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MEMORANDUM

SUBJECT: OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT
AND RECOMMENDATIONS FOR THE REREGISTRATION
ELIGIBILITY DECISION DOCUMENT FOR
METHIDATHION

FROM: Bruce Kitchens, Chemist
Special Review and Reregistration Section II
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

TO: Mike S. Metzger, Chief
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

THRU: Mark Dow, Section Head
Special Review and Reregistration Section II
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Please find the OREB review of methidathion.

DP Barcode: D223664

Pesticide Chemical Codes: 100301

EPA Reg Nos: 100-501, 100-530, 100-567, 100-719, 100-754, 100-721

EPA MRID No.: None

PHED: Yes, Version 1.1

OCCUPATIONAL AND RESIDENTIAL EXPOSURE CHAPTER

In this document, which is for use in EPA's development of the Methidathion Reregistration Eligibility Decision Document (RED), EPA presents the results of its review of the potential human health effects of occupational and residential exposure to methidathion. Included is a discussion of the adequacy of the occupational and residential exposure data that have been submitted in support of the reregistration of methidathion.

(RED SECTION III - TOXICITY, EXPOSURE, AND RISK)

(EXPOSURE)

Occupational and Residential

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete.

Use Summary

Use Patterns

Methidathion, 0,0-dimethyl phosphorodithioate, S-ester with 4-(mercaptomethyl)-2-methoxy-delta²-1,3,4-thiadiazolin-5-one is an insecticide/acaricide.^{1,2,3} Methidathion is formulated as an emulsifiable concentrate (22.6 to 24.4 percent active ingredient), a wettable powder (24.4 to 25 percent active ingredient), a liquid intermediate formulation (50 percent active ingredient), and a solid/technical formulation (95 percent active ingredient).^{2,3} The following equipment is used to apply methidathion: fixed-wing aircraft, helicopter, airblast sprayer, low pressure handwand, backpack sprayer and groundboom sprayer.^{2,3} Methidathion is registered for use on terrestrial food crops including alfalfa, artichoke, citrus, clove, fruits and nuts, cotton, olives, safflowers, sun flowers, and sorghum.¹ Methidathion is also used on terrestrial nonfood crops like tobacco and ornamental pines.¹ Alfalfa and citrus are the predominant uses. Application rates for methidathion range from 0.25 to 10 lb ai/acre.^{2,3}

The target pests include peach twig borer, scale insects, artichoke plume moth, leafminers, spider mites, boll weevil, bollworms, lygus bug, pink bollworm, whiteflies, aphids, pear psylla, mealybugs, thrips, sunflower stem weevil, sunflower moth, sunflower seed weevils, sunflower midge, Banks grass mites, flea beetles, hornworms, tobacco budworm, codling moth, and hickory shuckworms.¹

Occupational-use products and homeowner use products

Methidathion is a restricted use pesticide. At this time products containing methidathion are intended only for occupational uses.

Summary of Toxicity Concerns Impacting Occupational and Residential Exposures

Acute Toxicology Categories

The toxicological data base for methidathion is adequate and will support reregistration. Guideline studies for acute toxicity indicate that the technical grade of methidathion is classified as category I for acute oral toxicity, category II for acute dermal toxicity, category III for primary eye irritation, category IV for primary skin irritation, and is not classified as a skin sensitizer.⁴ No acute inhalation studies have been conducted with technical methidathion. There is however, a 50% end use product that is classified as a tox category II compound by the inhalation route.⁴ Methidathion's vapor pressure is 2.50×10^{-6} as stated in the Environmental Fate and Ground Water Branch (EFGWB) One-Liner Data Base.

Other Endpoints of Concern

The *Toxicity Endpoint Selection Document*, dated June 4, 1996, indicates that there are toxicological endpoints of concern for methidathion.⁴ Endpoints have been identified, for short-term, intermediate-term, and chronic exposures. The NOEL for both short-term and intermediate-term exposure is 0.2 mg/kg/day based on a rabbit dermal study which focused on effects to plasma, RBC and brain ChE.⁴ This study was a dermal study, thus dermal absorption was not necessary. The NOEL for chronic exposure is 0.15 mg/kg/day based on a chronic toxicity study in dogs in which plasma and RBC ChE inhibition was observed. Chronic exposure assessment was not calculated due to the absence of potential chronic exposure. Methidathion is classified a Group C carcinogen without a Q* based on liver tumors in mice.

Epidemiological Information

The following are conclusions from the review of poisoning incident data related to methidathion (See Attachment 1).

