0005	0.0001	0.000400	14.0
Female 13+ nursing	0.6-1.26	0.0005	0.00015	0.000150	10.5
Infants <1 yr not nursing	0.6-1.26	0.0005	0.000143	0.000357	3.57
Children 1-6	0.6-1.26	0.0005	0.000181	0.000319	3.19

nn = not nursing, np = not pregnant

2. Ground Water Drinking Water Risk

The $DWLOCs_{acute}$ and $DWLOCs_{chronic}$ for ground water are the same as for surface water concentrations, so the estimated ground water concentration of 0.002 μg/L is well below the Agency's level of concern. Though some very limited monitoring data drawn from wells, detected some residues above 0.002 μg/L, no residues could be found in these same wells in follow-up samples.

D. Occupational Risk Assessment

1. Handler Risk

i) Methods for calculating risks from dermal/inhalation exposures

The calculations of the daily dermal and inhalation dose of dimethoate received by handlers are used to assess the dermal and inhalation risks to those handlers. Short- and intermediate-term MOEs, regardless of the exposure scenario, were calculated using the following

formula:

$$\text{MOE} = \text{NOAEL (mg/kg/d)}/\text{Dose}_{\text{Dermal or Inhalation}} \text{ (mg/kg/d)}$$

In addition, since the endpoints of concern for dermal and inhalation routes were based on identical adverse effects (i.e., cholinesterase inhibition) the risks are aggregated. For short-term risks, the uncertainty factor for both dermal and inhalation risk is 100, whereas for intermediate-term risks, the uncertainty factor for both dermal and inhalation risk is 300. Therefore, the total risk can be calculated as follows:

$$\text{Total MOE} = \frac{1}{\frac{1}{\text{dermal MOE}} + \frac{1}{\text{inhalation MOE}}}$$

The calculations used to estimate *Daily Dose* and *MOE* for the post-application scenarios are similar. The only significant difference is the manner in which the *Daily Dose* will be calculated using a transfer coefficient, transferable residue levels, and accounting for the dissipation of dimethoate over time. *Daily Dose* and *MOE* values are calculated for each postapplication day until a restricted-entry interval is achieved based on the MOE value in occupational settings (i.e., REIs are based on MOE values $\geq$ 300).

ii) General risk characterization considerations

Several issues must be considered when interpreting the occupational risk assessment. These include:

- No acceptable chemical-specific data for handlers were submitted. As a result, all analyses were completed using surrogate data from sources such as PHED.

- Several handler assessments were completed using “low quality” PHED data due to the lack of a more acceptable dataset (see Appendix F for further details).

- Several generic protection factors were used to calculate handler exposures. The protection factors used for clothing layers and gloves have not been completely evaluated by EPA. The key element being evaluated by EPA is the factor for clothing. The value used for respiratory protection is based on the *NIOSH Respirator Decision Logic*.

- Various exposure factors used in the calculations (e.g., acres treated per day for each application method) are based on the best professional judgement of EPA due to a lack of extensive pertinent data.

- Exposure descriptors have not been assigned to each scenario that has been assessed because the data to describe distributions for each exposure factor are not available. The PHED surrogate exposure values can be described in terms, however, as values that are generally between the geometric mean and the median of the dataset used for calculation

of the value. Calculations were completed for a variety of maximum application rates that varied based on crop type for each handler/equipment scenario assessed. No specific data were available pertaining to typical rates was available. However, an assessment was completed *de facto* because of the large range of application rates assessed for each scenario. Additionally, as indicated above, the area treated values were based on the best-professional judgement of EPA. These values, however, are believed to represent typical to high-end acreages and volumes.

Refinement of the EPA exposure and risk assessment calculations presented in this chapter is possible if the issues presented above are addressed by the registrant or if more refined approaches and data become available to EPA.

iii) Total risks to handlers

Dermal, inhalation, and total risks for occupational handlers were assessed using the short-term and intermediate-term toxicological endpoints. Results from the assessment are presented below (i.e., short and intermediate-term assessment). A chronic risk assessment was not completed as EPA believes that dimethoate use patterns do not lend themselves to chronic exposure scenarios.

EPA identified exposure scenarios based on available labels and other use information, such as the LUIS report. As indicated earlier, surrogate data were used to develop the exposure/risk assessment for occupational handlers. In some cases, appropriate surrogate data were not available to serve as the basis for an assessment. The scenarios for which no appropriate data are available are presented below:

- (4) Application of liquids with helicopter aircraft (Note: scenario (3) applying liquids with aircraft is used as a surrogate);
- (8) Application of ready-to-use liquids;
- (10) Application via soil injection for ornamental cultivation purposes;
- (14) Application via sprinkler can; and
- (15) Soil drench application.

iv) Short- and intermediate-term occupational handler risks

The calculations of short- and intermediate-term total risks to handlers indicate that the MOEs are a concern:

- even with the use of engineering controls at the 33.2 pounds per acre application rates (conifer seed nursery) for:

-- applying with an airblast/mistblower sprayer (short-term total MOE = 50 with an uncertainty factor (UF) of 100; intermediate-term total MOE = 130 with a UF of 300).

- even with the use of engineering controls at the 4.0 pound per acre application rates (ornamentals) for:
  - -- mixing/loading liquids to support aerial applications (short-term total MOE = 55 with an uncertainty factor (UF) of 100; intermediate-term total MOE = 160 with a UF of 300),
  - -- applying aerially (short-term total MOE = 94 with a UF of 100; intermediate-term total MOE = 260 with a UF of 300), and
  - -- flagging (short-term total MOE = 96 with a UF of 100; intermediate-term total MOE = 270 with a UF of 300);

- even with the use of engineering controls at the 2.0 pound per acre application rates (grapes) for mixing/loading wettable powders to support aerial applications (short-term total MOE = 91 with a UF of 100; intermediate-term total MOE = 240 with a UF of 300);

- even with the use of maximum personal protective equipment, including chemical-resistant gloves, double-layer body protection, and a dust-mist respirator, for mixing, loading, and applying with a high-pressure handwand sprayer on ornamentals at application rates ranging from:
  - -- 0.1 lb ai/gal (short-term total MOE = 4.1 with a UF of 100; intermediate-term total MOE = 11 with a UF of 300)
  - -- 0.06 lb ai/gal (ornamentals) (short-term total MOE = 6.8 with a UF of 100; intermediate-term total MOE = 19 with a UF of 300).
  - -- to 0.01 lb ai/gal (ornamentals) (short-term total MOE = 41 with a UF of 100; intermediate-term total MOE = 110 with a UF of 300).

  No engineering controls are currently available for this scenario.

- even with the use of maximum personal protective equipment, including chemical-resistant gloves, double-layer body protection, for applying liquids with a paintbrush to agricultural-animal and poultry industry premises at 2 lb ai/gal (short-term total MOE = 7.5 with a UF of 100; intermediate-term total MOE = 21 with a UF of 300). No engineering controls are currently available for this scenario.

The following table summarizes the risks to handlers by crop type and application rate. The application rate is the *proposed* maximum application rate for each crop as submitted by a registrant.

TABLE 10: SUMMARY OF HANDLER RISKS FOR DIMETHOATE BY CROP TYPE

NOTE: Application Rate = maximum application rate for the crop based on *proposed* maximum rates submitted by a registrant.

CROP	HANDLER SCENARIO	APPLICATION RATE	BASELINE TOTAL MOE		ADDITIONAL PPE TOTAL MOE		ENGINEERING CONTROLS TOTAL MOE	
			Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300
Grapes	Mixing/loading wettable powder for aerial and chemigation applications	2.0 lb ai/A (proposed)	0.26	0.71	5.8 g,dl,r	14 g,dl,r	91 g	240 g
	Aerial spray applications	2.0 lb ai/A (proposed)	no data	no data	no data	no data	190	520
	Flagging for aerial spray	2.0 lb ai/A (proposed)	78	210	85 dl	220 dl	190	540
	Mixing/loading wettable powders for groundboom	2.0 lb ai/A (proposed)	1.1	3.1	25 g,dl,r	61 g, dl, r	400 g	1100 g
	Groundboom application	2.0 lb ai/A (proposed)	250	610	NA	NA	NA	NA
	Mixing/loading wettable powders for airblast	2.0 lb ai/A (proposed)	2.2	6.2	51 g, dl, r	120 g,dl,r	800 g	2100 g
	Airblast application	2.0 lb ai/A (proposed)	23	63	36 g,dl	98 g,dl	210	550

SUMMARY OF HANDLER RISKS FOR DIMETHOATE BY CROP TYPE (continued)

CROP	HANDLER SCENARIO	APPLICATION RATE	BASELINE TOTAL MOE		ADDITIONAL PPE TOTAL MOE		ENGINEERING CONTROLS TOTAL MOE	
			Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300
Citrus	Mixing/loading liquids for aerial and chemigation applications	2.0 lb ai/A (current)	0.34	1	55 g,dl,r	150 g,dl,r	110 g	310 g
		0.5 lb ai/A (proposed)	1.4	4	140 g	340 g	NA	NA
	Aerial spray applications	2.0 lb ai/A (current)	no data	no data	no data	no data	190	520
		0.5 lb ai/A (proposed)	no data	no data	no data	no data	750	2100
	Flagging for aerial spray	2.0 lb ai/A (current)	78	210	85 dl	220 dl	190	540
		0.5 lb ai/A (proposed)	310	820	NA	NA	NA	NA
	Mixing/loading liquids for airblast	2.0 lb ai/A (current)	3	8.7	300 g	750 g	NA	NA
		0.5 lb ai/A (proposed)	12	35	1200 g	3000 g	NA	NA
	Airblast application	2.0 lb ai/A (current)	23	63	36 g,dl	98 g,dl	410	1100
		0.5 lb ai/A	92	250	130 g	360 g	NA	NA
Wheat	Mixing/loading liquids for aerial and chemigation applications	0.67	1	3	100 g	310 g,dl	NA	NA
	Aerial spray applications		no data	no data	no data	no data	560	1500
	Flagging for aerial spray		230	610	NA	NA	NA	NA
	Mixing/loading liquids for groundboom		4.5	13	450 g	1100 g	NA	NA
	Groundboom application		740	1800	NA	NA	NA	NA
Broccoli, cabbage, cauliflower, field corn, sorghum, melons, watermelons, tomatoes, beans, lentils, soybeans, celery, alfalfa, potatoes, cotton, and safflower	Mixing/loading liquids for aerial and chemigation applications	0.5 lb ai/A	1.4	4	140 g	340 g	NA	NA
	Aerial spray applications		no data	no data	no data	no data	750	2100
	Flagging for aerial spray		310	820	NA	NA	NA	NA

SUMMARY OF HANDLER RISKS FOR DIMETHOATE BY CROP TYPE (continued)

CROP	HANDLER SCENARIO	APPLICATION RATE	BASELINE TOTAL MOE		ADDITIONAL PPE TOTAL MOE		ENGINEERING CONTROLS TOTAL MOE	
			Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300
	Mixing/loading liquids for groundboom		6	17	600 g	1500 g	NA	NA
	Groundboom application		990	2500	NA	NA	NA	NA
Tree fruit & nuts (pears & apples at maximum of 0.5 lb ai/A and cherries & pecans at maximum of 0.33 lb ai/A)	Mixing/loading liquids for aerial and chemigation applications	0.5 lb ai/A	1.4	4	140 g	340 g	NA	NA
		0.33 lb ai/A	2.1	6.1	210 g	520 g	NA	NA
	Aerial spray applications	0.5 lb ai/A	no data	no data	no data	no data	750	2100
		0.33 lb ai/A	no data	no data	no data	no data	1100	3100
	Flagging for aerial spray	0.5 lb ai/A	310	820	NA	NA	NA	NA
		0.33 lb ai/A	480	1200	NA	NA	NA	NA
	Mixing/loading liquids for airblast	0.5 lb ai/A	12	35	1200 g	3000 g	NA	NA
		0.33 lb ai/A	18	53	1800 g	4500 g	NA	NA
	Airblast application	0.5 lb ai/A	92	250	130 g	360 g	NA	NA
		0.33 lb ai/A	140	380	NA	NA	NA	NA

SUMMARY OF HANDLER RISKS FOR DIMETHOATE BY CROP TYPE (continued)

CROP	HANDLER SCENARIO	APPLICATION RATE	BASELINE TOTAL MOE		ADDITIONAL PPE TOTAL MOE		ENGINEERING CONTROLS TOTAL MOE	
			Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300
Peppers	Mixing/loading liquids for aerial and chemigation applications	0.33 lb ai/A	2.1	6.1	210 g	520 g	NA	NA
	Aerial spray applications		no data	no data	no data	no data	1100	3100
	Flagging for aerial spray		480	1200	NA	NA	NA	NA
	Mixing/loading liquids for groundboom		9.1	26	910 g	2300 g	NA	NA
	Groundboom application		1500	3700	NA	NA	NA	NA
Collards, kale, mustard greens, endive (escarole), head lettuce, leaf lettuce, spinach, Swiss chard, and turnips	Mixing/loading liquids for aerial and chemigation applications	0.25	2.8	8	280 g	690 g	NA	NA
	Aerial spray applications		no data	no data	no data	no data	1500	4100
	Flagging for aerial spray		630	1600	NA	NA	NA	NA
	Mixing/loading liquids for groundboom		12	35	1200 g	3000 g	NA	NA
	Groundboom application		200	4900	NA	NA	NA	NA
Peas	Mixing/loading liquids for aerial and chemigation applications	0.16 lb ai/A	4.3	12	430 g	1100 g	NA	NA
	Aerial spray applications		no data	no data	no data	no data	2300	6500
	Flagging for aerial spray		980	2600	NA	NA	NA	NA
	Mixing/loading liquids for groundboom		19	55	1900 g	4700 g	NA	NA
	Groundboom application		3100	7700	NA	NA	NA	NA

SUMMARY OF HANDLER RISKS FOR DIMETHOATE BY CROP TYPE (continued)

CROP	HANDLER SCENARIO	APPLICATION RATE	BASELINE TOTAL MOE		ADDITIONAL PPE TOTAL MOE		ENGINEERING CONTROLS TOTAL MOE	
			Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300
Ornamentals	Mixing/loading liquids for aerial and chemigation applications	4.0 lb ai/A	0.17	0.5	27 g,dl,r	76 g,dl,r	55 g	160 g
		2.0 lb ai/A	0.34	1	55 g,dl,r	150 g,dl,r	110 g	310 g
	Aerial spray applications	4.0 lb ai/A	no data	no data	no data	no data	94	260
		2.0 lb ai/A	no data	no data	no data	no data	190	520
	Flagging for aerial spray	4.0 lb ai/A	39	100	48 dl,r 43 dl	140 dl,r 110 dl	96	270
		2.0 lb ai/A	78	210	85 dl	220 dl	190	540
	Mixing/loading liquids for groundboom	4.0 lb ai/A	0.75	2.2	120 g,dl,r 95 g,dl	330 g,dl,r 230 g,dl	NA	NA
		2.0 lb ai/A	1.5	4.4	150 g	380 g	NA	NA
	Groundboom application	4.0 lb ai/A	120	310	NA	NA	NA	NA
		2.0 lb ai/A	250	610	NA	NA	NA	NA
	Mixing/loading liquids for airblast	4.0 lb ai/A	1.5	4.4	150 g	380 g	NA	NA
		2.0 lb ai/A	3.	8.7	300 g	750 g	NA	NA
	Airblast application	4.0 lb ai/A	11	32	18 g,dl	49 g,dl	210	550
		2.0 lb ai/A	23	63	36 g, dl	98 g,dl	410	1100

SUMMARY OF HANDLER RISKS FOR DIMETHOATE BY CROP TYPE (continued)

CROP	HANDLER SCENARIO	APPLICATION RATE	BASELINE TOTAL MOE		ADDITIONAL PPE TOTAL MOE		ENGINEERING CONTROLS TOTAL MOE	
			Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300
Ornamentals (continued)	Mixing/loading/applying with backpack and knapsack sprayers	0.1 lb ai/gal	No data	No data	110 g,dl,r 100 g,dl	310 g,dl,r 270 g,dl	NA	NA
		0.06 lb ai/gal	No data	No data	110 g	310 g	NA	NA
		0.01 lb ai/gal	No data	No data	660 g	1800 g	NA	NA
	Mixing/loading/applying with low pressure handwand sprayers	0.1 lb ai/gal	1.7	5.1	300 g	720 g	NA	NA
		0.06 lb ai/gal	2.9	8.5	500 g	1200 g	NA	NA
		0.01 lb ai/gal	17	51	3000 g	7200 g	NA	NA
	Mixing/loading/applying with high pressure handwand sprayers	0.1 lb ai/gal	No data	No data	4.1 g,dl,r	11 g,dl,r	None	None
		0.06 lb ai/gal	No data	No data	6.8 g,dl,r	19 g,dl,r	None	None
		0.01 lb ai/gal	No data	No data	41 g,dl,r	110 g,dl,r	None	None
Agricultural-animal premises and poultry industry	Mixing/loading/applying with backpack and knapsack sprayers	0.1 lb ai/gal	No data	No data	110 g,dl,r 100 g,dl	310 g,dl,r 270 g,dl	NA	NA
		0.06 lb ai/gal	No data	No data	110 g	310 g	NA	NA
		0.01 lb ai/gal	No data	No data	660 g	1800 g	NA	NA
	Mixing/loading/applying with low pressure handwand sprayers	0.1 lb ai/gal	1.7	5.1	300 g	720 g	NA	NA
		0.06 lb ai/gal	2.9	8.5	500 g	1200 g	NA	NA
		0.01 lb ai/gal	17	51	3000 g	7200 g	NA	NA
	Applying Liquids with a paintbrush	2 lb ai/gal	0.96	2.8	7.5 g,dl	21 g,dl	None	None

SUMMARY OF HANDLER RISKS FOR DIMETHOATE BY CROP TYPE (continued)

CROP	HANDLER SCENARIO	APPLICATION RATE	BASELINE TOTAL MOE		ADDITIONAL PPE TOTAL MOE		ENGINEERING CONTROLS TOTAL MOE	
			Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300	Short-T UF=100	Inter.-T UF=300
Conifer seed nursery	Mixing/loading liquids for airblast/ mistblower applications	33.2 lb ai/A	0.4	1.1	58 g,dl,r	160 g,dl,r	120	330
		8.3 lb ai/A	1.5	4.2	150 g	360 g	NA	NA
	Applying with airblast/mistblower sprayers	33.2 lb ai/A	2.8	7.6	4.7 g,dl,r	13 g,dl,r	50	130
		8.3 lb ai/A	11	31	19 g,dl,r	54 g,dl,r	200	530
Non-crop land adjacent to vineyards (using rights-of-way-type equipment)	Mixing/loading wettable powders for non-crop land	2.0 lb ai/A	8.9	25	100 g,dl 160 g,r	200 g,dl 410 g,r	NA	NA
	Applying to non-crop land (uses rights-of-way data)		27	76	110 g,dl	310 g,dl	NA	NA

Note: g indicates a gloved hand scenario
dl indicates addition of a double layer of protective clothing
r indicates use of a dust mist respirator
NA indicates that MOEs ≥100 for short-term and ≥300 for intermediate-term assessment.
No Data indicates an exposure scenario was identified, but there are no acceptable data to complete assessment.
None indicates that no engineering controls are known for this exposure scenario.