1. Of the eight Incident Data System reports, only one involved human exposure to methidathion alone. A mixer/loader in California spilled Supracide® on his coveralls, but continued to work before changing clothes. Two days later, he developed ataxia, dizziness and vomiting and was treated for organophosphate poisoning.
2. Methidathion was one of the 28 organophosphate and carbamate chemicals for which Poison Control Center (PCC) data (from 1985-1992) were requested as part of Data-Call-Ins. The 28

chemicals were ranked using three types of measures: (A) number and percent occupational and non-occupational adult exposures reported to PCCs requiring treatment, hospitalization, displaying symptoms or serious life-threatening effects; (B) California data for handlers and field workers comparing number of agricultural poisonings to reported applications; and (C) ratios of poisonings and hospitalization for PCC cases to estimated pounds reported in agriculture for pesticides used primarily in agriculture.

There were a total of 46 methidathion cases in the PCC data base. Of these, 21 cases were occupational exposure; 15 (72%) involved exposure to methidathion alone and 6 (28%) involved exposure to multiple chemicals, including methidathion. There were a total of 25 adult non-occupational exposures; 20 (80%) involved this chemical alone and 5 (20%) were attributed to multiple chemicals.¹

Four measures of occupational and non-occupational hazard were developed to rank chemicals used alone or in combination. Methidathion scored near the median for all of the measures except for percent of cases with life-threatening symptoms. When used in combination with other chemicals, methidathion ranked number one (most hazardous) for this measure. However, this calculation is not reliable because it is based on less than 25 cases. (See Table 1.)

Methidathion, when used alone, ranked number three in the ratio of poisonings per 1,000 applications in field workers using California data. When Poison Control Center data were used, methidathion ranked number three in exposure per use, poisonings per use and health care referral per use. (See Tables 2 and 3.)

Only three cases of methidathion poisoning in children were reported to the Poison Control Centers from 1985 through 1992.

3. Detailed descriptions of incidents reported to the California Pesticide Illness Surveillance Program from 1982 through 1993 were reviewed. There were a total of 59 cases in which methidathion was either used alone or in combination with one other chemical (dicofol, dimethoate or xylene) but methidathion was judged to be responsible for the health effects. The majority of the illnesses were of a systemic type. (See Table 4.) Exposure to drift was the most frequently involved activity category. (See Table 5.) However, 14 of the 21 drift systemic illnesses resulted after exposure to a group of grape pickers. Applicator was the second most frequently exposed category. Accidents, such as hoses breaking or pressure building up in cans, were responsible for 5 exposures. The comments sections of the reports noted that workers were not wearing personal protective equipment in two cases.

¹ Workers who were indirectly exposed (not handlers) were classified as non-occupational cases.

4. Methidathion was not on the list of the top 200 chemicals for which NPTN received calls from 1984-1991, inclusively.

Handler Exposures & Assumptions

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with methidathion. Based on the use patterns seven major exposure scenarios were identified for methidathion: (1a) mixing/loading wettable powder for aerial application; (1b) mixing/loading wettable powder for groundboom; (1c) mixing/loading wettable powder for airblast sprayer application; (2a) mixing/loading liquid for aerial application; (2b) mixing/loading liquids for groundboom; (2c) mixing/loading liquid for airblast sprayer application; (3) aerial application of liquids (fixed-wing); (4) aerial application of liquids (helicopter); (5) groundboom application of liquids; (6) airblast sprayer application of liquids; (7) mixing/loading/applying with a low pressure handwand; (8) mixer/loader/applying liquids with a backpack sprayer; and, (9) flagging liquid aerial applications.

Short-term and intermediate-term dermal and inhalation exposure assessments using PHED Version 1.1 surrogate data are presented in Table 1. *No chemical-specific data were submitted.* Table 2 presents the corresponding risk assessment for the short-term and intermediate-term dermal and inhalation exposures. Table 3 summarizes the caveats and parameters specific to each exposure scenario and corresponding risk assessment.

Potential daily exposure is calculated using the following formula:

$$\text{Daily Exposure} \left(\frac{\text{mg ai}}{\text{day}} \right) = \text{Unit Exposure} \left(\frac{\text{mg ai}}{\text{lb ai}} \right) \times \text{Max. Appl. Rate} \left(\frac{\text{lb ai}}{\text{acre}} \right) \times \text{Max. Area Treated} \left(\frac{\text{acres}}{\text{day}} \right)$$