2. Postapplication Risk

i) Postapplication exposure and risk calculations

When the application rate of the crops being assessed for postapplication risk differs from the application rate used in the surrogate crop DFR study, the dimethoate-specific DFR data were normalized using the following formula:

$$DFR_{(norm)} = DFR_{(study)} \; x \; \frac{application \;\; rate_{(norm)}}{application \;\; rate_{(study)}}$$

The calculation of daily exposure to dimethoate by persons entering the treated area after application is used to assess the risk to those persons. The average daily dermal dose is calculated using the following formula:

$$Dermal \;\; Dose \;\; (mg/kg/day) = \frac{(DFR \;\; (mg/cm^2) \;\; x \;\; Tc \;\; (cm^2/hr) \;\; x \;\; Abs \;\; (0.11) \;\; x \;\; ED \;\; (8hrs/day))}{BW} \; (70kg)$$

and MOE is calculated using the following formula:

$$Total \;\; MOE = \frac{LOAEL \left(\frac{mg}{kg/day} \right)}{Average \;\; Daily \;\; Dermal \;\; Dose \left(\frac{mg}{kg/day} \right)}$$

where: intermediate-term dermal LOAEL = 3.2 mg/kg/d and UF = 300.

The residues for dimethoate and omethoate (the oxon formed by dimethoate) were combined to obtain a total residue value for the three studies used for the assessment. For both the tomato and lettuce studies the residue levels (i.e., combined dimethoate and omethoate values) and dissipation rates at the California sites were significantly different from those at the Florida and Pennsylvania sites. Therefore, the results are reported for all three sites separately. The results for all three sites are also reported for the apple and grape studies.

Whenever feasible, EPA prefers to use the actual data reported in a chemical-specific study, rather than using a regression analysis to predict residue levels. Typically, postapplication studies initially collect data daily (i.e., days 0, 1, 2, and 3) and thereafter collect data at intervals (i.e., days 5, 7, 10, 14, 21). If residues dissipate below EPA's level of concern during the time period when data are collected daily, EPA prefers to use the actual data reported in a chemical-specific study to assess postapplication risks. However, if residues remain a concern beyond the

period of daily data collection, EPA uses a regression analysis to predict residue levels for those days where data are not collected. Since residues dissipated to a level not of concern within the time period where the tomato and lettuce studies reported residue data each day, actual data were used to assess postapplication exposures for all crops for which these studies were used. However, since residues were of concern for the apple and grape studies beyond the point were daily residue data were being gathered, a regression analysis was conducted using the natural log-transformed DFR data from each test site using the following equation:

$$y = mx + b$$

where:

x	=	days postapplication;
m	=	slope of the regression line;
b	=	constant; and
y	=	residue on day x.

The linear regression parameters from the grape and apple studies are described in Appendix G-1. The actual DFR data can be found in the EPA review of the respective studies. The table in Appendix G-2 lists the predicted residue values determined using natural log transformed DFR data after the last dimethoate application and the y = mx + b formula.

ii) Risk from postapplication exposures

Postapplication occupational exposure is likely following applications of dimethoate to fruit, vegetable, grain, fiber, feed, conifer seed nursery, ornamental, and other crops and sites during typical post-application activities such as harvesting, scouting, pruning, and transplanting. The results of the risk assessment for postapplication exposures indicate that the location and/or the environmental conditions near the time of application influence the estimated restricted-entry interval as does the type of plant to which the application is directed.

- For non-woody food and feed crops, margins of exposure (MOEs) exceed 300 by the day after treatment (ranging from 12-24 hours) for study sites in Florida and Pennsylvania; whereas MOEs exceed 300 by 5 days after treatment (ranging from 12 hours to 5 days) in California (See Appendix G-3 and G-4).

- For non-woody ornamentals where the application rates are relatively high (2 to 4 pounds active ingredient per acre), MOEs exceed 300 by 5 days after treatment (ranging from 2 to 5 days) for study sites in Florida and Pennsylvania; whereas MOEs exceed 300 at > 14 days after treatment (ranging from 7 to > 14 days) in California (See Appendix G-4).

- For grape crops, MOEs exceed 300 by 9 days after treatment (ranging from 6-9 days) in New York, 17 days after treatment (ranging from 8-17 days) in California, and 23 days after treatment (ranging from 14-23 days) in Washington (See Appendix G-5).

- For woody food and feed crops (i.e., tree fruits/nuts), MOEs exceed 300 by day 22 (ranging from 12 to 22 days) after treatment in New York and Michigan, whereas MOEs exceed 300 by 32 days after treatment (ranging from 27-32 days) in Washington (See Appendix G-6).

- For woody ornamentals where the application rates are relatively high (2 to 4 pounds active ingredient per acre), MOEs exceed 300 by 41 days after treatment (ranging from 18 to 41 days) for study sites in New York and Michigan; whereas MOEs exceed 300 by 60 days after treatment (ranging from 38 to 60 days) in Washington (See Appendix G-6).

- For conifer seed nurseries where rates are very high (8.3 to 33.2 pounds active ingredient per acre), MOEs exceed 300 by day 61 (ranging from 29-61 days) after treatment in New York and Michigan, whereas, MOEs exceed 300 by day 87 (ranging from 60 to 87 days) after treatment in Washington (See Appendix G-6).

3. Incident Reports

For a review of the pesticide poisoning incident data for dimethoate (Dobozy, 10/2/96 and Blondell, 12/2/99), the Agency consulted the following data bases: (1) OPP Incident Data System (IDS); (2) Poison Control Centers (PCCs); (3) California Department of Pesticide Regulation); and (4) National Pesticide Telecommunications Network (NPTN).

A review of the published incident data indicates that in outdoor agricultural uses, the primary occupational exposures associated with poisoning are post-application field residues and spray drift (see attachments Dobozy 10/02/96, Blondell 12/02/99). Compared to other organophosphates used in residential settings (many organophosphates are classified “restricted use” chemicals), dimethoate has the highest reported incidence of poisonings (none life-threatening). Residential uses are not being supported for reregistration and this is expected to mitigate any concerns for future residential exposures.

E. Aggregate Risk

Under the Food Quality Protection Act, the Agency considers contributions to risk from various exposure sources, specifically, food, drinking water, and residential. The registrants are not supporting any residential uses for dimethoate, therefore only exposures through food and drinking water were considered in the aggregate risk assessment.

The potential for other non-occupational exposures to individuals living in or near agricultural areas where dimethoate is being used were not included in the aggregate risk assessment but will be addressed at a later time when methodologies to perform such assessments are in place.

The acute aggregate risk estimate (food + water) does not exceed the Agency’s level of concern (i.e. < 100% aPAD) for most uses. The chronic aggregate risk assessment is also not of

concern. Aggregate risks based on higher application rates (4 lbs ai/A or greater) are of concern, though some of them are not being supported in reregistration.

F. Cumulative Risk

The Agency is in the process of formulating guidance for conducting cumulative risk assessment. When the guidance is completed, peer reviewed, and finalized, dimethoate and other organophosphates will be revisited to assess the cumulative effects of exposure to multiple organophosphates.

Data Needs

There are numerous dermal exposure scenarios for which HED has concerns. Based on the inadequacy of the repeated dose 21-day dermal toxicity study and the need to sufficiently characterize dermal toxicity and absorption, it is recommended that a 21-day dermal toxicity study be conducted in the rat.

Characterization/identification of radioactive residues in milk is required for confirmatory purposes. The registrant has submitted the data concerning further characterization of dimethoate residues in milk which are under review.

Radiovalidation data from the livestock metabolism studies are required for confirmatory purposes. The registrant has submitted these data which are under review.

Adequate magnitude of residue data are available for commodities used for human consumption except for the processed commodities of apples and safflower seed. The registrant has submitted safflower seed processing data which are under review.

Meat, milk, poultry, and egg storage stability data and test sample storage interval/condition information are required and are considered confirmatory. The registrant has submitted test sample storage interval/condition information, which is under review.

Short- and intermediate-term dermal and inhalation exposure assessments were made using PHED Version 1.1 surrogate data since no acceptable chemical-specific handler data were submitted. dimethoate-specific handler studies may be required pending the outcome of recommended discussions with the registrants and others on handler risk and risk mitigation.

Postapplication exposure is likely following applications of dimethoate to fruit, vegetable, grain, fiber, feed, ornamental, and other crops and sites during typical post-application activities such as harvesting, scouting, pruning, transplanting, etc. Additional chemical-specific data, particularly data to allow calculation of a transfer coefficient, from which to estimate postapplication exposure to dimethoate may be required pending the outcome of discussions with registrants and others on postapplication risk and risk mitigation.

List of Attachments

1. Dimethoate Tolerance Reassessment Summary

2. Appendix A. Residue Chemistry Science Assessments for Reregistration of Dimethoate.

3. Appendix B. Tolerance Reassessment Summary for Dimethoate (Table)

4. Appendix C. Dimethoate Codex MRLs

5. Appendix D. Baseline Occupational Short- and Intermediate-term Dermal, Inhalation, and Total Risks to Dimethoate

6. Appendix E. PPE Mitigated Occupational Short- and Intermediate-term Inhalation, Dermal, and Total Risks for Dimethoate

7. Appendix F. Engineering Controls for Occupational Short- and Intermediate-term Dermal, Inhalation, and Total Risks for Dimethoate

8. Appendix G-1. Parameters of Clean Crop® Dimethoate 400 Series Used in Postapplication Assessment

9. Appendix G-2. Predicted DFR Levels Based on Actual DFRs Detected After Clean Crop® Dimethoate 400 Application to Grapes and Apples

10. Appendix G-3. Estimated Entry-restricted Periods for Dimethoate (Derived from Lettuce DFR Data)

11. Appendix G-4. Estimated Entry-restricted Periods for Dimethoate (Derived from Tomato DFR Data)

12. Appendix G-5. Estimated Entry-restricted Periods for Dimethoate (Derived from Grape DFR Data)

13. Appendix G-6. Estimated Entry-restricted Periods for Dimethoate (Derived from Apple DFR Data)

14. Appendix H. Exposure Scenario Descriptions for the Use of Dimethoate (Occupational Exposure)

15. Dimethoate: A Comprehensive Report of the Toxicology Endpoint Selection. Paul Chin, July 20, 1999.

16. Dimethoate Addendum: Reevaluation of 5-Day Dermal Toxicity Study in Rats and Short-

term Dermal Endpoint Selection. Paul Chin, December 6, 1999.

17. Response to Novigen Acute Monte-Carlo Analysis. Mohsen Sahafeyan, January 19, 1999.

18. Probabilistic Acute Dietary Exposure Estimates for Dimethoate. Mohsen Sahafeyan, August 18, 1999.

19. Dimethoate: Interim Memorandum on the Effect of Peeling, Washing or Cooking on Concentrations of Dimethoate in Foods. Stephen DeVito, July 2, 1999.

20. Dietary Exposure Analysis for Dimethoate in Support of the Reregistration Eligibility Decision. Brian Steinwand, August 6, 1998.

21. Dietary Exposure Analysis for Dimethoate in Support of the Reregistration Eligibility Decision. Brian Steinwand, August 19, 1998. Amendment.

22. Dimethoate - Review of Pesticide Poisoning Incident Data. Virginia Dobozy, October 2, 1996.

23. Update of Dimethoate Incident Review. Jerome Blondell, December 2, 1999.

APPENDIX A

Appendix A. Residue Chemistry Science Assessments for Reregistration of Dimethoate.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
860.1200: Directions for Use	N/A = Not Applicable	Yes [2, 3]	
860.1300 (a): Plant Metabolism	N/A	No	00052088, 00052096, 00052102, 00077548, 00075584, GS008807, GS008808, GS008809
Animal Metabolism	N/A	Yes [4]	00051682, 00051683, 00077511, 00077512, 00077514, 00077525, 43583301 [5], 43583302 [5]
860.1340 & 860.1360 (c/d): Residue Analytical Methods			
- Plant commodities	N/A	No	00051669, 00051670, 00075607, 00077471, 00077547, **00159749**
- Animal commodities	N/A	Yes [6]	00075619, 00077471
860.1380 (e): Storage Stability	N/A	Yes [7]	00075553, 00075578, 00077548, **00160683**, 43348801 [8], 43828101 [9] 44001301 [10]
860.1500 (k): Magnitude of the Residue in Plants			
Root and Tuber Vegetables Group			
- Potatoes	0.2 [§180.204(a)]	No	00034364
- Turnip roots	2 [§180.204(a)]	No	00075552
Leaves of Root and Tuber Vegetables Group			
- Turnip tops	2 [§180.204(a)]	No	00077552
Leafy Vegetables (except Brassica Vegetables) Group			
- Celery	2 [§180.204(a)]	No	00075665

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
- Endive (escarole)	2 [§180.204(a)]	No	00077552
- Lettuce (head and leaf)	2 [§180.204(a)]	No	00077552
- Spinach	2 [§180.204(a)]	No	00077552
- Swiss Chard	2 [§180.204(a)]	No	00077552
Brassica (Cole) Leafy Vegetables Group			
- Broccoli	2 [§180.204(a)]	No	00077551
- Brussels sprouts	5 [§180.204(b)]	No	41619201 [11]
- Cabbage	2 [§180.204(a)]	No [12]	00077551
- Cauliflower	2 [§180.204(a)]	No	00077551
- Collards	2 [§180.204(a)]	No	00077552
- Kale	2 [§180.204(a)]	No	00077552, GS0088011
- Mustard Greens	2 [§180.204(a)]	No	00077552
Legume Vegetables Group			
- Beans (dried and succulent)	2, dry 2, lima 2, snap [§180.204(a)]	No [13]	PP3F0385, 00075607, 43910701 [14]
- Lentils	2.0 [§180.204(a)]	No [15]	

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
- Peas (dried and succulent)	2 [§180.204(a)]	No	00075554, 00075624, 43279801 [16]
- Soybean seed and aspirated grain fractions[17]	0.05(N), seed [§180.204(a)]	No	00075577
<u>Foliage of Legume Vegetables Group</u>			
- Cowpea forage and hay	None established	Yes [18]	43910701 [14]
- Field pea vines and hay	None established	No [19]	43279801 [16]
- Soybean forage and hay	2, forage and hay [§180.204(a)]	No	00075577
<u>Fruiting Vegetables (except Cucurbits) Group</u>			
- Peppers	2 [§180.204(a)]	No	00077549
- Tomatoes	2 [§180.204(a)]	No	00077550, **00159758**
<u>Cucurbits Vegetables Group</u>			
- Melons	1 [§180.204(a)]	No	00075529
<u>Citrus Fruits Group</u>			
- Grapefruit	2 [§180.204(a)]	No	00077499
- Lemons	2 [§180.204(a)]	No	00073441
- Oranges	2 [§180.204(a)]	No	00073441, 43308701[20]
- Tangerines	2 [§180.204(a)]	No	00077499

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
Pome Fruits Group			
- Apples	2 [§180.204(a)]	No	00051669, 00051684, 00077548, 00075557, **00159757**
- Pears	2 [§180.204(a)]	No	00051685, 00077548
Stone Fruits Group			
- Cherries	2 [§180.204(b)]	No	PP#7E1949, **00163323** [21] Note[22]
Berries Group			
- Blueberries	1 [§180.204(a)]	No	60 FR 42446 [23]
Tree Nuts Group			
- Pecans	0.1 [§180.204(a)]	No	00077484
Cereal Grains Group			
- Corn (field) grain and aspirated grain fractions[17]	0.1(N), corn grain [§180.204(a)]	No	00050742
- Corn (pop) grain	0.1(N), corn grain [§180.204(a)]	No [24]	
- Sorghum grain and aspirated grain fractions[17]	0.1, grain [§180.204(a)]	No	00075549, 43279802 [16]
- Wheat grain and aspirated grain fractions[17]	0.04(N), grain [§180.204(a)]	No	00075540, 00075662, 40650801 [25]
Forage, Fodder, Hay, and Straw of Cereal Grains Group			
- Corn (field) forage and stover (fodder)	1, corn forage and corn fodder [§180.204(a)]	No	00050742, 00075594
- Corn (pop) stover (fodder)	1, corn forage and corn fodder [§180.204(a)]	No [24]	
- Sorghum forage and stover (fodder)	0.2, forage [§180.204(a)]	No[26]	00075549, 43279802 [16]

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
- Wheat forage, hay, and straw	2, green fodder and straw [§180.204(a)]	No	00075540, 00075662, 40650801 [25]
<u>Non-Grass Animal Feeds</u>			
- Alfalfa forage and hay	2, alfalfa [§180.204(a)]	No	00075584, 00075659
- Alfalfa grown for seed	None Established	Yes[27]	
<u>Miscellaneous Commodities</u>			
- Asparagus	0.15 [§180.204(b)]	No	43280901 [28]
- Cottonseed and cotton gin byproducts	0.1, cottonseed [§180.204(a)]	Yes [29]	00075601, **00147852** [30]
- Grapes	1 [§180.204(a)]	No	00075531, 00075590, 00077471
- Safflower seed	0.1 [§180.204(a)]	No	00075601
- Tobacco	None established	No [31]	00045838
- Grasses grown for seed	None established	Yes [32]	
860.1520 (l): Magnitude of the Residues in Processed Food/Feed			
- Apples	--	Yes [33]	**00159757** [34]
- Citrus	5, dried citrus pulp [§186.2100]	No	43308701[20]
- Corn, Field	--	No	43293701 [20]
- Cottonseed	--	No	43318401 [20]
- Grapes	--	No	00075590, 00075637
- Potatoes	--	No	43288202 [20]
- Safflower	--	Yes [35]	

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
- Soybeans	--	No[36]	
- Tomatoes	--	No	**00159758,** 43554401 [20]
- Wheat	--	No[37]	43288201 [20]
860.1480 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs[38]			
- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	0.02, fat, meat and mbyp of cattle, goats, hogs, horses, and sheep; and 0.002, milk [§180.204(a)]	No[39]	00073444, 00077494, 00077501, 00077543
- Eggs and the Fat, Liver, Meat, and Meat Byproducts of Poultry	0.02 [§180.204(a)]	No	00077495
860.1400 (f): Nature and Magnitude of the Residue in Potable Water	N/A	N/A	
(g): Nature and Magnitude of the Residue in Fish	N/A	N/A	
(h): Nature and Magnitude of the Residue in Irrigated Crops	N/A	N/A	
860.1460 (i): Magnitude of the Residue in Food-Handling Establishments	N/A	N/A	
860.1850: Rotational Crops (Confined)	--	No	43698001 [40]
860.1900: Rotational Crops (Field)	--	No	

1. Unbolded references were reviewed in the Residue Chemistry Chapter of the Dimethoate Reregistration Standard dated 9/30/82. References in **bold** were reviewed in the Residue Chemistry Chapter of the Dimethoate Final Reregistration Standard and Tolerance Reassessment (FRSTR) dated 10/1/87. All other references were reviewed as noted.

2. All end-use product labels must be amended, as recommended, such that they are consistent with the food/feed use patterns specified in the table on page 18.

3. CBRS has found that at least one product (EPA Reg. No. 34704-207; Clean Crop® Dimethoate 400, registered to Platte Chemical Co., Inc.) permits aerial applications of Dimethoate to crops (e.g., wheat, potatoes, field corn, cotton, and tomatoes) in minimum spray volumes less than 2 gallons/A and to tree crops (e.g., oranges) in minimum spray volumes less than 10 gallons/A. The basic producer has previously stated that no field trials reflecting use of aerial equipment would be conducted for Dimethoate. Therefore, the registrant(s) must either: (I) revise their product label(s) to permit aerial applications to crops in a minimum of 2 gallons water per acre (or 10 gallons per acre in the case of tree crops), (ii) delete aerial applications to crops from their product labels, or (iii) submit residue data reflecting applications in less than 2 gallons per acre (or 10 gallons per acre in the case of tree crops).

4. Further characterization and identification of radioactive residues in milk samples collected from the submitted ruminant metabolism study (MRID 43583302) are required for confirmatory purposes. The polar residues extracted with acetonitrile: water which accounted for 57% of the total radioactive residues in milk should be hydrolyzed, characterized chromatographically, and identified. The acidic fractions following anion exchange chromatography of solvent-extracted milk residues which contained almost one-half of the total radioactivity must be further characterized and identified.

5. CBRS No. 15404, DP Barcode D213956, 4/30/96, B. Cropp-Kohlligian.

6. Radiovalidation data from the livestock metabolism studies (MRIDs 43583301 and 43583302) are required. Representative samples from the livestock metabolism studies must be analyzed using the currently accepted enforcement analytical method. If additional metabolites of concern are identified in milk which are not detected using existing analytical methods, then new animal analytical methods will be required.

7. Storage stability data depicting the stability of Dimethoate residues of concern in meat, milk, poultry, and eggs are required. Data should adequately reflect test sample storage intervals and conditions from available animal magnitude of the residue data.

   When new apple processing studies are conducted, they should include supporting concurrent storage stability studies.

8. CBRS No. 14333, DP Barcode D207004, 8/17/95, B. Cropp-Kohlligian.

9. CBRS No. 16837, DP Barcode D222835, 4/15/96, B. Cropp-Kohlligian.

10. CBRS No. 17465, DP Barcode D228186, 8/28/96, B. Cropp-Kohlligian.

11. CBTS No. 7073, 2/28/91, S. Malak.

12. The registrant must amend all pertinent label(s) to reflect an increase in the established PHI for application of Dimethoate to cabbage from 3 days to 7 days.

13. If the registrant wishes to support the use of Dimethoate on beans (including cowpeas grown for livestock feeding) at a maximum use rate of 0.17 lb ai/A (a rate equivalent to 1/3 the currently registered maximum use rate to beans but harmonized with the use pattern on peas), then the registrant must amend end-use product labels permitting use on beans to lower the currently registered use rate of Dimethoate on beans from 0.5 lb ai/A to 0.17 lb ai/A.

14. CBRS No. 16916, DP Barcode No. D223220, 5/13/96, B. Cropp-Kohlligian.

15. Data to support use of Dimethoate on lentils were translated from dried beans.

16. CBRS No. 14025, DP Barcode D205590, 11/6/95, B. Cropp-Kohlligian.

17. CBRS recommended in favor of the request for a waiver from the need to provide Dimethoate aspirated grain fractions data (CBRS No. 12575, DP Barcode D195313, 10/13/93, B. Cropp-Kohlligian).

18. The registrant is required to either petition the Agency for the establishment of tolerances for total residues of dimethoate and omethoate in/on bean forage and bean hay or amend product labels to restrict the use of dimethoate to beans (not including cowpeas). The following options are available to the registrant:

    If the registrant wishes to support the use of dimethoate on beans (including cowpeas grown for livestock feeding) at the currently registered maximum use rate of 0.5 lb ai/A, then the registrant must: (I) submit new bean forage and hay magnitude of the residue data reflecting the currently registered maximum use rate of dimethoate on beans (0.5 lb ai/A), and (ii) propose tolerances for the combined residues of dimethoate and omethoate in/on bean forage and bean hay.

    If, however, the registrant wishes to support the use of dimethoate on beans (including cowpeas grown for livestock feeding) at a maximum use rate of 0.17 lb ai/A (a rate equivalent to 1/3 the currently registered maximum use rate to beans but harmonized with the use pattern on peas), then the registrant must: (I) amend end-use product labels permitting use on beans to lower the currently registered use rate of dimethoate on beans from 0.5 lb ai/A to 0.17 lb ai/A and (ii) propose tolerances for the combined residues of dimethoate and omethoate in/on bean forage and bean hay. The available data indicate that the combined residues of dimethoate and omethoate in/on bean forage and bean hay harvested on the day of an application of the 4 lb/gal EC formulation at 0.17 lb ai/A will not exceed 6 ppm and 10 ppm, respectively.

    If the registrant wishes to support the use of Dimethoate on beans (not including cowpeas), then the registrant must amend end-use product labels permitting use on beans to specify "beans (not including cowpeas)", in which case tolerances for the combined residues of Dimethoate and Omethoate in/on bean forage and bean hay would not be required.

19. The registrant is required to either petition the Agency for the establishment of tolerances for total residues of dimethoate and omethoate in/on pea vines and pea hay or amend product labels to restrict the use of dimethoate to peas (not including field peas).

    If the registrant wishes to support the use of dimethoate on peas (including field peas grown for livestock feeding only), then the registrant must propose tolerances for the combined residues of dimethoate and omethoate in/on pea vines and hay. Based on the available pea field trial data and assuming that the registrant wishes to harmonize the registered PHIs for peas (currently 0-days) and that for pea vines and hay (currently 21-days), CBRS concludes that appropriate tolerances would be 8 ppm and 13 ppm for pea vines and pea hay, respectively. The registrant should amend the currently registered use of dimethoate on peas to include a 0-day PHI for pea vines and hay.

    If, however, the registrant wishes to support the use of dimethoate on peas (not including field peas), then the registrant must amend product labels permitting use on peas to specify "peas (not including field peas)" and tolerances for the combined residues of dimethoate and omethoate in/on pea vines and hay would not be required.

20. CBRS Nos. 14023, 14250, 14224, and 15267, DP Barcodes D205591, D206804, D206555, and D213099, 2/15/96, B. Cropp-Kohlligian.

21. Reviewed in CB No. 1428, 9/26/86, L. Cheng, and also reviewed in the Dimethoate FRSTR.

22. A magnitude of the residue study, entitled "Analysis of Sweet Cherries for the Residues of Dimethoate and Dimethoxon." by L. Durand and M. Deinzer, Dept. of Agricultural Chemistry, Oregon State University, Corvallis, OR (3/8/88), was submitted in support of a Special Local Needs Registration and reviewed by M. Metzger 11/22/88 (CB#4496, -97, -98, -99, 4500, -01, and -02). No MRID assigned.

23. See memoranda by R. Perfetti dated 5/25/94 and 2/6/95, no assigned CBRS No. or DP Barcode.

24. Data to support the use of dimethoate on popcorn (SLNs TX93002100 and TX93001900) were translated from field corn (CBTS No. 12782, DP Barcode D196467, 12/3/93, D. Davis).

25. CB No. 4558, 1/10/89, L. Propst.

26. Available grain sorghum forage and hay data are adequate to satisfy data requirements and indicate that tolerances for residues of dimethoate and omethoate in/on grain sorghum forage and grain sorghum stover should be 0.1 ppm (Memo S. Mason, 01/18/99).

27. Alfalfa seed data are required to support the use of dimethoate on alfalfa grown for seed.

28. CBTS No. 14062, DP Barcode D205269, 3/21/95, W. Cutchin; CBTS No. 15427, DP Barcode D214187, 5/1/95, W. Cutchin.

29. As a result of changes in the Livestock Feeds Table (Table 1, July 1996), the Agency now considers cotton gin byproducts to be a significant livestock feed item. Data depicting the combined residues of dimethoate and omethoate in/on cotton gin byproducts resulting from the maximum registered use rate of dimethoate to cotton are now required. The field trials should be of sufficient acreage such that adequate amounts of cotton gin byproducts obtained by commercial ginning machinery are yielded for residue analysis. At least three field trials for each type of harvesting (stripper and picker) are needed, for a total of six field trials.

30. Reviewed in CB No. 757, 5/28/85, J. Garbus, and also reviewed in the Dimethoate FRSTR.

31. According to REFs (7/2/96) tobacco is no longer an active use site for any registrant. Therefore, previously requested magnitude of the residue data on tobacco are no longer required. However, should Cheminova or any other registrant decide to support dimethoate uses on tobacco in the future, data will be required to assess the exposure of man to dimethoate residues of concern in/on tobacco and its products.

32. Magnitude of the residue data on grass forage, hay, and seed are required to support registrations in OR (including SLN OR85004400) for grass grown for seed. Data are required depicting residues in/on grass forage and hay regrowth after seed harvest reflecting the maximum use rate permitted for the use of dimethoate on grass grown for seed.

33. CBRS has reevaluated a previously submitted apple processing study and concluded that it is inadequate to satisfy reregistration requirements. A new apple processing study is required for confirmatory purposes.

34. This MRID was reviewed in the Dimethoate FRSTR and reevaluated in CBRS No. 17107, DP Barcode D225105, 4/15/96, B. Cropp-Kohlligian.

35. As requested in the Dimethoate FRSTR, a safflower processing study must be conducted. Data depicting total residues of dimethoate and omethoate in meal and refined oil processed from safflower seed bearing measurable, weathered residues are required. It may be necessary to use exaggerated rates to obtain measurable residues in the RAC.

36. Soybean processing data are not required. Based on field trial data (MRID 00075577) demonstrating that dimethoate residues of concern in/on soybeans were below the LOQ after treatment with dimethoate at an exaggerated application rate (5x).

37. As a result of changes in the Livestock Feeds Table (Table 1, July 1996), magnitude of the residue data are currently required by the Agency for wheat germ. Based on available wheat processing data, the Agency has determined that residues of dimethoate and omethoate are not likely to concentrate in wheat germ and will waive the requirement for residue data on wheat germ. No tolerance for residues of dimethoate and omethoate are required on wheat germ (Memo S. Mason, 01/18/99).

38. Magnitude of the residue data are available to support livestock premise treatments with 1% spray emulsions. Labels permitting livestock premise treatments must be modified, as needed, to reflect the spray application/treatment patterns for which adequate magnitude of the residue data are available.

39. Metabolism data are outstanding on milk. Once these data are submitted, the available magnitude of the residue data for milk will be reevaluated and tolerance revisions may be required (D215029, CBTS No. 15499, G. Kramer, 5/9/95).

40. CBRS No. 15845, DP Barcode D217165, 7/3/96, B. Cropp-Kohlligian.

APPENDIX B

Dimethoate Tolerance Reassessment Summary

Tolerances for dimethoate residues in/on plant and animal commodities [40 CFR §180.204 (a) and (b)] and in dried citrus pulp [40 CFR §186.2100] are currently expressed in terms of the total residues of dimethoate [*O,O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorodithioate] and its oxygen analog, omethoate, [*O,O*-dimethyl *S*-(*N*-methylcarbamoylmethyl) phosphorothioate]. A summary of dimethoate tolerance reassessment and recommended modifications in commodity definitions are presented in Appendix B.

1. Tolerances Listed Under 40 CFR §180.204(a)

Adequate data are available to reassess the established tolerances for dimethoate residues of concern in/on: alfalfa; apples; blueberries; broccoli; cabbage; cauliflower; celery; collards; corn, fodder; corn, forage; corn, grain; cottonseed; endive (escarole); grapefruit; grapes; kale; lemons; lentils; lettuce; melons; mustard greens; oranges; pears; peas; pecans; peppers; potatoes; safflower seed; sorghum, forage; sorghum, grain; soybeans; soybean, forage; soybean, hay; spinach; Swiss chard; tangerines; tomatoes; turnips, roots; turnips, tops; wheat grain; wheat green fodder; wheat straw; eggs; and the fat, meat, and mbyp of cattle, goats, hogs, horses, poultry, and sheep. [Note: Some commodity definitions must be corrected. See Appendix B for details.]