Table 1: Summary Exposure Values for Methidathion

| Table 1: Summary Exposure Values for Mitigation | | | | | | | |
|--|-------------------------------------|---|-------------------------------|----------------------|---|---|--|
| Exposure Scenario | Baseline Dermal Exposure (mg/lb ai) | Baseline Inhalation Exposure (µg/lb ai) | Application Rate (lb ai/acre) | Max. Treated (acres) | Daily Dermal Exposure (mg/day) ^a | Daily Inhalation Exposure (mg/day) ^b | Daily Total Exposure (mg/day) ^c |
| Mixer/Loader Exposure | | | | | | | |
| Mixing/Loading Wettable Powder for Aerial Application (1a) | 3.8 | 43.4 | 5 | 350 | 6,650 | 75.95 | 6,725.95 |
| Mixing/Loading Wettable Powder for Groundboom Application (1b) | | | 5 | 80 | 1,520 | 17.36 | 1,537.36 |
| Mixing/Loading Wettable Powder for Airblast Sprayer Application (1c) | | | 5 | 40 | 760 | 8.68 | 768.68 |
| Mixing/Loading Liquids for Aerial Application (2a) | 2.9 | 1.2 | 10 | 350 | 10,130 | 4.2 | 10,154.2 |
| Mixing/Loading Liquids for Groundboom Application (2b) | | | 10 | 80 | 2,320 | 0.96 | 2,320.96 |
| Mixing/Loading Liquids for Airblast Sprayer Application (2c) | | | 10 | 40 | 1,160 | 0.48 | 1,160.48 |
| Applicator Exposure | | | | | | | |
| Aerial Application with a Fixed-Wing Aircraft (3) | See Eng. Controls | See Eng. Controls | 10 | 350 | See Eng. Controls | See Eng. Controls | See Eng. Controls |
| Aerial Application with a Helicopter (4) | See Eng. Controls | See Eng. Controls | 10 | 350 | See Eng. Controls | See Eng. Controls | See Eng. Controls |
| Groundboom (5) | 0.015 | 0.7 | 10 | 80 | 12 | 0.56 | 12.56 |
| Airblast Sprayer (6) | 0.36 | 4.5 | 10 | 40 | 144 | 1.8 | 145.8 |
| Mixer/Loader/Applicator Exposure | | | | | | | |
| Low Pressure Handwand (7) | 103.8 | 31.2 | 2 lbs ai/gal. | 40 gallons | 8,304 | 2.5 | 8,306.5 |
| Backpack Sprayer (8) | 2.5 | 30.2 | 2 lbs ai/gal. | 40 gallons | 200 | 2.4 | 202.4 |
| Flagger Exposure | | | | | | | |
| Liquid Application (9) | 0.01 | 0.28 | 10 | 350 | 35 | 0.98 | 35.98 |

- a Daily dermal exposure (mg/day) = Unit exposure (mg/lb ai) * Max. Appl. Rate (lb ai/acre) * Max. Treated (acres/day)
- b Daily inhalation exposure (μg/day) = Unit exposure (μg/lb ai) * 1mg/1000μg (conversion factor) * Max. Appl. Rate (lb ai/acre) * Max. Treated (acres/day)
- c Total daily exposure (mg/day) = Dermal exposure (mg/day) + inhalation exposure (mg/dt.y)

Table 2. Short-Term and Intermediate-Term Risk from Methidathion

| Table 2. Short-Term and Intermediate-Term Risk from Application | | | | | | | | | | |
|--|---------------------------------|----------------------------------|---------------------------------|-------------------------------------|-------------------------------------|------------------------|---------------------------------|-------------------------------------|-------------------------------------|------------------------|
| Exposure Scenario (Scen #) | Baseline Total Dose (mg/kg/day) | Baseline Dermal MOE ^b | Additional PPE | | | Engineering Controls | | | | |
| | | | Dermal Unit Exposure (mg/lb ai) | Inhalation Unit Exposure (μg/lb ai) | Total Dose ^a (mg/kg/day) | Total MOE ^b | Dermal Unit Exposure (mg/lb ai) | Inhalation Unit Exposure (μg/lb ai) | Total Dose ^a (mg/kg/day) | Total MOE ^b |
| Mixer/Loader Risk | | | | | | | | | | |
| Mixing/Loading Wettable Powder for Aerial Application (1a) | 96.1 | 0.002 | 0.089 | 43.4 | 3.31 | 0.06 | 0.02 | 0.24 | 0.51 | 0.39 |
| Mixing/Loading Wettable Powder for Groundboom Application (1b) | 22.0 | 0.009 | | | 0.76 | 0.26 | | | 0.12 | 2 |
| Mixing/Loading Wettable Powder for Airblast Application (1c) | 11.0 | 0.02 | | | 0.38 | 0.53 | | | 0.058 | 3 |
| Mixing/Loading Liquid for Aerial Application (2a) | 145 | 0.001 | 0.025 | 1.2 | 1.32 | 0.15 | 0.009 | 0.08 | 0.46 | 0.43 |
| Mixing/Loading Liquid for Groundboom Application (2b) | 33.2 | 0.006 | | | 0.30 | 0.67 | | | 0.10 | 2 |
| Mixing/Loading Liquid for Airblast Application (2c) | 16.6 | 0.01 | | | 0.15 | 1 | | | 0.052 | 4 |
| Applicator Risk | | | | | | | | | | |
| Aerial Application of Liquids - Fixed-Wing Aircraft - Enclosed Cockpit (3) | See Eng. Controls | See Eng. Controls | See Eng. Controls | See Eng. Controls | See Eng. Controls | See Eng. Controls | 0.005 | 0.068 | 0.26 | 0.77 |
| Aerial Application of Liquids - Helicopter Aircraft - Enclosed Cockpit (4) | See Eng. Controls | See Eng. Controls | See Eng. Controls | See Eng. Controls | See Eng. Controls | See Eng. Controls | 0.0021 | 0.0018 | 0.11 | 2 |
| Groundboom Application of Liquids (5) | 0.18 | 1 | 0.01 | 0.7 | 0.12 | 2 | 0.0067 | 0.043 | 0.066 | 3 |
| Airblast Sprayer (6) | 2.0 | 0.1 | 0.122 | 4.5 | 0.72 | 0.28 | 0.016 | 0.4 | 0.094 | 2 |
| Mixer/Loader/Applicator Risk | | | | | | | | | | |
| Low Pressure Handwand (7) | 118.7 | 0.0017 | 3.2 | 31.2 | 3.7 | 0.05 | None | None | None | None |