Based on the available magnitude of the residue data reflecting the maximum use rate for dimethoate on turnips, the currently established tolerance for dimethoate residues of concern in/on turnip roots should be lowered from 2 ppm to 0.2 ppm.

The established tolerance for lentils should be revoked since the tolerance for peas applies to lentils [40 CFR §180.1(h)].

The adequacy of the established tolerances for dry beans, lima beans, and snap beans cannot be ascertained at this time since clarification (and appropriate label amendments) are required concerning the maximum use rate the registrant wishes to support for beans.

The adequacy of the currently established tolerance on milk cannot be reassessed until outstanding metabolism data on milk are evaluated. Once these data are reviewed, the available magnitude of the residue data for milk will be reevaluated and tolerance revisions may be required.

As requested in the dimethoate FRSTR, the designation "(N)" should be deleted from the entries for the following commodities: the fat, meat, and mbyp of cattle, goats, hogs, horses, poultry, and sheep; corn, grain; eggs; milk; soybeans; and wheat, grain.

2. Tolerances Needed Under 40 CFR §180.204(a)

The registrant must propose a tolerance for the total residues of dimethoate and its oxygen analog, omethoate in/on wheat hay. CBRS does not expect residues to be higher than the tolerance level established for wheat straw. Therefore, a level of 2 ppm may be proposed for wheat hay.

The Agency has determined that the available data for grain sorghum hay are sufficient to satisfy grain sorghum stover data requirements and to establish a tolerance of 0.1 ppm for grain sorghum stover.

The Agency will determine the need for tolerances for the combined residues of dimethoate and its oxygen analog omethoate in the processed commodities of safflower and apples once the requested processing data have been submitted and evaluated.

As a result of changes in the Livestock Feeds Table (Table 1, July 1996), magnitude of the residue data are currently required by the Agency for cotton gin byproducts and the RACs will be determined on receipt of the requested data.

The need for tolerances for bean forage, bean hay, pea vines, and pea hay depends on whether or not the registrant wishes to support use of dimethoate on the field type(s) of beans (including cowpeas grown for livestock feeding) and peas (including field peas).

3. Tolerances Listed Under 40 CFR §180.204(b)

Adequate data are available to reassess the established tolerances with regional registration, as defined in §180.1(n), for dimethoate residues of concern in/on asparagus and cherries.

The available magnitude of the residue data in Brussels sprouts are adequate to support a national registration for the use of dimethoate on Brussels sprouts. Therefore, the currently established tolerance with regional registrations for dimethoate residue of concern in/on Brussels sprouts should be changed to a tolerance <u>without</u> regional registrations at the same level (5 ppm) and listed under 40 CFR §180.204(a).

4. Tolerances Listed Under 40 CFR §186.2100

Based on the results of an acceptable orange processing study, the currently established feed additive tolerance listed under 40 CFR §186.2100 for the combined residues of dimethoate and its oxygen analog omethoate in citrus dried pulp should be revoked concomitant with the

establishment of a tolerance listed under 40 CFR §180.204(a) for these same residues in citrus dried pulp. The available data indicate that a 4 ppm tolerance for the combined residues of dimethoate and its oxygen analog omethoate in citrus dried pulp would be appropriate.

Tolerance Reassessment Summary for Dimethoate.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.204(a):			
Alfalfa	2	2	Separate tolerances should be established for *Alfalfa, forage* and *Alfalfa, hay*, each at 2 ppm
Apples	2	2	
Pears	2	2	
Beans, dry	2	TBD [1]	The adequacy of these tolerances cannot be ascertained until the registrant clarifies the maximum use rate they wish to support on beans. [*Beans, dried and succulent*]
Beans, lima	2	TBD	
Beans, snap	2	TBD	
Blueberries	1	1	
Broccoli	2	2	
Cabbage	2	2	
Cauliflower	2	2	
Collards	2	2	
Kale	2	2	
Mustard greens	2	2	
Cattle, fat	0.02(N)	0.02	Negligible residue designation is inappropriate.
Cattle, mbyp	0.02(N)	0.02	
Cattle, meat	0.02(N)	0.02	
Celery	2	2	
Endive (escarole)	2	2	
Lettuce	2	2	
Spinach	2	2	
Swiss chard	2	2	
Corn, fodder	1	1	Separate tolerances should be established for *Corn, field, stover (fodder)* and *Corn, pop, stover (fodder)*, each at 1 ppm.
Corn, forage	1	1	*[Corn, field, forage]*
Corn, grain	0.1(N)	0.1	Separate tolerances should be established for *Corn, field, grain* and *Corn, pop, grain*, each at 0.1 ppm. Negligible residue designation is inappropriate.
Cottonseed	0.1	0.1	*[Cotton, undelinted seed]*

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Eggs	0.02(N)	0.02	Negligible residue designation is inappropriate.
Goats, fat	0.02(N)	0.02	
Goats, mbyp	0.02(N)	0.02	
Goats, meat	0.02(N)	0.02	
Grapefruit	2	2	
Lemons	2	2	
Oranges	2	2	
Tangerines	2	2	
Grapes	1	1	
Hogs, fat	0.02(N)	0.02	Negligible residue designation is inappropriate.
Hogs, mbyp	0.02(N)	0.02	
Hogs, meat	0.02(N)	0.02	
Horses, fat	0.02(N)	0.02	
Horses, mbyp	0.02(N)	0.02	
Horses, meat	0.02(N)	0.02	
Lentils	2.0	Revoke	The established tolerance for peas applies to lentils.
Melons	1	1	
Milk	0.002(N)	TBD	Once outstanding metabolism data are submitted, the available magnitude of the residue data for milk will be reevaluated and tolerance revisions may be required. Negligible residue designation is inappropriate.
Peas	2	2	[*Peas, dried and succulent*]
Pecans	0.1	0.1	
Peppers	2	2	
Tomatoes	2	2	
Potatoes	0.2	0.2	
Poultry, fat	0.02(N)	0.02	Negligible residue designation is inappropriate.
Poultry, mbyp	0.02(N)	0.02	
Poultry, meat	0.02(N)	0.02	
Safflower seed	0.1	0.1	*[Safflower, seed]*
Sheep, fat	0.02(N)	0.02	Negligible residue designation is inappropriate.
Sheep, mbyp	0.02(N)	0.02	
Sheep, meat	0.02(N)	0.02	
Sorghum, forage	0.2	0.1	Based on available field trial data, HED recommends a lower tolerance.
Sorghum, grain	0.1	0.1	
Soybeans	0.05(N)	0.05	Negligible residue designation is inappropriate.
Soybeans, forage	2	2	
Soybeans, hay	2	2	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Turnips, roots	2	0.2	Based on available field trial data, HED recommends a lower tolerance for dimethoate residues of concern in/on turnip roots.
Turnips, tops	2	2	
Wheat, grain	0.04(N)	0.04	Negligible residue designation is inappropriate.
Wheat, green fodder	2	2	*[Wheat, forage]*
Wheat, straw	2	2	
Tolerances That Need To Be Proposed/Established Under 40 CFR §180.204(a):			
Cowpeas, forage	None	TBD	Tolerances for these commodities will be required if the registrant wishes to support use of dimethoate on cowpeas grown for livestock feeding.
Cowpeas, hay	None	TBD	
Cotton, gin byproducts	None	TBD	Residue data are required.
Peas, field, vines	None	TBD	Tolerances for these commodities will be required if the registrant wishes to support use of dimethoate on field peas.
Peas, field, hay	None	TBD	
Sorghum, stover (fodder)	None	0.1	
Wheat hay	None	2 ppm	CBRS does not expect residues in/on wheat hay to be higher than the tolerance level established for wheat straw. Therefore, a level of 2 ppm may be proposed for wheat hay.
Tolerances Listed Under 40 CFR §180.204(b)			
Asparagus	0.15	0.15	
Brussels sprouts	5	5	CBRS recommends that this tolerance be listed under 40 CFR §180.204(a).
Cherries	2	2	
Tolerances Listed Under 40 CFR §186.2100			
Dried citrus pulp	5	Revoke	Revoked concomitant with the establishment of tolerance for *[Citrus, pulp, dried]* - to be listed under 40 CFR §180.204(a).

1. TBD = To be determined. Residue data and/or label revisions are outstanding.

APPENDIX C

CODEX HARMONIZATION

The Codex Alimentarius Commission has established separate maximum residue limits (MRLs) for dimethoate *per se* and omethoate *per se* in/on various commodities (see *Guide to Codex*

Maximum Limits for Pesticide Residues, Part 2, FAO CX/PR, 4/93) resulting from application of the insecticides dimethoate, formothion, and omethoate. Formothion and omethoate are presently not registered for use in the U.S. The Codex and U.S. tolerance are not harmonized with respect to MRL/tolerance expression since the U.S. tolerance expression is in terms of the combined residues of dimethoate and omethoate, as a metabolite.

The U.S. at this time does not support separate dimethoate and omethoate limits for dimethoate uses, nor does it support coverage of dimethoate residues resulting from use of formothion, for which there are no registered U.S. uses.

A comparison of the Codex MRLs and the corresponding **reassessed** U.S. tolerances is presented in Appendix C. Although not harmonized with respect to expression, Appendix C shows that the reassessed U.S. tolerances and Codex MRLs are at the same levels for: cabbages, head; cherries; citrus fruits; grapes; and lettuce, head.

APPENDIX C cont'd

Dimethoate Codex MRLs (expressed as dimethoate *per se*) and applicable dimethoate U.S. tolerances (expressed in terms of the combined residues of dimethoate and omethoate).

Codex			Reassessed U.S. Tolerance (ppm)	Recommendation And Comments
Commodity (As Defined)	MRL [1] (mg/kg)	Step		
Apple	1	CXL	2	
Banana	1	CXL	--	
Beetroot	0.2	CXL	--	
Brussels sprouts	2	CXL	5	
Cabbages, Head	2	CXL	2	
Carrot	1	CXL	--	
Celery	1	CXL	2	
Cherries	2	CXL	2	
Citrus fruits	2	CXL	2	
Currant, Black	2	CXL	--	
Grapes	1	CXL	1	
Hops, Dry	3	CXL	--	
Kale	0.5	CXL	2	
Lettuce, Head	2	CXL	2	
Olive oil, Refined	0.05 *	CXL	--	
Olives	1	CXL	--	
Olives, Processed	0.05 *	CXL	--	
Onion, Bulb	0.2	CXL	--	
Peach	2	CXL	--	
Pear	1	CXL	2	
Peas (pods and succulent = immature seeds)	0.5	CXL	2	
Peppers	1	CXL	2	
Plums (including prunes)	0.5	CXL	--	
Potato	0.05	CXL	0.2	
Spinach	1	CXL	2	
Strawberry	1	CXL	--	
Sugar beet	0.05	CXL	--	
Sugar beet leaves or tops	1	CXL	--	
Tomato	1	CXL	2	
Turnip, Garden	0.5	CXL	2	
Witloof chicory (sprouts)	0.5	CXL	--	

1. An asterisk (*) signifies that the MRL was established at or about the limit of detection.

APPENDIX D. Baseline Occupational Short-and Intermediate-Term Dermal, Inhalation and Total Risks to Dimethoate

Exposure Scenario (Scen #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (ug/lb ai)[b]	Maximum Application Rate (lb ai/A)[c]	Daily Acres Treated[d]	Baseline Inhalation Dose (mg/kg/d)[e]	Baseline Inhalation MOE[f]		Baseline Dermal Dose (mg/kg/d)[g]		Baseline Dermal MOE[h]		Baseline Total Daily Dose (mg/kg/d)[I]		Total MOE[j]	
						Short-term (UF 100)	Int.-term (UF 300)	Short-term	Int.-term	Short-term (UF 100)	Int.-term (UF 300)	Short-term	Int.-term	Short-term (UF 100)	Int.-term (UF 300)
Mixer/Loader Risks															
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	2.9	1.2	4.0	350	0.024	83	130	58	6.4	0.17	0.5	58	6.4	0.17	0.5
			2.0		0.012	170	270	29	3.2	0.34	911	29	3.2	0.34	1
			0.67		0.004	500	800	9.7	1.1	1.0	3	9.7	1.1	1.0	3
			0.5		0.003	670	1100	7.3	0.8	1.4	4	7.3	0.8	1.4	4
			0.33		0.002	1000	1600	4.8	0.53	2.1	6.1	4.8	0.53	2.1	6.1
			0.25		0.0015	1300	2100	3.6	0.4	2.8	8	3.6	0.4	2.8	8
			0.16		0.00096	2100	3300	2.3	0.26	4.3	13	2.3	0.26	4.3	12
Mixing/Loading Liquids for Groundboom Application (1b)			4.0	80	0.0055	360	580	13	1.5	0.75	2.2	13	1.5	0.75	2.2
			2.0		0.0027	730	1200	6.6	0.73	1.5	4.4	6.6	0.73	1.5	4.4
			0.67		0.00092	2200	3500	2.2	0.24	4.5	13	2.2	0.25	4.5	13
			0.5		0.00069	2900	4700	1.7	0.18	6	18	1.7	0.18	6	17
			0.33		0.00045	4400	7100	1.1	0.12	9.1	27	1.1	0.12	9.1	26
			0.25		0.00034	5800	9300	0.83	0.091	12	35	0.83	0.091	12	35
			0.16		0.00022	9100	15000	0.53	0.058	19	55	0.53	0.059	19	55
Mixing/Loading Liquids for Airblast Sprayer (1c)			33.2	20	0.011	180	280	28	3	0.4	1.1	28	3.0	0.4	1.1
			8.3		0.0028	700	1100	6.0	0.76	1.5	4.2	6.9	0.76	1.5	4.2
			4.0	40	0.0027	730	1200	6.6	0.73	1.5	4.4	6.6	0.73	1.5	4.4
			2.0		0.0014	1500	2300	3.3	0.36	3	8.8	3.3	0.37	3	8.7
			0.5		0.00034	5800	9300	0.83	0.091	12	35	0.83	0.091	12	35
			0.33		0.00023	8800	14000	0.55	0.06	18	53	0.55	0.06	18	53

APPENDIX D. Baseline Occupational Short-and Intermediate-Term Dermal, Inhalation and Total Risks to Dimethoate (continued)

Exposure Scenario (Scen #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (ug/lb ai)[b]	Maximum Application Rate (lb ai/A)[c]	Daily Acres Treated[d]	Baseline Inhalation Dose (mg/kg/d)[e]	Baseline Inhalation MOE[f]		Baseline Dermal Dose (mg/kg/d)[g]		Baseline Dermal MOE[h]		Baseline Total Daily Dose (mg/kg/d)[I]		Total MOE[j]	
						Short-term (UF 100)	Int.-term (UF 300)	Short-term	Int.-term	Short-term (UF 100)	Int.-term (UF 300)	Short-term	Int.-term	Short-term (UF 100)	Int.-term (UF 300)
Mixing/Loading Wettable-Powders for Aerial/Chemigation Application (2a)	3.7	43	2.0	350	0.43	4.7	7.4	37	4.1	0.27	0.79	37	4.5	0.26	0.71
Mixing/Loading Wettable-Powders for Groundboom Application (2b)			2.0	80	0.098	20	33	8.5	0.93	1.2	3.4	8.6	1.0	1.1	3.1
Mixing/Loading Wettable Powders for Airblast Sprayer (2c)			2.0	40	0.049	41	65	4.2	0.47	2.4	6.9	4.3	0.51	2.2	6.2
Mixing/Loading Wettable Powders for Non-crop land adjacent to vineyards (2d)			2.0	10	0.012	160	260	1.1	0.12	9.5	28	1.1	0.13	8.9	25
Applicator Risks															
Applying Liquids with Aircraft (3)	See Eng. Controls	See Eng. Controls	4.0	350	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.
			2.0												
			0.67												
			0.5												
			0.33												
			0.25												
			0.16												
Applying Liquids with Helicopter Aircraft (4)	Insuff. Data (see applying liquids with aircraft)	Insuff. Data (see applying liquids with aircraft)	same as aircraft	350	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.	See Eng. Cont.