| Exposure Scenario (Scen #) | Baseline Total Dose (mg/kg/day) | Baseline Dermal MOE ^b | Additional PPE | | | | Engineering Controls | | | |
|----------------------------|---------------------------------------|--|--|--|--|---------------------------|--|--|---|---------------------------|
| | | | Dermal Unit Exposure (mg/lb ai) | Inhalation Unit Exposure (μ g/lb ai) | Total Dose ^a (mg/kg/day) | Total MOE ^b | Dermal Unit Exposure (mg/lb ai) | Inhalation Unit Exposure (μ g/lb ai) | Total Dose ^a (mg/kg/ day) | Total MOE ^b |
| Backpack Sprayer (8) | 2.9 | 0.069 | 1.3 | 30.2 | 1.5 | 0.13 | None | None | None | None |

| Exposure Scenario (Scen #) | Baseline Total Dose (mg/kg/day) | Baseline Dermal MOE ^b | Additional PPE | | | | Engineering Controls | | | |
|-------------------------------------|---------------------------------------|--|--|--|--|---------------------------|--|--|---|---------------------------|
| | | | Dermal Unit Exposure (mg/lb ai) | Inhalation Unit Exposure (μg/lb ai) | Total Dose ^a (mg/kg/day) | Total MOE ^b | Dermal Unit Exposure (mg/lb ai) | Inhalation Unit Exposure (μg/lb ai) | Total Dose ^a (mg/kg/ day) | Total MOE ^b |
| | | | Flagger Risk | | | | | | | |
| Flagging for Liquid Application (9) | 0.52 | 0.38 | 0.0053 | 0.28 | 0.28 | 0.71 | 0.00042 | 0.0056 | 0.02 | 10 |

None = No engineering controls are possible.

^a Total Dose (daily dermal exposure + daily inhalation exposure) / 70 kg.

^b MOE = NOEL (0.2 mg/kg/day) / daily dermal dose.

Baseline dermal unit exposure represents long pants, long sleeve shirts, no gloves, open mixing/loading, open cab tractor. Baseline inhalation exposure represents no respirator.

Additional PPE dermal unit exposure represents coveralls over single layer of clothing and chemical resistant gloves, open mixing/loading, open cab tractor. Unless noted otherwise, no respirators were used.

Engineering controls:

Scenarios 1a, 1b and 1c: Closed mixing/loading system, water soluble packets, single layer clothing and no gloves.

Scenarios 2a, 2b and 2c: Closed mixing/loading system, single layer clothing and no gloves.

Scenarios 3 and 4: Closed cockpit, single layer clothing and no chemical resistant gloves.

Scenarios 5, 6 and 7: Closed cab, single layer clothing and no chemical resistant gloves.