APPENDIX D. Baseline Occupational Short-and Intermediate-Term Dermal, Inhalation and Total Risks to Dimethoate (continued)

Exposure Scenario (Scen #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (ug/lb ai)[b]	Maximum Application Rate (lb ai/A)[c]	Daily Acres Treated[d]	Baseline Inhalation Dose (mg/kg/d)[e]	Baseline Inhalation MOE[f]		Baseline Dermal Dose (mg/kg/d)[g]		Baseline Dermal MOE[h]		Baseline Total Daily Dose (mg/kg/d)[I]		Total MOE[j]	
						Short-term (UF 100)	Int.-term (UF 300)	Short-term	Int.-term	Short-term (UF 100)	Int.-term (UF 300)	Short-term	Int.-term	Short-term (UF 100)	Int.-term (UF 300)
Applying Liquids with a Groundboom Sprayer (5)	0.014	0.74	4.0	80	0.0034	590	950	0.064	0.007	160	450	0.067	0.01	120	310
			2.0		0.0017	1200	1900	0.032	0.0035	310	910	0.034	0.0052	250	610
			0.67		0.00057	3500	5600	0.011	0.0012	930	2700	0.011	0.0017	740	1800
			0.5		0.00042	4700	7600	0.008	0.00088	1300	3600	0.0084	0.0013	990	2500
			0.33		0.00028	7200	11000	0.0053	0.00058	1900	5500	0.0056	0.0009	1500	3700
			0.25		0.00021	9500	15000	0.0040	0.00044	2500	7300	0.0042	0.0007	2000	4900
			0.16		0.00014	15000	24000	0.0026	0.00028	3900	11000	0.0027	0.0004	3100	7700
Applying Liquids Using a Paintbrush (6)	180	280	2 lb ai/gal	2 gal	0.016	130	200	10	1.1	0.97	2.8	10	1.1	0.96	2.8
Applying Liquids Using an Airblast Sprayer (7)	0.36	4.5	33.2	20	0.043	47	75	3.4	0.38	2.9	8.5	3.5	0.42	2.8	7.6
			8.3		0.011	190	300	0.85	0.094	12	34	0.86	0.10	11	31
			4.0	40	0.01	190	310	0.82	0.91	12	35	0.83	0.1	11	32
			2.0		0.0051	390	620	0.41	0.045	24	71	0.42	0.05	23	63
			0.5		0.0013	1600	2500	0.1	0.011	97	280	0.10	0.013	92	250
			0.33		0.00085	2400	3800	0.068	0.0075	150	430	0.069	0.0083	140	380
Applying Ready-to-Use Liquids (8)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Applying Liquids to Non-crop land adjacent to vineyards (rights-of-way data) (9)	1.3	3.9	2	10	0.0011	1800	2900	0.37	0.041	27	78	0.37	0.042	27	76
Mixer/Loader/Applicator Risks															
Soil Injection (10)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Backpack Sprayer/Knapsack (11)	No Data See PPE	30	0.10 lb ai/gal	40 gal	0.0017	1200	1900	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE
			0.06 lb ai/gal		0.001	1900	3100	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE

APPENDIX D. Baseline Occupational Short-and Intermediate-Term Dermal, Inhalation and Total Risks to Dimethoate (continued)

Exposure Scenario (Scen #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (ug/lb ai)[b]	Maximum Application Rate (lb ai/A)[c]	Daily Acres Treated[d]	Baseline Inhalation Dose (mg/kg/d)[e]	Baseline Inhalation MOE[f]		Baseline Dermal Dose (mg/kg/d)[g]		Baseline Dermal MOE[h]		Baseline Total Daily Dose (mg/kg/d)[I]		Total MOE[j]	
						Short-term (UF 100)	Int.-term (UF 300)	Short-term	Int.-term	Short-term (UF 100)	Int.-term (UF 300)	Short-term	Int.-term	Short-term (UF 100)	Int.-term (UF 300)
			0.01 lb ai/gal		0.00017	12000	19000	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE
Low Pressure Handwand (liquid formulation) (12)	100	30	0.10 lb ai/gal	40 gal	0.0017	1200	1900	5.7	0.63	1.8	5.1	5.7	0.63	1.7	5.1
			0.06 lb ai/gal		0.001	1900	3100	3.4	0.38	2.9	8.5	3.4	0.38	2.9	8.5
			0.01 lb ai/gal		0.00017	12000	19000	0.57	0.063	18	51	0.57	0.063	17	51
High Pressure Handwand (13)	No Data See PPE	120	0.10 lb ai/gal	1000 gal	0.17	12	19	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE
			0.06 lb ai/gal		0.1	19	31	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE
			0.01 lb ai/gal		0.017	120	190	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE	See PPE
Sprinkler Can (14)	No Data	No Data	0.10 lb ai/gal	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
			0.06 lb ai/gal												
			0.01 lb ai/gal												
Drencher (Soil Drench) (15)	No Data	No Data	1.0/2.0	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Flagger Risks															
Flagging (Sprays) (16)	0.011	0.35	4.0	350	0.007	290	460	0.22	0.024	45	130	0.23	0.031	39	100
			2.0		0.0035	570	910	0.11	0.012	91	260	0.11	0.016	78	210
			0.67		0.0012	1700	2700	0.037	0.0041	270	790	0.038	0.0052	230	610
			0.5		0.00088	2300	3700	0.028	0.003	360	1100	0.028	0.0039	310	820
			0.33		0.00058	3500	5500	0.018	0.002	550	1600	0.019	0.0026	480	1200
			0.25		0.00044	4600	7300	0.014	0.0015	730	2100	0.014	0.0020	630	1600
			0.16		0.00028	7100	11000	0.0088	0.00097	1100	3300	0.0091	0.0012	980	2600

a Baseline Dermal Unit Exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, and open cab tractors as appropriate. In some cases, appropriate protection factors were applied to calculate baseline exposures using available data (see *Exposure Scenarios Descriptions Table* for further information).

b Baseline Inhalation Exposure represents no respiratory protection.

c Application rates are based on maximum values found in various sources including LUIS and various labels. In most scenarios, a range of maximum application rates is used to represent the range of rates for different crops/sites/uses. Most application rates upon which the analysis is based are presented as lb ai/A. In some cases, the application rate is based on applying a solution at concentrations specified by the label (i.e., presented as lb ai/gallon). Specific application rates and the corresponding EPA Reg. numbers that are intended as examples of each exposure assessment scenario are presented below:

33.2 lb/A EC formulations:	conifer nursery (memo 10/14/99 Weyerhaeuser)
8.3 lb/A EC formulations:	conifer nursery (memo 10/14/99 Weyerhaeuser)
4.0 lb/A EC formulations:	ornamentals (EPA Reg. No. 5905-493)
2.0 lb/A EC formulations:	citrus - foliar application (EPA Reg. No. 19713-232); ornamentals
1.0 lb/A EC formulations:	citrus - soil drench
0.67 lb/A EC formulations:	wheat
0.5 lb/A EC formulations:	broccoli, cabbage, cauliflower, field corn, sorghum, citrus (foliar applications), melons, watermelons, tomatoes, beans (excluding cowpeas), lentils, soybeans, celery, alfalfa, pears, apples, potatoes, cotton, and safflower
0.33 lb/A EC formulations:	peppers, cherries, and pecans
0.25 lb/A EC formulations:	collards, kale, mustard greens, endive (escarole), head lettuce, leaf lettuce, spinach, swiss chard, and turnips; current label - lettuce (EPA Reg. No. 5905-497)
0.16 lb/A EC formulations:	peas
2.0 lb/A WP formulations:	grapes (EPA Reg. No. 2749-134); non-crop land adjacent to vineyards (rights-of-way data) in California
0.10 lb ai/gal EC formulations:	ornamentals; current label - agricultural buildings/poultry industry (EPA Reg. No. 1386-449)
0.06 lb ai/gal EC formulations:	ornamentals; current label - agricultural buildings/poultry industry (EPA Reg. No. 51036-198)
0.01lb/ gal EC formulations:	ornamentals (EPA Reg. No. 572-224)

d Daily acres treated values are from EPA estimates of acreage that could be treated or volume handled in a single day for each exposure scenario of concern based on the application method and formulation/packaging type.

e Baseline Inhalation Dose (mg/kg/d) = (unit exposure (μg/lb ai) * (1mg/1000 μg) conversion * appl. rate (lb ai/A) * acres treated/day)/body weight (70 kg) [Note: application rate and acres treated/day are replaced by concentration (lb ai/gal) and gallons used/day (gal/day) if appropriate handheld types of equipment are used (e.g., low pressure handwand, backpack, or high pressure handwand sprayers).]

f Short-term inhalation MOE = NOAEL (2.0 mg/kg/d) / short-term inhalation dose. UF = 100.
Intermediate-term inhalation MOE = LOAEL (3.2 mg/kg/d) / intermediate-term inhalation dose. UF = 300.

g Daily dermal dose (mg/kg/d) = [unit dermal exposure (mg/lb ai) * application rate (lb ai/acre) * daily acres treated * dermal absorption (11% for intermediate-term assessment and 100% for short-term assessment)]/ body weight (70 kg).

h Short-term dermal MOE = NOAEL (10 mg/kg/d) / short-term daily dermal dose. UF = 100.
Intermediate-term dermal MOE = LOAEL (3.2 mg/kg/d). UF = 300.

I Total daily dose (mg/kg/d) = daily inhalation dose (mg/kg/d) + daily dermal dose (mg/kg/d).

j Total MOE =

$$\frac{1}{\frac{1}{\text{dermal MOE}} + \frac{1}{\text{inhalation MOE}}}$$

APPENDIX E. PPE Mitigated Occupational Short-and Intermediate-term Inhalation, Dermal and Total Risks for Dimethoate

Exposure Scenario (Scen. #)	Maximum Application Rate (lb ai/A)	Additional PPE Mitigation Measures[a]										
		Unit Dermal Exposure[b] (mg/lb ai)	Unit Inhalation Exposure[b] (μg/lb ai)	Dermal				Inhalation			Total MOE[g]	
				Daily Dose[c] (mg/kg/d)		MOE[d]		Daily Dose[e] (mg/kg/d)	MOE[f]			
				Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)		Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)
Mixer/Loader Risks												
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	4.0	0.017 g,dl 0.023 g	0.24	0.34 g,dl	0.037 g,dl	29 g,dl	86 g,dl	0.0048 r	420 r	670 r	27 g,dl,r	76 g,dl,r
	2.0			0.17 g,dl	0.019 g,dl	59 g,dl	170 g,dl	0.0024 r	830 r	1300 r	55 g,dl,r	150 g,dl,r
	0.67			0.077 g	0.0063 g,dl	130 g	510 g,dl	Not needed	Not needed	Not needed	100 g	310 g,dl
	0.5			0.058 g	0.0063 g	170 g	510 g	Not needed	Not needed	Not needed	140 g	340 g
	0.33			0.038 g	0.0042 g	260 g	770 g	Not needed	Not needed	Not needed	210 g	520 g
	0.25			0.029 g	0.0032 g	350 g	1000 g	Not needed	Not needed	Not needed	280 g	690 g
	0.16			0.018 g	0.002 g	540 g	1600 g	Not needed	Not needed	Not needed	430 g	1100 g
Mixing/Loading Liquids for Groundboom Application (1b)	4.0			0.078 g,dl	0.0085 g,dl	130 g,dl	370 g, dl	0.0011 r 0.0055 nr	1800 r 365 nr	2900 r 580 nr	120 g,dl,r 95 g,dl	330 g,dl,r 230 g,dl
	2.0			0.053 g	0.0058 g	190 g	550 g	Not needed	Not needed	Not needed	150 g	380 g
	0.67			0.018 g	0.0019 g	570 g	1700 g	Not needed	Not needed	Not needed	450 g	1100 g
	0.5			0.013 g	0.0014 g	760 g	2200 g	Not needed	Not needed	Not needed	600 g	1500 g
	0.33			0.0087 g	0.00095 g	1200 g	3400 g	Not needed	Not needed	Not needed	910 g	2300 g
	0.25			0.0066 g	0.00072 g	1500 g	4400 g	Not needed	Not needed	Not needed	1200 g	3000 g
	0.16			0.0042 g	0.00046 g	2400 g	6900 g	Not needed	Not needed	Not needed	1900 g	4700 g
Mixing/Loading Liquids for Airblast Sprayer (1c)	33.2			0.16 g,dl	0.018 g,dl	62 g, dl	160g, dl	0.0023 r	Not needed	1400 r	46 g,dl	160 g,dl,r
	8.3			0.055 g	0.0060 g	180 g	530 g	Not needed	Not needed	Not needed	150 g	360 g
	4.0			0.053 g	0.0058 g	190 g	550 g	Not needed	Not needed	Not needed	150 g	380 g
	2.0			0.026 g	0.0029 g	380 g	1100 g	Not needed	Not needed	Not needed	300 g	750 g
	0.5			0.0066 g	0.00072 g	1500 g	4400 g	Not needed	Not needed	Not needed	1200 g	3000 g
	0.33			0.0043 g	0.00048 g	2300 g	6700 g	Not needed	Not needed	Not needed	1800 g	4500 g

APPENDIX E. PPE Mitigated Occupational Short-and Intermediate-term Inhalation, Dermal and Total Risks for Dimethoate (continued)

Exposure Scenario (Scen. #)	Maximum Application Rate (lb ai/A)	Additional PPE Mitigation Measures[a]										
		Unit Dermal Exposure[b] (mg/lb ai)	Unit Inhalation Exposure[b] (μg/lb ai)	Dermal				Inhalation			Total MOE[g]	
				Daily Dose[c] (mg/kg/d)		MOE[d]		Daily Dose[e] (mg/kg/d)	MOE[f]			
				Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)		Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)
Mixing/Loading Wettable-Powders for Aerial/Chemigation Application (2a)	2.0	0.13 g,dl 0.17 g	8.6	1.3 g,dl	0.14 g,dl	7.7 g,dl	22 g,dl	0.086 r	23 r	37 r	5.8 g,dl,r	14 g,dl,r
Mixing/Loading Wettable-Powders for Groundboom Application (2b)	2.0			0.3 g,dl	0.033 g,dl	34 g,dl	98 g,dl	0.02 r	100 r	160 r	25 g,dl,r	61 g,dl,r
Mixing/Loading Wettable-Powders for Airblast Sprayer (2c)	2.0			0.15 g,dl	0.016 g,dl	67 g,dl	200 g,dl	0.0098 r	200 r	330 r	51g,dl,r	120 g,dl,r
Mixing/Loading Wettable Powders for Non-crop land adjacent to vineyards (2d)	2.0			0.037 g,dl	0.0053 g	270 g,dl	600 g	0.0025 r 0.012 nr	810r 160 nr	1300 r 260 nr	100 g, dl 160 g,r	200 g,dl 410 g,r
Applicator Risks												
Applying Liquids with Aircraft (3)	4.0	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls
	2.0											
	0.67											
	0.5											
	0.33											
	0.25											
	0.16											

APPENDIX E. PPE Mitigated Occupational Short-and Intermediate-term Inhalation, Dermal and Total Risks for Dimethoate (continued)

Exposure Scenario (Scen. #)	Maximum Application Rate (lb ai/A)	Additional PPE Mitigation Measures[a]										
		Unit Dermal Exposure[b] (mg/lb ai)	Unit Inhalation Exposure[b] (μg/lb ai)	Dermal				Inhalation			Total MOE[g]	
				Daily Dose[c] (mg/kg/d)		MOE[d]		Daily Dose[e] (mg/kg/d)	MOE[f]			
				Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)		Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)
Applying Liquids with Helicopter Aircraft (4)		Insuffic. data (see apply liquids with aircraft)	Insuffic. data (see apply liquids with aircraft)	Insuffic. data (see apply liquids with aircraft)	Insuffic. data (see apply liquids with aircraft)	Insuffic. data (see apply liquids with aircraft)	Insuffic. data (see apply liquids with aircraft)	Insuffic. data (see apply liquids with aircraft)	Insuffic. data (see apply liquids with aircraft)	Insuffic. data (see apply liquids with aircraft)	Insuffic. data (see apply liquids with aircraft)	Insuffic. data (see : apply liquids with aircraft)
Applying Liquids with a Groundboom Sprayer (5)	4.0	0.011 g,dl 0.014 g	0.15	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	2.0			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.67			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.5			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.33			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.25			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.16			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
Applying Liquids Using a Paintbrush (6)	2 lb ai/gal	22 g,dl 24 g	56	1.3 g,dl	0.14 g,dl	8 g,dl	23 g,dl	Not needed	Not needed	Not needed	7.5 g,dl	21 g,dl

APPENDIX E. PPE Mitigated Occupational Short-and Intermediate-term Inhalation, Dermal and Total Risks for Dimethoate (continued)

Exposure Scenario (Scen. #)	Maximum Application Rate (lb ai/A)	Additional PPE Mitigation Measures[a]										
		Unit Dermal Exposure[b] (mg/lb ai)	Unit Inhalation Exposure[b] (μg/lb ai)	Dermal				Inhalation			Total MOE[g]	
				Daily Dose[c] (mg/kg/d)		MOE[d]		Daily Dose[e] (mg/kg/d)	MOE[f]			
				Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)		Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)
Applying Liquids Using an Airblast Sprayer (7)	33.2	0.22 g,dl 0.24 g	0.90	2.1 g,dl	0.23 g,dl	4.8 g,dl	14 g,dl	0.0085 r	230 r	370 r	4.7 g,dl,r	13 g,dl,r
	8.3			0.52 g, dl	0.057 g,dl	19 g,dl	56 g,dl	0.0021	940	1500	19 g,dl,r	54 g,dl,r
	4.0			0.5 g,dl	0.055 g,dl	20 g,dl	58 g,dl	Not needed	Not needed	Not needed	18 g,dl	49 g,dl
	2.0			0.25 g,dl	0.028 g,dl	40 g,dl	120 g,dl	Not needed	Not needed	Not needed	36 g,dl	98 g,dl
	0.5			0.069 g	0.0075 g	150 g	420 g	Not needed	Not needed	Not needed	130 g	360 g
	0.33			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
Applying Ready-to-Use Liquids (8)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Applying Liquids to Non-crop land adjacent to vineyards (rights-of-way data) (9)	2	0.29 g,dl 0.38 g	0.78	0.083 g,dl	0.0091 g,dl	120 g,dl	350 g,dl	Not needed	Not needed	Not needed	110 g,dl	310 g,dl
Mixer/Loader/Applicator Risks												
Soil Injection (10)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Backpack Sprayer and Knapsack Sprayer (11)	0.10 lb ai/gal	1.6 g,dl 2.5 g	6.0	0.091 g,dl	0.01 0 g,dl	110 g,dl	320 g,dl	0.00034 r 0.0017 nr	5800 r 1200 nr	9300 r 1900 nr	110 g,dl,r 100 g,dl	310 g,dl,r 270 g,dl
	0.06 lb ai/gal			0.086 g	0.0094 g	120 g	340 g	Not needed	Not needed	Not needed	110 g	310 g
	0.01 lb ai/gal			0.014 g	0.0016 g	700 g	2000 g	Not needed	Not needed	Not needed	660 g	1800 g
Low Pressure Handwand (12)	0.10 lb ai/gal	0.37 g,dl 0.43 g	6.0	0.025 g	0.0027 g	410 g	1200 g	Not needed	Not needed	Not needed	300 g	720 g
	0.06 lb ai/gal			0.015 g	0.0016 g	680 g	2000 g	Not needed	Not needed	Not needed	500 g	1200 g

APPENDIX E. PPE Mitigated Occupational Short-and Intermediate-term Inhalation, Dermal and Total Risks for Dimethoate (continued)

Exposure Scenario (Scen. #)	Maximum Application Rate (lb ai/A)	Additional PPE Mitigation Measures[a]										
		Unit Dermal Exposure[b] (mg/lb ai)	Unit Inhalation Exposure[b] (μg/lb ai)	Dermal				Inhalation			Total MOE[g]	
				Daily Dose[c] (mg/kg/d)		MOE[d]		Daily Dose[e] (mg/kg/d)	MOE[f]			
				Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)		Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)
	0.01 lb ai/gal			0.0025 g	0.00027 g	4100 g	12000 g	Not needed	Not needed	Not needed	3000 g	7200 g

APPENDIX E. PPE Mitigated Occupational Short-and Intermediate-term Inhalation, Dermal and Total Risks for Dimethoate (continued)

Exposure Scenario (Scen. #)	Maximum Application Rate (lb ai/A)	Additional PPE Mitigation Measures[a]										
		Unit Dermal Exposure[b] (mg/lb ai)	Unit Inhalation Exposure[b] (μg/lb ai)	Dermal				Inhalation			Total MOE[g]	
				Daily Dose[c] (mg/kg/d)		MOE[d]		Daily Dose[e] (mg/kg/d)	MOE[f]			
				Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)		Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)
High Pressure Handwand (13)	0.10 lb ai/gal	1.6 g,dl	24	2.3 g,dl	0.25 g,dl	4.4 g,dl	13 g,dl	0.034 r	58 r	93 r	4.1 g,dl,r	11 g,dl,r
	0.06 lb ai/gal			1.4 g,dl	0.15 g,dl	7.3 g,dl	21 g,dl	0.021 r	97 r	160 r	6.8 g,dl,r	19 g,dl,r
	0.01 lb ai/gal			0.23 g,dl	0.025 g,dl	44 g,dl	130 g,dl	0.0034 r	580 r	930 r	41 g,dl,r	110 g,dl,r
Sprinkler Can (14)	0.10 lb ai/gal	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
	0.06 lb ai/gal											
	0.01 lb ai/gal											
Drencher (Soil Drencher) (15)	1.0/2.0	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Flagger Risks												
Flagging (Sprays) (16)	4.0	0.010 dl	0.070	0.20 dl	0.022 dl	50dl	150 dl	0.0014 r 0.0070 nr	1400 r 290 nr	2300 r 460 nr	48 dl,r 43 dl	140 dl,r 110 dl
	2.0			0.10 dl	0.011 dl	100 dl	290 dl	Not needed	Not needed	Not needed	85 dl	220 dl
	0.67			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.5			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.33			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.25			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.16			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed

Note: g indicates a gloved hand scenario
dl indicates addition of a double layer of protective clothing
r indicates use of a dust mist respirator
Not needed indicates that baseline MOEs ≥100 for short-term and ≥300 for intermediate-term assessment.
No Data = An exposure scenario was identified, but there are no acceptable data to complete assessment.

a Additional PPE:

1a, 1b, 1c, 1d:	Double layer of clothing (PF = 50% for the second layer) (dl), chemical resistant gloves (g), and dust-mist respirator (5 Fold PF) (r) if applicable
2a, 2b, 2c, 2d:	Double layer of clothing (PF = 50% for the second layer) (dl), chemical resistant gloves (g), and dust-mist respirator (5 Fold PF)(r) if applicable
6:	Double layer of clothing (PF = 50% for the second layer) (dl), chemical resistant gloves (g) (PF = 90%), and dust-mist respirator (5 Fold PF)(r) if applicable
7:	Double layer of clothing (PF = 50% for the second layer) (dl), chemical resistant gloves (g), and dust-mist respirator (5 Fold PF)(r) if applicable
9:	Double layer of clothing (PF = 50% for the second layer) (dl), chemical resistant gloves (g), and dust-mist respirator (5 Fold PF)(r) if applicable
12:	Double layer of clothing (PF = 50% for the second layer) (dl), chemical resistant gloves (g), and dust-mist respirator (5 Fold PF)(r) if applicable
13:	Double layer of clothing (PF = 50% for the second layer) (dl), chemical resistant gloves (g), and dust-mist respirator (5 Fold PF)(r) if applicable
16:	Double layer of clothing (PF = 50% for the second layer) (dl), and dust-mist respirator (5 Fold PF)(r) if applicable

b PHED surrogate unit exposure values from PHED V1.1, August 1998.

c Daily dermal dose (mg/kg/d) = [unit dermal exposure (mg/lb ai) * application rate (lb ai/acre) * daily acres treated * dermal absorption (11% for intermediate-term assessment and 100% for short-term assessment)]/ body weight (70 kg).

d Short-term dermal MOE = NOAEL (10 mg/kg/d) / short-term daily dermal dose. UF = 100.
Intermediate-term dermal MOE = LOAEL (3.2 mg/kg/d). UF = 300.

e Daily inhalation dose (mg/kg/d) = [unit inhalation exposure (μg/lb ai) * application rate (lb ai/acre) * daily acres treated * (1 mg/1000 μg)] / body weight (70 kg).

f Short-term inhalation MOE = NOAEL (2.0 mg/kg/d) / short-term inhalation dose. UF = 100.
Intermediate-term inhalation MOE = LOAEL (3.2 mg/kg/d) / intermediate-term inhalation dose. UF = 300.

g Total MOE =

$$\frac{1}{\frac{1}{\text{dermal MOE}} + \frac{1}{\text{inhalation MOE}}}$$

APPENDIX F. Engineering Controls for Occupational Short- and Intermediate-term Dermal, Inhalation, and Total Risks for Dimethoate

Exposure Scenario (Scen. #)	Maximum Application Rate (lb ai/A)	Engineering Controls Mitigation Measures[a]										
		Unit Dermal Exposure[b] (mg/lb ai)	Unit Inhalation Exposure[b] (μg/lb ai)	Dermal				Inhalation			Total MOE[g]	
				Daily Dose[c] (mg/kg/d)		MOE[d]		Daily Dose[e] (mg/kg/d)	MOE[f]			
				Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)		Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)
Mixer/Loader Risks												
Mixing/Loading Liquids for Aerial/Chemigation Application (1a)	4.0	0.0086 (gloves)	0.083	0.17 g	0.019 g	58 g	170 g	0.0017	1200	1900	55 g	160 g
	2.0			0.086 g	0.0095 g	120 g	340 g	0.00083	2400	3900	110 g	310 g
	0.67			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.5			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.33			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.25			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.16			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
Mixing/Loading Liquids for Groundboom Application (1b)	4.0			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	2.0			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.67			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.5			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.33			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.25			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.16			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
Mixing/Loading Liquids for Airblast Sprayer (1c)	33.2			0.08	0.009	120	360	0.0008	2,500	4,100	120	330
	8.3			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	4.0			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	2.0			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.5			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.33			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed

APPENDIX F. Engineering Controls for Occupational Short- and Intermediate-term Dermal, Inhalation, and Total Risks for Dimethoate (continued)

Exposure Scenario (Scen. #)	Maximum Application Rate (lb ai/A)	Engineering Controls Mitigation Measures[a]										
		Unit Dermal Exposure[b] (mg/lb ai)	Unit Inhalation Exposure[b] (μg/lb ai)	Dermal				Inhalation			Total MOE[g]	
				Daily Dose[c] (mg/kg/d)		MOE[d]		Daily Dose[e] (mg/kg/d)	MOE[f]			
				Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)		Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)
Mixing/Loading Wettable-Powders for Aerial/Chemigation Application (2a)	2.0	0.0098 (gloves)	0.24	0.098 g	0.011 g	100 g	300 g	0.0024	830	1,300	91 g	240 g
Mixing/Loading Wettable-Powders for Groundboom Application (2b)	2.0			0.022 g	0.0025 g	450 g	1,300 g	0.00055	3,600	5,800	400 g	1,100 g
Mixing/Loading Wettable-Powders for Airblast Sprayer (2c)	2.0			0.011 g	0.0012 g	890 g	2,600 g	0.00027	7,300	12,000	800 g	2,100 g
Mixing/Loading Wettable Powders for Non-crop land adjacent to vineyards (2d)	2.0			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
Applicator Risks												
Applying Liquids with Aircraft (3)	4.0	0.005	0.068	0.1	0.011	100	290	0.0014	1,500	2,400	94	260
	2.0			0.05	0.0055	200	580	0.00068	2,900	4,700	190	520
	0.67			0.017	0.0018	600	1,700	0.00023	8,800	14,000	560	1,500
	0.5			0.013	0.0014	800	2,300	0.00017	12,000	19,000	750	2,100
	0.33			0.0083	0.00091	1,200	3,500	0.00011	18,000	29,000	1,100	3,100
	0.25			0.0063	0.00069	1,600	4,700	0.000085	24,000	38,000	1,500	4,100
	0.16			0.004	0.00044	2,500	7,300	0.000054	37,000	59,000	2,300	6,500

APPENDIX F. Engineering Controls for Occupational Short- and Intermediate-term Dermal, Inhalation, and Total Risks for Dimethoate (continued)

Exposure Scenario (Scen. #)	Maximum Application Rate (lb ai/A)	Engineering Controls Mitigation Measures[a]										
		Unit Dermal Exposure[b] (mg/lb ai)	Unit Inhalation Exposure[b] (μg/lb ai)	Dermal				Inhalation			Total MOE[g]	
				Daily Dose[c] (mg/kg/d)		MOE[d]		Daily Dose[e] (mg/kg/d)	MOE[f]			
				Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)		Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)
Applying Liquids with Helicopter Aircraft (4)		Insuffuc. data see apply liquids with aircraft)	Insuffuc. data (see apply liquids with aircraft)	Insuffuc. data (see apply liquids with aircraft)	Insuffuc. data (see apply liquids with aircraft)	Insuffuc. data (see apply liquids with aircraft)	Insuffuc. data (see apply liquids with aircraft)	Insuffuc. data (see apply liquids with aircraft)	Insuffuc. data (see apply liquids with aircraft)	Insuffuc. data (see apply liquids with aircraft)	Insuffuc. data (see apply liquids with aircraft)	Insuffuc. data (see apply liquids with aircraft)
Applying Liquids with a Groundboom Sprayer (5)	4.0	0.005	0.043	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	2.0			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.67			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.5			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.33			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.25			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.16			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
Applying Liquids Using an Paintbrush (6)	2 lb ai/gal	None	None	None	None	None	None	None	None	None	None	None
Applying Liquids Using an Airblast Sprayer (7)	33.2	0.019 (gloves)	0.45	0.08	0.009	120	360	0.0008	2,500	4,100	120	330
	8.3			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	4.0			0.043	0.0048	230	670	0.0010	1900	3100	210	550
	2.0			0.022	0.0024	460	1300	0.00051	3900	6200	410	1100
	0.5			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.33			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
Applying Ready-to-Use Liquids (8)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data

APPENDIX F. Engineering Controls for Occupational Short- and Intermediate-term Dermal, Inhalation, and Total Risks for Dimethoate (continued)

Exposure Scenario (Scen. #)	Maximum Application Rate (lb ai/A)	Engineering Controls Mitigation Measures[a]										
		Unit Dermal Exposure[b] (mg/lb ai)	Unit Inhalation Exposure[b] (μg/lb ai)	Dermal				Inhalation			Total MOE[g]	
				Daily Dose[c] (mg/kg/d)		MOE[d]		Daily Dose[e] (mg/kg/d)	MOE[f]			
				Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)		Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)
Applying Liquids to Non-crop land adjacent to vineyards (rights-of-way data) (9)	2			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed

APPENDIX F. Engineering Controls for Occupational Short- and Intermediate-term Dermal, Inhalation, and Total Risks for Dimethoate (continued)

Exposure Scenario (Scen. #)	Maximum Application Rate (lb ai/A)	Engineering Controls Mitigation Measures[a]										
		Unit Dermal Exposure[b] (mg/lb ai)	Unit Inhalation Exposure[b] (μg/lb ai)	Dermal				Inhalation			Total MOE[g]	
				Daily Dose[c] (mg/kg/d)		MOE[d]		Daily Dose[e] (mg/kg/d)	MOE[f]			
				Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)		Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)
Mixer/Loader/Applicator Risks												
Soil Injection (10)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Backpack Sprayer and Knapsack Sprayer (11)	0.10 lb ai/gal	NF	NF	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.06 lb ai/gal			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.01 lb ai/gal			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
Low Pressure Handwand (12)	0.10 lb ai/gal	NF	NF	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.06 lb ai/gal			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.01 lb ai/gal			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
High Pressure Handwand (13)	0.10 lb ai/gal	NF	NF	None	None	None	None	None	None	None	None	None
	0.06 lb ai/gal			None	None	None	None	None	None	None	None	None
	0.01 lb ai/gal			None	None	None	None	None	None	None	None	None

APPENDIX F. Engineering Controls for Occupational Short- and Intermediate-term Dermal, Inhalation, and Total Risks for Dimethoate (continued)

Exposure Scenario (Scen. #)	Maximum Application Rate (lb ai/A)	Engineering Controls Mitigation Measures[a]										
		Unit Dermal Exposure[b] (mg/lb ai)	Unit Inhalation Exposure[b] (μg/lb ai)	Dermal				Inhalation			Total MOE[g]	
				Daily Dose[c] (mg/kg/d)		MOE[d]		Daily Dose[e] (mg/kg/d)	MOE[f]			
				Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)		Short-term (UF=100)	Int.-term (UF=300)	Short-term (UF=100)	Int.-term (UF=300)
Sprinkler Can (14)	0.10 lb ai/gal	NF	NF	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
	0.06 lb ai/gal			No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
	0.01 lb ai/gal			No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Drencher (Soil Drencher) (15)	1.0/2.0	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Flagger Risks												
Flagging (Sprays) (16)	4.0	0.0050	0.043	0.1	0.011	100	290	0.00086	2,300	3,700	96	270
	2.0			0.05	0.0055	200	580	0.00043	4700	7,400	190	540
	0.67			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.5			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.33			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.25			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed
	0.16			Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed	Not needed

"Not needed" indicates that MOEs were acceptable at either baseline or with PPE.
"None" indicates that no engineering controls are available for this scenario.

a Engineering Controls include:

- 1a, 1b, 1c, 1d: Closed mixing, single layer clothing, and chemical resistant gloves (empirical data are based on the use of chemical-resistant gloves)
- 2a, 2b, 2c, 2d: Water soluble bags, single layer of clothing, and chemical-resistant gloves
- 3: Enclosed cockpit, single layer of clothing, no gloves (engineering controls are the only application scenario for this application method for which data are available)
- 5: Enclosed cab, single layer of clothing, no gloves
- 7: Enclosed cab, single layer of clothing, and chemical-resistant gloves (empirical data are based on the use of chemical-resistant gloves)
- 16: Enclosed vehicle (PF = 90% for vehicle or other suitable engineering control), single layer of clothing, and no gloves

b PHED surrogate unit exposure values from PHED V1.1, August 1998.

c Daily dermal dose (mg/kg/d) = [unit dermal exposure (mg/lb ai) * application rate (lb ai/acre) * daily acres treated * dermal absorption (11% for intermediate-term assessment and 100% for short-term assessment)]/ body weight (70 kg).

d Short-term dermal MOE = NOAEL (10 mg/kg/d) / short-term daily dermal dose. UF = 100.