Table 3. Exposure Scenario Descriptions for Uses of Methidathion

| Exposure Scenario (Number) | Data Source | Standard Assumptions ^a (8-hr work day) | Comments ^b |
|---|-------------|--|--|
| Mixer/Loader Exposure | | | |
| Mixing/Loading Wettable Powder (1a, 1b and 1c) | PHED V1.1 | 80 acres groundboom, 350 acres aerial and 40 acres airblast | <p>Baseline: "Best Available" grades: Hands all grades, dermal and inhalation grades ABC. Hands = 28 replicates; Dermal = 22 to 45 replicates; Inhalation = 44 replicates. Low confidence in dermal data; medium confidence in inhalation data.</p> <p>PPE: "Best Available" grades: Hands all grades, dermal and inhalation grades ABC. Hands = 24 replicates; Dermal = 22 to 45 replicates. Inhalation = 44 replicates. Medium confidence in dermal and inhalation data.</p> <p>Engineering Controls (water soluble packets): "Best Available" grades: Hands, dermal and inhalation all grades. Hands = 5 replicates; Dermal = 6 to 15 replicates; Inhalation = 15 replicates. Low confidence in dermal and inhalation data. Water soluble packets used for dermal and inhalation unit exposures.</p> <p>PHED data used for baseline and engineering controls, no Protection Factor (PF) were necessary. Fifty percent PF was used for coveralls (PPE).</p> |
| Mixing Liquid (2a, 2b and 2c) | PHED V1.1 | 80 acres groundboom, 350 acres aerial, and 40 acres airblast | <p>Baseline: "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 53 replicates; Dermal = 25 to 122 replicates; Inhalation = 85 replicates. High confidence in dermal data; high confidence in inhalation data.</p> <p>PPE: "Best Available" grades: Hands and dermal acceptable grades. Hands = 59 replicates; Dermal = 25 to 122 replicates. High confidence in dermal and inhalation data.</p> <p>Engineering Controls (closed system): "Best Available" grades: Dermal and inhalation acceptable grades. Dermal = 16 to 22 replicates; Inhalation = 27 replicates. High confidence in dermal and inhalation data.</p> <p>PHED data used for baseline and engineering controls, no Protection Factor (PF) were necessary. Fifty percent PF was used for coveralls (PPE).</p> |
| Applicator Exposure | | | |
| Aerial equipment--fixed wing enclosed cab (liquids) (3) | PHED V1.1 | 350 acres | <p>Engineering Controls (enclosed cockpit): "Best Available" grades: Hands acceptable grades, dermal and inhalation grades A,B,C. Hands = 34 replicates; Dermal = 24 to 48 replicates; Inhalation = 23 replicates. Medium confidence in dermal and inhalation data.</p> <p>PHED data used for engineering controls, no PFs were necessary.</p> |

| Exposure Scenario (Number) | Data Source | Standard Assumptions ^a (8-hr work day) | Comments ^b |
|---|-------------|--|---|
| Aerial equipment--helicopter enclosed cab (liquids) (4) | PHED V1.1 | 350 acres | <p>Engineering Controls (enclosed cockpit): "Best Available" grades: dermal and hand grades A,B,C; inhalation grades "acceptable". Dermal = 2 to 3 replicates; Inhalation = 3 replicates. Low confidence in dermal and inhalation data.</p> <p>PHED data used for engineering controls, no PFs were necessary.</p> |
| Groundboom Application (liquids) (5) | PHED V1.1 | 80 acres | <p>Baseline: "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 29 replicates; Dermal = 32 to 42 replicates; Inhalation = 22 replicates. High confidence in dermal and inhalation data.</p> <p>PPE: "Best Available" grades: Hands, dermal and inhalation acceptable grades. Dermal = 32 to 42 replicates; inhalation = 22 replicates. Medium confidence in dermal data; high confidence in inhalation data.</p> <p>Engineering Controls (enclosed cab): "Best Available" grades: Hands, and dermal = ABC grades; Inhalation = acceptable grades. Dermal = 20 to 31 replicates; Inhalation = 16 replicates. Medium confidence in dermal data; high confidence in inhalation.</p> <p>PHED data used for baseline and engineering controls, no PFs were necessary. Fifty percent PF was added for coveralls for PPE.</p> |

| Exposure Scenario (Number) | Data Source | Standard Assumptions ^a (8-hr work day) | Comments ^b |
|----------------------------|-------------|--|---|
| Airblast Sprayer (6) | PHED V1.1 | 40 acres | <p>Baseline: "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 22 replicates; Dermal = 32 to 49 replicates; Inhalation = 47 replicates. High confidence in dermal and inhalation data.</p> <p>PPE: "Best Available" grades: Hands, dermal and inhalation acceptable grades. Hands = 18 replicates; dermal = 32 to 49 replicates; inhalation = 47 replicates. High confidence in dermal and inhalation data.</p> <p>Engineering Controls (enclosed cab): "Best Available" grades: Hands, and dermal = acceptable grades; Inhalation = grades ABC. Hands = 20 replicates; Dermal = 20 to 30 replicates; Inhalation = 9 replicates. High confidence in dermal data; low confidence in inhalation.</p> <p>PHED data used for baseline and engineering controls, no PFs were necessary. Fifty percent PF was added for coveralls for PPE.</p> |
| | | | Mixer/Loader/Applicator Exposure |