Intermediate-term dermal MOE = LOAEL (3.2 mg/kg/d). UF = 300.

e Daily inhalation dose (mg/kg/d) = [unit inhalation exposure (μg/lb ai) * application rate (lb ai/acre) * daily acres treated * (1 mg/1000 μg)] / body weight (70 kg).

f Short-term inhalation MOE = NOAEL (2.0 mg/kg/d) / short-term inhalation dose. UF = 100.

Intermediate-term inhalation MOE = LOAEL (3.2 mg/kg/d) / intermediate-term inhalation dose. UF = 300.

g Total MOE =

$$\frac{1}{\frac{1}{\text{dermal MOE}} + \frac{1}{\text{inhalation MOE}}}$$

Appendix G-1. Parameters of Clean Crop® Dimethoate 400 Studies Used In Postapplication Assessment

Crop/ MRID Number	Study Location	Days included in Regression Analysis[a]	Half Life of Dimethoate+ Omethoate Residues	m	b	R^2 Value
Lettuce MRID 446903-01	California	not needed	2.2	not needed	not needed	not needed
	Florida	not needed	0.66[b]	not needed	not needed	not needed
	Pennsylvania	not needed	0.66[b]	not needed	not needed	not needed
Tomatoes MRID 446903-02	California	not needed	2.6	not needed	not needed	not needed
	Florida	not needed	0.58	not needed	not needed	not needed
	Pennsylvania	not needed	0.60	not needed	not needed	not needed
Grapes MRID 447882-01	New York	0-35 days	1.54	-0.449	-0.061	0.94
	Washington	0-35 days	4.92	-0.141	-0.359	0.86
	California	0-35 days	4.71	-0.147	-1.182	0.84
Apples MRID 448276-01	New York	0-35 days	6.42	-0.108	0.577	0.95
	Michigan	0-28 days	4.58	-0.151	0.380	0.95
	Washington	0-35 days	9.15	-0.076	0.636	0.88

Footnotes:

"Not needed" means regression analysis was not used in the postapplication assessment; actual DFR values were used instead.

a Natural log transformed data (after 2nd application) from days with one or more replicate >LOQ were used in the regression analysis. Days in which ≥ two of the replicates had values < LOQ were not included in the regression. Residues were still detectable after 35 days in the apple study, therefore, all replicates were used in the regression.

b Omethoate residues were all < LOQ at these sites.

Appendix G-2. Predicted DFR Levels Based on Actual DFRs Detected After Clean Crop® Dimethoate 400 Application to Grapes and Apples

Sample Interval (DAT)[a]	Grape DFR $\mu g/cm^2$[b] Application rate = 1.0 lb ai/acre			Apple DFR $\mu g/cm^2$[c] Application rate = 1.0 lb ai/acre		
	California	Washington	New York	Michigan	New York	Washington
0	0.31	0.7	1.1	1.46	1.78	1.89
1	0.26	0.61	0.68	1.26	1.60	1.75
2	0.23	0.53	0.43	1.08	1.43	1.62
3	0.2	0.46	0.28	0.93	1.29	1.50
4	0.17	0.4	0.18	0.80	1.16	1.39
5	0.15	0.35	0.11	0.69	1.04	1.29
6	0.13	0.3	0.072	0.59	0.93	1.20
7	0.11	0.26	0.046	0.51	0.84	1.11
8	0.094	0.23	0.029	0.44	0.75	1.03
9	0.082	0.2	0.019	0.37	0.67	0.96
10	0.07	0.17	0.012	0.32	0.60	0.89
11	0.061	0.15	0.0076	0.28	0.54	0.82
12	0.052	0.13	0.0049	0.24	0.49	0.76
13	0.045	0.11	0.0031	0.20	0.44	0.71
14	0.039	0.097	0.002	0.18	0.39	0.65
15	0.034	0.084	0.0013	0.15	0.35	0.61
16	0.029	0.073	0.00081	0.13	0.32	0.56
17	0.025	0.064	0.00052	0.11	0.28	0.52
18	0.022	0.055	0.00033	0.096	0.25	0.48
19	0.019	0.048	0.00021	0.083	0.23	0.45
20	0.016	0.042	0.00013	0.071	0.21	0.42
21	0.014	0.036	0.000086	0.061	0.18	0.38
22	0.012	0.031	0.000055	0.052	0.17	0.36
23	0.01	0.027	0.000035	0.045	0.15	0.33
24	0.009	0.024	0.000022	0.039	0.13	0.31
25	0.0077	0.021	0.000014	0.033	0.12	0.28
26	0.0067	0.018	9.1E-06	0.029	0.11	0.26
27	0.0058	0.016	5.8E-06	0.025	0.096	0.24
28	0.005	0.014	3.7E-06	0.021	0.086	0.23
29	0.0043	0.012	2.4E-06	0.018	0.078	0.21
30	0.0037	0.01	1.5E-06	0.016	0.070	0.19
31	0.0032	0.0089	9.7E-07	0.013	0.062	0.18
32	0.0028	0.0077	6.2E-07	0.012	0.056	0.17
33	0.0024	0.0067	4E-07	0.010	0.050	0.16
34	0.0021	0.0058	2.5R-07	0.0085	0.045	0.14
35	0.0018	0.005	1.6E-07	0.0073	0.041	0.13

[a] DAT = days after treatment.

[b] Predicted residues determined from linear regression analysis of dimethoate + omethoate grape leaves (MRID 447882-01)

[c] Predicted residues determined from linear regression analysis of dimethoate + omethoate apple leaves (MRID 448276-01)

Appendix G-3. Estimated Entry-Restricted Periods for Dimethoate (based on actual -- not predicted) DFR data from lettuce study)

Application Rate	Crop/Use	Days After Treatment	Dislodgeable Foliar Residue (DFR)[1]			Post Application Activity & Transfer Coefficient (TC)[2]	Margin of Exposure (MOE)[3] (UF = 300)			Secondary Post Application Activity & Transfer Coefficient (TC)	Margin of Exposure (MOE)[3] (UF = 300)		
			FL	PA	CA		FL	PA	CA		FL	PA	CA
0.16 lb ai/A	Peas (M)[4]	0[5]	0.083	0.22	0.40	hand harvest, stake/tie, scout, irrigate; TC = 4000[4]	770	290	160	NA for these crops	NA	NA	NA
		1	--	0.038	0.27		--	1,700	240		NA	NA	NA
		2	--	--	0.14		--	--	470		NA	NA	NA
0.25 lb ai/ A	Collards, kale, mustard greens, endive, escarole, head lettuce, leaf lettuce, spinach, swiss chard, turnips (L)[6]	0[5]	0.13	0.35	0.62	Hand harvesting, hand thinning: TC = 2500[4]	790	290	160	Scouting, irrigating: TC = 1000[4]	2,000	730	410
		1	--	0.059	0.42		--	1,700	240		--	--	--
		2	--	--	0.21		--	--	480		--	--	--

Footnotes:

1 DFR source: lettuce study MRID # 44690301, which was conducted using an application rate of 0.25 lb ai/acre. When assessing activities involving a different application rate than was used in the study, the DFR values were adjusted proportionately to reflect different application rates. For example; peas which have a maximum application rate (AR) of 0.16 lb ai/acre,

$$\text{adjusted DFR} = \frac{\text{Lettuce DFR x 0.16 lb ai/A (AR)}}{\text{0.25 lb ai/A (AR)}}$$

2 Transfer coefficient from Science Advisory Council for Exposure: Policy Memo #3 "Agricultural Default Transfer Coefficients," May 7, 1998.

3 MOE = Intermediate-term LOAEL (3.2 mg/kg/d) / absorbed dermal dose (mg/kg/d), where absorbed dermal dose = DFR (μg/cm^2) x TC (cm^2/hr) x conversion factor (1 mg/1,000 μg) x exposure time (hrs) x dermal absorption (0.11) / body weight (70 kg).

4 M = crops with *medium* potential for dermal transfer.

5 0 = on the day of treatment, after sprays have dried; assumed approximately 12 hours.

6 L = crops with *low* potential for dermal transfer

Appendix G-4. Estimated Entry-Restricted Periods for Dimethoate (based on actual (not predicted) DFR data from tomato study)

Application Rate	Crop/Use	Days After Treatment	Dislodgeable Foliar Residue (DFR)[1]			Post Application Activity & Transfer Coefficient (TC)[2]	Margin of Exposure (MOE) (UF = 300)			Secondary Post Application Activity & Transfer Coefficient (TC)	Margin of Exposure (MOE) (UF = 300)		
			FL	PA	CA		FL	PA	CA		FL	PA	CA
0.33 lb ai/A	Peppers (M)[4]	0[5]	0.75	0.42	0.39	Hand harvest, stake/tie, scout, irrigate: TC = 4000	85	150	170	NA for these crops	NA	NA	NA
		1	0.048	0.055	0.28		1300	1200	220		NA	NA	NA
		2	--	--	0.060		--	--	1100		NA	NA	NA
0.5 lb ai/A	Broccoli, cabbage, cauliflower, celery, alfalfa, sorghum (L)[6]	0[5]	1.1	0.63	0.59	Hand harvest: TC = 2,500	89	160	170	Scout, irrigate: TC = 1,000	220	400	440
		1	0.073	0.083	0.43		1400	1200	240		3500	--	--
		2	--	--	0.090		--	--	1100		--	--	--
	Melons, watermelons, lentils, soybeans (M)[4]	0[3]	1.1	0.63	0.59	Hand harvest, stake/tie, scout, irrigate TC = 4,000	56	100	110	NA for these crops	NA	NA	NA
		1	0.073	0.083	0.43		880	760	150		NA	NA	NA
		2	--	--	0.09				700		NA	NA	NA
	Field corn, tomatoes, beans (excluding cowpeas) (H)[7]	0[3]	1.1	0.63	0.59	Hand harvest TC = 10,000	22	40	44	Stake/tie, scout, irrigate TC = 4,000	56	100	110
		1	0.073	0.083	0.43		350	310	59		880	760	150
		2	--	--	0.09		--	--	280		--	--	700
		5	--	--	0.074		--	--	340		--	--	--
	Potatoes	0[5]	1.1	0.63	0.59	Hand dig/harvest TC = 10,000	22	40	44	Sort, pack TC = 2,500	89	160	170
		1	0.073	0.083	0.43		350	300	59		1400	1200	240
		2	--	--	0.090		--	--	280		--	--	1100
		5	--	--	0.074		--	--	340		--	--	--
	Cotton, safflower	0[5]	1.1	0.63	0.59	Late season scouting TC = 4,000	56	100	110	Early season scouting TC = 1,000	220	400	440
		1	0.073	0.083	0.43		880	760	150		3500	--	--
		2	--	--	0.09				700		--	--	--

Application Rate	Crop/Use	Days After Treatment	Dislodgeable Foliar Residue (DFR)[1]			Post Application Activity & Transfer Coefficient (TC)[2]	Margin of Exposure (MOE) (UF = 300)			Secondary Post Application Activity & Transfer Coefficient (TC)	Margin of Exposure (MOE) (UF = 300)		
			FL	PA	CA		FL	PA	CA		FL	PA	CA
0.67 lb ai/A	Wheat	0[5]	1.5	0.84	0.78	Hand harvest TC = 2,500	67	120	130	Scout, irrigate TC = 1,000	170	300	330
		1	0.097	0.11	0.58		1000	910	180		2600	--	--
		2	--	--	0.12		--	--	840		--	--	--
2.0 lb ai/A	Herbaceous Ornamentals	0[3]	4.6	2.5	2.3	Cut, harvest, ball/burlap, transplant, prune TC = 10,000	6.0	10	11	Irrigate TC = 4,000	14	25	27
		1	0.29	0.33	1.7		88	76	15		220	190	37
		2	0.17	0.16	0.36		150	160	70		380	400	180
		3	0.10	--	0.44		250	350	57		--	--	140
		5	0.010	--	0.30		2500	--	86		--	--	214
		7	--	--	0.20		--	--	130		--	--	330
		10	--	--	0.069		--	--	370		--	--	--
4.0 lb ai/A	Herbaceous Ornamentals	0[3]	9.1	5.0	4.7	Cut, harvest, ball/burlap, transplant, prune TC = 10,000	3.0	5.0	5.0	Irrigate TC = 4,000	7.0	13	14
		1	0.58	0.67	3.5		44	38	7.0		110	95	18
		2	0.34	0.32	0.72		76	80	35		190	200	88
		3	0.20	0.14	0.89		130	180	29		310	440	72
		5	0.020	0.02	0.59		1300	1300	43		--	--	110
		7	--	--	0.39		--	--	65		--	--	160
		10	--	--	0.14		--	--	180		--	--	460
		14	--	--	0.098		--	--	260		--	--	--

Footnotes:

[1] DFR source: tomato study MRID # 44690302, which was conducted using an application rate of 0.5 lb ai/acre. When assessing activities involving a different application rate than was used in the study, the DFR values were adjusted proportionately to reflect the different application rates. For example, for wheat, which has a maximum label rate of 0.67 lb ai/acre,

$$\text{adjusted DFR} = \frac{\text{Tomato DFR x 0.67 lb ai/A for wheat}}{\text{0.5 lb ai/A for tomatoes}}$$

[2] Transfer coefficient from Science Advisory Council for Exposure: Policy Memo #003 "Agricultural Default Transfer Coefficients," May 7, 1998.

[3] MOE = Intermediate-term LOAEL (3.2 mg/kg/d) / absorbed dermal dose where absorbed dose = DFR (μg/cm^2) x TC (cm^2/hr) x conversion factor (1 mg/1,000 μg) x exposure time (hrs) x dermal absorption (0.11) / body weight (70 kg).

[4] M = crops with *medium* potential for dermal transfer.

[5] 0 = On the day of treatment, after sprays have dried; assumed approximately 12 hours.

[6] L = crops with *low* potential for dermal transfer.

[7] H = crops with *high* potential for dermal transfer.

Appendix G-5. Estimated Entry-Restricted Periods for Dimethoate (Derived from Grape DFR Data, MRID No. 447882-01)

Application Rate	Crop/Use	Days After Treatment	Dislodgeable Foliar Residue (DFR)[1]			Post Application Activity & Transfer Coefficient (TC)[2]	Margin of Exposure (MOE = 300)[3]			Secondary Post Application Activity & Transfer Coefficient (TC)[2]	Margin of Exposure (MOE = 300)		
			NY	CA	WA		NY	CA	WA		NY	CA	WA
2.0 lb ai/A	Grapes	0[4]	2.1	0.61	1.4	Harvest, hand girdle, cane, tie, prune, thin, tip TC = 15,000	8	28	12	Irrigation TC =4,000	30	100	46
		1	1.4	0.53	1.21		13	32	14		47	120	52
		2	0.87	0.46	1.05		20	37	16		73	140	60
		6	0.14	0.25	0.60		120	67	28		440	250	110
		8	0.059	0.19	0.45		290	90	38		--	340	140
		9	0.037	0.16	0.39		450	100	43		--	--	160
		13	--	0.091	0.22		--	190	76		--	--	280
		14	--	0.078	0.19		--	220	87		--	--	330
		17	--	0.050	0.13		--	340	130		-	--	--
		22	--	--	0.063		--	--	270		--	--	--
		23	--	--	0.055		--	--	310		--	--	--

NA= Not Applicable

[1] DFR source: grape study MRID # 448276-01, which was conducted using an application rate of 1.0 lb ai/acre. DFR values were adjusted proportionately to reflect different application rates. Grapes have a maximum application rate (AR) of 2.0 lb ai/acre. The adjusted DFR is based on the following equation:

$$DFR = \frac{\text{Grape DFR x 2.0lbai/A}}{\text{Grape 1.0lbai/A}}$$

[2] Transfer coefficient from Science Advisory Council for Exposure: Policy Memo #003 "Agricultural Transfer Coefficients," May 7, 1998.[4]

[3] MOE = Intermediate-term dermal LOAEL (3.2 mg/kg/d) / absorbed dermal dose (mg/kg/d) when absorbed dermal dose = DFR (μg/cm^2) x TC (cm^2/hr) x conversion factor (1 mg/1,000 μg) x exposure time (hrs) x dermal absorption (0.11) / body weight(70 kg).
0 = On the day of treatment, after sprays have dried; assumed approximately 12 hours.