| Exposure Scenario (Number) | Data Source | Standard Assumptions ^a (8-hr work day) | Comments ^b |
|--------------------------------------|-------------|--|---|
| Low Pressure Handwand (7) | PHED V1.1 | 40 gallons | <p>Baseline: "Best Available" grades: Hands, dermal, and inhalation all grades. Hands = 70 replicates; Dermal = 25 to 96 replicates; Inhalation = 96 replicates. Low confidence in dermal and inhalation data.</p> <p>PPE: "Best Available" grades: Hands, dermal, and inhalation all grades. Hands = 15 replicates; dermal = 25 to 96 replicates; inhalation = 96 replicates. Low confidence in dermal and inhalation data.</p> <p>PHED data used for baseline data no PFs were necessary. Fifty percent PF was added for coveralls for PPE.</p> |
| Backpack Sprayer (8) | PHED V1.1 | 40 gallons | <p>Baseline: "Best Available" grades: Dermal = A,B,C data, and inhalation acceptable grades. Dermal = 9 to 11 replicates; Inhalation = 11 replicates. Low confidence in dermal and inhalation data.</p> <p>PPE: "Best Available" grades: Hands = A,B,C data, dermal = A,B,C, and inhalation acceptable grades. Hands = 11 replicates; dermal = 9 to 11 replicates; inhalation = 11 replicates. Low confidence in dermal and inhalation data.</p> <p>PHED data used for baseline data no PFs were necessary. Fifty percent PF was added for coveralls for PPE.</p> |
| Flagger Exposure | | | |
| Flagging for Liquid Applications (9) | PHED V1.1 | 350 Acres | <p>Baseline: "Best Available" grades: Hands, dermal, and inhalation acceptable grades. Hands = 16 replicates; Dermal = 16 to 18 replicates; Inhalation = 18 replicates. High confidence in dermal and inhalation data.</p> <p>PHED data used for baseline data. Fifty percent PF was added for coveralls and a 90 percent PF was added for gloves for the additional PPE scenario. Ninety-eight percent PF was added for closed cab for the engineering controls scenario.</p> |

^a Standard Assumptions based on an 8-hour work day as estimated by OREB. BEAD data were not available.

^b "Best Available" grades are defined by OREB SOP for meeting Subdivision U Guidelines. Best available grades are assigned as follows: matrices with grades A and B data and a minimum of 15 replicates; if not available, then grades A, B, and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality and number of replicates. Data confidence are assigned as follows:

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

These calculations of daily exposure to methidathion by handlers are used to calculate the daily dose to those handlers.

Post Application Exposure & Assumptions

(RISK)

Occupational and Residential

The daily dose is calculated using the following formula:

$$\text{Daily Dose} \left(\frac{\text{mg ai}}{\text{kg/day}} \right) = \text{Daily Exposure} \left(\frac{\text{mg ai}}{\text{day}} \right) \times \left(\frac{1}{\text{body weight (kg)}} \right)$$

These calculations of daily dose of methidathion received by handlers are used to assess the dermal risk to those handlers. The short-term and intermediate-term MOEs were calculated using the following formula:

$$\text{MOE} = \frac{\text{NOEL} \left(\frac{\text{mg}}{\text{kg/day}} \right)}{\text{Daily Dose} \left(\frac{\text{mg}}{\text{kg/day}} \right)}$$

These calculations of daily dose of methidathion by handlers are used to assess the risk to those handlers. For the short-term risk assessment, a NOEL of 0.2 mg/kg/day was used along with a 70 kg body weight. The intermediate-term risk assessment, also used a NOEL of 0.2 mg/kg/day and a 70 kg body weight.

Risk From Handler Exposures

Short-Term and Intermediate-Term Risk

The calculations of risk indicate that the MOEs are more than 100 at **baseline** for short-term and intermediate-term risk for the following scenario:

- None

The calculations of risk indicate that the MOEs are more than 100 with **Additional PPE** for short-term and intermediate-term risk for the following scenarios:

- None

The calculations of risk indicate that the MOEs are more than 100 with **Engineering Controls** for short-term and intermediate-term risk for the following scenarios:

- None

The calculations of risk indicate that the MOEs are not more than 100 despite maximum mitigation measures for the following scenarios:

- (1a, 1b and 1c) mixing/loading wettable powder for aerial, groundboom sprayer and airblast sprayer application;
- (2a, 2b and 2c) mixing/loading liquids for aerial, groundboom sprayer and airblast sprayer application;
- (3) liquid aerial application with a fixed-wing aircraft;
- (4) liquid aerial application with a helicopter;
- (5) liquid groundboom sprayer application;
- (6) liquid airblast sprayer application;
- (7) liquid mixing/loading/application with a low pressure sprayer;
- (8) liquid mixing/loading/application with a backpack sprayer; and,
- (9) flagging of aerial liquid application.

There were no data for the following scenarios:

- (3) baseline and additional PPE data for liquids aerial application with a fixed-wing aircraft. There are engineering controls data for this scenario.
- (4) baseline and additional PPE data for liquids aerial application with a helicopter. There are engineering controls data for this scenario.
- (7) engineering controls for liquid mixing/loading/application with a low pressure handwand. There are baseline and additional PPE data for this scenario.
- (8) engineering controls for liquid mixing/loading/application with a backpack sprayer. There are baseline and additional PPE data for this scenario.

Risk From Post-Application Exposures

Despite the potential for post-application exposure, EPA/OREB has decided not to assess this exposure at this time. The decision was based on the fact that all of the short-term

and intermediate-term handler MOEs were unacceptable. Until the issues surrounding the handling of methidathion can be resolved, EPA/OREB decided to wait on creating the post application exposure assessment.

Additional Occupational/Residential Exposure Studies

EPA/OREB needs to meet with the registrant concerning risk mitigation measures.

Handler Studies

EPA/OREB needs to meet with the registrant concerning risk mitigation measures.

Post-Application Studies

Despite the potential for post-application exposure, EPA/OREB has decided not to assess this exposure at this time. The decision was based on the fact that all of the short-term and intermediate-term handler MOEs were unacceptable. Until the issues surrounding the handling of Methidathion can be resolved, EPA/OREB decided to postpone creating the post application exposure assessment.

References

- 1) US EPA 1988, Pesticide Fact Sheet for Methidathion.
- 2) US EPA 1996, Methidathion LUIS Report, dated 2/12/96.
- 3) Methidathion labels.
- 4) US EPA 1996. Tox Endpoint Selection Committee meeting notes, dated 6/4/96.
- 5) US EPA 1996. Methidathion - Review of Pesticide Poisoning Incident Data, dated 5/7/96.

ATTACHMENT 1

Pesticide Poisoning Incident Data Report

MEMORANDUM

SUBJECT: Methidathion - Review of Pesticide Poisoning Incident Data

FROM: Virginia A. Dobozy, V.M.D., M.P.H., Veterinary Medical Officer
Registration and Special Review Section
Occupational and Residential Exposure Branch

THRU: Jerome Blondell, Ph.D., M.P.H.
Registration and Special Review Section
Occupational and Residential Exposure Branch

and

Francis B. Suhre, Acting Section Head
Registration and Special Review Section
Occupational and Residential Exposure Branch

TO: Bruce Kitchens
Registration and Special Review Section
Occupational and Residential Exposure Branch

The following data bases have been consulted for the poisoning incident data on the active ingredient methidathion (PC Code: 100301):

1) OPP Incident Data System (IDS) - reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992.

2) Poison Control Centers - as the result of Data-Call-Ins issued in 1993, OPP received Poison Control Center data covering the years 1985 through 1992 for 28 organophosphate and carbamate chemicals. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System which obtains data from 70 centers at hospitals or universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings, involving drugs, household products, pesticides, etc.

3) California Department of Food and Agriculture (replaced by the Department of Pesticide Regulation in 1991) - California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the

incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in hospital are provided.

4) National Pesticide Telecommunications Network (NPTN) - NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive has been prepared. The total number of calls was tabulated for the categories humans, animals, calls, incidents and others.

METHIDATHION REVIEW

I. IDS

As of March 23, 1996, there were 8 IDS reports of adverse effects involving methidathion. Two reports involved ecological or environmental damage and were reviewed by EFED. In three incidents, there was exposure to multiple pesticides and the cause of the health effects could not be determined. In two reports, the same person mixed Supracide® with fertilizer and then spread the mixture on the ground on two separate occasions. He developed systemic signs of illness (dizziness, nausea, sore throat and shortness of breath) on both occasions. In the last incident, a mixer/loader in California spilled Supracide® on his coveralls, but continued to work before changing clothes. Two days later, he developed ataxia, dizziness and vomiting and was treated for organophosphate poisoning. This incident occurred in 1995 and is not included with the analysis of the California data which follows under II. California Data - 1982 through 1992.

II. Poison Control Center Data

Methidathion was one of 28 chemicals for which Poison Control Center (PCC) data were requested. The following text and statistics are taken from an analysis of these data; see December 5, 1994 memo from Jerome Blondell to Joshua First.