Appendix G-6. Estimated Entry-Restricted Periods for Dimethoate (Derived from Apple DFR Data, MRID 448276-01)

Application Rate	Crop/Use	Days After Treatment	Dislodgeable Foliar Residue (DFR)[1]			Post Application Activity & Transfer Coefficient (TC)[2]	Margin of Exposure (MOE = 300)[3]			Secondary Post Application Activity & Transfer Coefficient (TC)[2]	Margin of Exposure (MOE = 300)		
			NY	MI	WA		NY	MI	WA		NY	MI	WA
0.33 lb ai/A	Cherries, pecans	0[4]	0.59	0.48	0.62	Hand harvest, prune, prop, summer shake, rake, pole and pickup (nuts): TC = 10,000	43	53	41	NA for these crops	NA	NA	NA
		1	0.53	0.41	0.58		48	61	44		NA	NA	NA
		2	0.47	0.36	0.54		54	71	48		NA	NA	NA
		12	0.16	0.079	0.25		160	320	101		NA	NA	NA
		18	0.084	--	0.16		300	--	160		NA	NA	NA
		27	--	--	0.081		--	--	320		NA	NA	NA
0.5 lb ai/A	Citrus (foliar applications), pears, apples	0[3]	0.89	0.73	0.94	Hand harvest, prune, prop, summer shake, rake, pole and pickup (nuts) TC = 10,000	29	35	27	NA for these crops	NA	NA	NA
		1	0.80	0.63	0.88		32	40	29		NA	NA	NA
		15	0.022	0.095	0.30		150	340	84				
		19	0.11	0.041	0.22		220	--	110		NA	NA	NA
		22	0.083	--	0.17		308	--	140		NA	NA	NA
		32	--	--	0.084		--	--	300		NA	NA	NA
2.0 lb ai/A	Woody Ornamentals	0[4]	3.6	2.9	3.8	Cut, harvest, ball/burlap, transplant, prune TC = 10,000	7.1	8.7	6.7	Irrigate TC = 4,000	18	22	17
		1	3.2	2.5	3.5		8.0	10	7.3		20	25	18
		2	2.9	2.2	3.2		8.9	12	7.8		22	29	20
		18	0.51	0.19	0.97		50	130	26		130	330	66
		24	0.27	0.078	0.61		96	330	42		240	--	100
		26	0.21	--	0.53		120	--	48		300	--	120
		35	0.081	--	0.27		310	--	96		--	--	240
		38	--	--	0.21		--	--	120		--	--	300
		50	--	--	0.086		--	--	300		--	--	--

Appendix G-6. Estimated Entry-Restricted Periods for Dimethoate (Derived from Apple DFR Data, MRID 448276-01) (continued)

Application Rate	Crop/Use	Days After Treatment	Dislodgeable Foliar Residue (DFR)[1]			Post Application Activity & Transfer Coefficient (TC)[2]	Margin of Exposure (MOE = 300)[3]			Secondary Post Application Activity & Transfer Coefficient (TC)[2]	Margin of Exposure (MOE = 300)		
			NY	MI	WA		NY	MI	WA		NY	MI	WA
4.0 lb ai/A	Woody Ornamentals	0[4]	7.1	5.9	7.6	Cut, harvest, ball/burlap, transplant, prune TC = 10,000	3.6	4.4	3.4	Irrigate TC = 4,000	8.9	11	8.4
		1	6.4	5.0	7		4.0	5.1	3.6		10	13	9.9
		2	5.7	4.3	6.5		4.4	5.9	4.0		11	15	10
		22	0.66	0.21	1.4		38	120	18		96	300	45
		28	0.35	0.085	0.91		74	300	28		180	--	70
		33	0.2	--	0.62		130	--	41		320	--	100
		41	0.085	--	0.34		300	--	75		--	--	190
		47	--	--	0.21		--	--	120		--	--	300
		60	--	--	0.08		--	--	320		--	--	--
8.3 lb ai/A	Conifer Seed Nursery (Douglas fir)	0*	15	12	16	Cone harvesting TC = 10,000	1.7	2.1	1.6	Cone harvesting TC = 5,000	3.4	4.2	3.2
		1	13	10	15		1.9	2.4	1.8		3.8	4.9	3.5
		2	12	9.0	13		2.1	2.8	1.9		4.3	5.7	3.8
		29	0.64	0.15	1.7		40	170	15		79	340	29
		33	0.42	0.082	1.3		61	310	20		120	--	40
		42	0.16	--	0.65		160	--	39		320	--	78
		48	0.083	--	0.41		310	--	62		--	--	120
		60	--	--	0.17		--	--	150		--	--	310
		69	--	--	0.084		--	--	300		--	--	--
33.2 lb ai/A	Conifer Seed Nursery (Douglas fir)	0*	59	49	63	Cone harvesting TC = 10,000	0.4	0.5	0.4	Cone efficiency monitoring TC = 5,000	0.9	1.0	0.8
		1	53	42	58		0.5	0.6	0.4		1.0	1.2	0.9
		2	48	36	54		0.5	0.7	0.5		1.1	1.4	0.9
		38	0.97	0.15	3.5		26	160	7.2		52	330	14
		42	0.63	0.085	2.6		40	300	9.8		81	--	20
		55	0.16	--	0.97		160	--	26		330	--	52

Appendix G-6. Estimated Entry-Restricted Periods for Dimethoate (Derived from Apple DFR Data, MRID 448276-01) (continued)

Application Rate	Crop/Use	Days After Treatment	Dislodgeable Foliar Residue (DFR)[1]			Post Application Activity & Transfer Coefficient (TC)[2]	Margin of Exposure (MOE = 300)[3]			Secondary Post Application Activity & Transfer Coefficient (TC)[2]	Margin of Exposure (MOE = 300)		
			NY	MI	WA		NY	MI	WA		NY	MI	WA
		61	0.081	--	0.62		310	--	41		--	--	83
		78	--	--	0.17		--	--	150		--	--	300
		87	--	--	0.086		--	--	300		--	--	--

NA= Not Applicable

[1] DFR source: apple study MRID # 448276-01, which was conducted using an application rate of 1.0 lb ai/acre. DFR values were adjusted proportionately to reflect different application rates. For example, cherries and pecans have a maximum application rate (AR) of 0.33 lb ai/acre. The adjusted DFR is based on the following equation:

$$\text{DFR} = \frac{\text{Apple DFR x AR}}{\text{Apple AR}}$$

[2] Transfer coefficient from Science Advisory Council for Exposure: Policy Memo #003 "Agricultural Transfer Coefficients," May 7, 1998.[4]

[3] MOE = Intermediate-term dermal LOAEL (3.2 mg/kg/d) / absorbed dermal dose (mg/kg/d) when absorbed dermal dose = DFR (μg/cm^2) x TC (cm^2/hr) x conversion factor (1 mg/1,000 μg) x exposure time (hrs) x dermal absorption (0.11) / body weight(70 kg).

0 = On the day of treatment, after sprays have dried; assumed approximately 12 hours.

Exposure Scenario (Number)	Data Source	Standard Assumptions	Comments
Occupational Mixer/Loader Exposure			
Mixing/Loading Liquid Formulations (1a, 1b, 1c, and 1 d)	PHED V1.1	350 acres for aerial and chemigation, 80 acres groundboom, 40 acres airblast, 20 acres mistblower (conifer seed nursery) and 10 acres for non-crop land adjacent to vineyards.	**Baseline:** Dermal (72 to 122 replicates); hand (53 replicates); and inhalation (85 replicates) exposure values are all based on AB grade data. High confidence in the unit exposure value. No protection factors were needed to define the unit exposure value. **PPE:** The same dermal and inhalation data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing and a 5-fold protection factor to account for the use of a dust/mist respirator. Hand (59 replicates) exposure value is based on AB grade data. High confidence in the unit dermal exposure value. **Engineering Controls:** Dermal (31 replicates) exposure value is based on AB grade data. Hand (31 replicates) and inhalation (27 replicates) exposure values are based on AB grade data. High confidence in the dermal unit exposure value. Low confidence in inhalation unit exposure value. Empirical data include the use of chemical-resistant gloves. No protection factors were needed to define the unit exposure value.
Mixing/Loading Wettable Powder (2a, 2b, 2c and 2d)	PHED V1.1	350 acres for aerial and chemigation, 80 acres for groundboom, 40 acres airblast, and 10 acres for right-of-way.	**Baseline:** Dermal (22 to 45 replicates); hand (7 replicates); and inhalation (44 replicates) exposure values are all based on ABC grade data. Low confidence in the dermal unit exposure value. Medium confidence in the inhalation unit exposure value. Medium confidence in the inhalation unit exposure value. No protection factors were needed to define the unit exposure value. **PPE:** The same dermal and inhalation data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing and a 5-fold protection factor to account for the use of a dust/mist respirator. Hand (24 replicates) exposure value is based on ABC grade data. Medium confidence in the unit exposure value. **Engineering Controls (water soluble packets):** Dermal (6 to 15 replicates); hand (5 replicates); and inhalation (15 replicates) exposure values are all based on AB grade data for dermal and “all” grade data for hands and inhalation. Low confidence in the unit exposure value. No protection factors were needed to define the unit exposure value.

Exposure Scenario (Number)	Data Source	Standard Assumptions	Comments
Occupational Applicator Exposure			
Aircraft Application (3)	PHED V1.1	350 acres	**Baseline and PPE:** These scenarios are not considered an option for this assessment as a vast majority of agricultural aircraft are closed cab vehicles (i.e., the scenario defaults to engineering controls). **Engineering controls:** Dermal (24 to 48 replicates) and inhalation (23 replicates) exposure values are based on ABC grade data. Hand (34 replicates) exposure value is based on AB grade data. Medium confidence in the unit exposure value. No protection factors were needed to define the unit exposure
Helicopter Application (4)	Insufficient Data -- see aircraft application (3)		
Groundboom Application (5)	PHED V1.1	80 acres	**Baseline:** Dermal (23 to 42 replicates); hand (29 replicates); and inhalation (22 replicates) exposure values are based on AB grade data. High confidence in the unit exposure value. No protection factors were required to define the unit exposure value. **PPE:** The same dermal and inhalation data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing and a 5-fold protection factor to account for the use of a dust/mist respirator. Hand (21 replicates) exposure value is based on ABC grade data. Medium confidence in the unit exposure value. **Engineering Controls:** Dermal (20 to 31 replicates) and hand (16 replicates) exposure values are based on ABC grade data. Inhalation (16 replicates) exposure value is based on AB grade data. Medium confidence in unit exposure value. No protection factors were required to define the unit exposure value.

Exposure Scenario (Number)	Data Source	Standard Assumptions	Comments
Applying Liquids with a Paintbrush (6)	PHED V1.1	2 gallons	**Baseline:** Dermal (14 to 15 replicates) and inhalation (15 replicates) exposure values are based on C grade data. Hand (15 replicates) exposure value is based on AB grade data. Low confidence in the unit exposure value. No protection factors were required to define the unit exposure value. **PPE:** The same data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing; a 5-fold protection factor to account for the use of a dust/mist respirator; and a 90% protection factor to account for the use of chemical-resistant gloves. Low confidence in the unit exposure value. **Engineering Controls:** Not considered a plausible option for this assessment.
Applying Liquids with an Airblast/ Mistblower Sprayer (7)	PHED V1.1	20 acres conifer seed nursery; 40 acres all other crops	**Baseline:** Dermal (32 to 49 replicates) and inhalation (47 replicates) exposure values are based on AB grade data. Hand (22 replicates) exposure value is based on AB grade data. High confidence in the unit exposure value. No protection factors were needed to define the unit exposure value. **PPE:** The same dermal and inhalation data are used as for baseline coupled with a 50% protection factor applied to the dermal data to account for the use of an additional layer of clothing and a 5-fold protection factor was applied to account for the use of a dust/mist respirator. Hand (18 replicates) exposure value is based on AB grade data. High confidence in unit exposure value. **Engineering Controls:** Dermal (27 to 30 replicates) and hand (20 replicates) exposure values are based on AB grade data. Inhalation (9 replicates) exposure value is based on ABC grade data. Low confidence in the dermal unit exposure value. Empirical data include the use of chemical-resistant gloves.
Applying Liquids Ready-to-Use (8)	No Data	No Data	No Data

Exposure Scenario (Number)	Data Source	Standard Assumptions	Comments
Applying Liquids to Non-crop land adjacent to vineyards (rights-of-way data) (9)	PHED V1.1	10 acres	**Baseline:** Dermal (4 to 20 replicates) exposure value is based on ABC grade data. Hand (16 replicates) exposure values based on AB grade data and inhalation (16 replicates) exposure values is based on A grade data. Low confidence in the dermal unit exposure value and high confidence in the inhalation data. No protection factors were needed to define the unit exposure value. **PPE:** The same dermal and inhalation data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing and a 5-fold protection factor to account for the use of a dust/mist respirator. Hand (4 replicates) exposure value is based on AB grade data. Low confidence in the hands and dermal unit exposure value. **Engineering Controls:** Not considered a plausible option for this assessment.
Occupational Mixer/Loader/Applicator Exposure			
Soil Injection (10)	No Data	No Data	No Data
Backpack Sprayer (11)	PHED V1.1	40 gallons	**Baseline:** Dermal (9 to 11 replicates) and inhalation (11 replicates) exposure values are based on AB grade data. Hand data (11 replicates) exposure value is based on C grade data. Low confidence in the unit exposure value. No protection factors were needed to define the unit exposure value. Empirical data include the use of chemical-resistant gloves. **PPE:** The same dermal, inhalation, and hand data are used as for the baseline coupled with a 50% protection factor to account for the use of an additional layer of clothing and a 5-fold protection factor to account for the use of a dust/mist respirator. Low confidence in the unit exposure value for hands (11 replicates). This data is based on C grade data. **Engineering Controls:** Not considered plausible for this assessment.

Exposure Scenario (Number)	Data Source	Standard Assumptions	Comments
Low Pressure Handwand (12)	PHED V1.1	40 gallons	**Baseline:** Dermal (9 to 80 replicates) and inhalation (80 replicates) exposure values are based on ABC grade data. Hand (70 replicates) exposure value is based on all grade data. Low confidence in the dermal and hands unit exposure value. Medium confidence in the inhalation unit exposure value. No protection factors were needed to define the unit exposure value. **PPE:** The same dermal, inhalation, and hand data are used as for baseline coupled with a 50% protection factor to account for the use of an additional layer of clothing and a 5-fold protection factor to account for the use of a dust/mist respirator. **Engineering Controls:** Not considered plausible for this assessment.
High Pressure Sprayer (13)	PHED V1.1	1,000 gallons	**Baseline:** Dermal (7 to 13 replicates) are based on AB grade data and inhalation (13 replicates) exposure values are based on A grade data. Hand data is back calculated from glove data assuming gloves provide 90% protection. A 90% PF was needed to define this unit exposure value. **PPE:** The same dermal, inhalation, and hand data are used as for the baseline coupled with a 50% protection factor to account for the use of an additional layer of clothing and a 5-fold protection factor to account for the use of a dust/mist respirator. Low confidence in the unit exposure value for hands (13 replicates). This data is based on C grade data. **Engineering Controls:** Not considered plausible for this assessment.
Sprinkler Can (14)	No Data	No Data	No Data
Drencher (Soil Drench) (15)	No Data	No Data	No Data

Exposure Scenario (Number)	Data Source	Standard Assumptions	Comments
Occupational Flagger Exposure			
Flagger (16)	PHED V1.1	350 acres	**Baseline:** Dermal (18 to 28 replicates); hand (30 replicates); and inhalation (28 replicates) exposure values are based on AB grade data. High confidence in the unit exposure value. No protection factors were needed to define the unit exposure value. **PPE:** The same dermal and inhalation data are used as for the baseline coupled with a 50% protection factor to account for the use of an additional layer of clothing and a 5-fold protection factor to account for the use of a dust/mist respirator. Hand (6 replicates) exposure value is based on AB grade data. Low confidence in the unit exposure value. **Engineering Controls:** Data is based on groundboom enclosed cab. Dermal (20 to 31 replicates); hand (16 replicates); and inhalation (16 replicates) exposure values are based on ABC grade data for dermal and hands and AB grade data for inhalation. Medium confidence for hands and dermal and high confidence for inhalation.

[a] Standard assumptions are based on the activities of a typical individual over a daily 8 hour interval. Occupational scenarios reflect what individuals could accomplish in an 8 hour workday.

[b] Data quality assessments are based on the PHED grading criteria and the guidance provided in the Dec 1997 surrogate exposure table. Acceptable grades are matrices with grade A and/or B data. The PHED surrogate exposure table upon which this assessment is based was developed using the best data available in the system that are appropriate to the exposure scenario. Data confidence descriptors are assigned as follows:

High = grades A and B and 15 or more replicates;
Medium = grades A, B, and C and 15 or more replicates; and
Low = grades A, B, C, D, and E or any combination of grades with less than 15 replicates