The 28 chemicals were ranked using three types of measures: (A) number and percent occupational and non-occupational adult exposures reported to PCCs requiring treatment, hospitalization, displaying symptoms or serious life-threatening effects; (B) California data for handlers and field workers comparing number of agricultural poisonings to reported applications; and (C) ratios of poisonings and hospitalization for PCC cases to estimated pounds reported in agriculture for pesticides used primarily in agriculture.

A. Occupational and Non-occupational Exposure

There were a total of 46 methidathion cases in the PCC data base. Of these, 21 cases were occupational exposure; 15 (72%) involved exposure to methidathion alone and 6 (28%) involved exposure to multiple chemicals, including methidathion. Of the 28 chemicals, only profenofos had fewer occupational cases. There were a total of 25 adult non-occupational exposures; 20 (80%) involved this chemical alone and 5 (20%) were attributed to multiple chemicals.² Only three other chemicals (dicrotophos, profenofos and sulfotepp) had fewer non-occupational cases.

In this analysis, four measures of hazard were developed based on the Poison Control Center data, as listed below.

1. Percent of all accidental cases that were seen in or referred to a health care facility (HCF).
2. Percent of these cases (seen in or referred to HCF) that were admitted for medical care.
3. Percent of cases reporting symptoms based on just those cases where the medical outcome could be determined.
4. Percent of those cases that had a major medical outcome which could be defined as life-threatening or resulting in permanent disability.

Exposure to methidathion alone or in combination with other chemicals was evaluated for each of these categories, giving a total of 8 measures. A ranking of the 28 chemicals was done based on these measures with the lowest number being the most frequently implicated in adverse effects. Table 1 presents the analyses for occupational and non-occupational exposures.

Table 1: Measures of Risk From Occupational and Non-occupational Exposure to Methidathion Using Poison Control Center Data from 1985-1992^a (Percents in shadow are not reliable; cases with outcome < 25.)

| | Occupational Exposure | Non-occupational Exposure |
|----------------------------|-----------------------|---------------------------|
| Percent Seen in HCF | | |
| Single chemical exposure | 73.3 (68.2) | 45.0 (44.0) |
| Multiple chemical exposure | 71.4 (69.8) | 56.0 (46.1) |
| Percent Hospitalized | | |
| Single chemical exposure | 9.1 (12.2) | 11.1 (9.9) |
| Multiple chemical exposure | 13.3 (14.3) | 14.3 (12.6) |
| Percent with Symptoms | | |

² Workers who were indirectly exposed (not handlers) were classified as non-occupational cases.

| | | |
|--|-------------|--------------------------|
| Single chemical exposure | 81.8 (85.8) | 66.7 (74.0) |
| Multiple chemical exposure | 87.5 (85.8) | 61.1 (75.2) |
| Percent with Life-threatening Symptoms | | |
| Single chemical exposure | 0.0 (0.0) | 0.0 (0.0) |
| Multiple chemical exposure | 0.0 (0.5) | 4.3* ¹ (0.05) |

a Extracted from Tables 2, 3, 5 and 6 in December 5, 1994 memo from Jerome Blondell to Joshua First; number in parentheses is median score for that category

* Top 25% of chemicals are ranked with a superscript of 1 to 7

As evidenced by the above table, in only two instances, both involving multiple exposures, was there sufficient numbers of cases to develop reliable measures of risk. These two measures were not high when compared to other organophosphates.

B. Ratios of poisoning - California Data

The incidence of **systemic poisoning cases** in agricultural workers reported to the California was compared to the number of applications of methidathion. Those calculations, along with the median score for a total of 29 pesticides, are presented in the Table 2 below.

Table 2: Systemic Poisonings/1,000 Applications in Selected Agricultural Workers Exposed to Methidathion in California, 1982-1989^a

| Pesticide | Number of Appl. | Poisonings/1,000 Appl. (N) Primary Pesticide Only | | | Poisonings/1,000 Appl. (N) Multiple Pesticide Exposure | | |
|--------------|-----------------|--|---------------|----------|---|---------------|-----------|
| | | Handlers | Field Workers | Total | Handlers | Field Workers | Total |
| Methidathion | 37,826 | .21 (8) | .61 (23) | .82 (31) | .40 (15) | .63 (24) | 1.03 (39) |
| Median | | .21 | .20 | .41 | .44 | .50 | 1.02 |

a Extracted from Table A5 in December 5, 1994 memo from Jerome Blondell to Joshua First; number in parentheses is the observed number of poisoned cases.

When used alone, methidathion ranked number 3 (in comparison to the other 28 chemicals) in the ratio of poisonings per 1,000 applications in field workers. Only methamidophos and azinphos-methyl ranked higher. (See Table 7 in the December 5, 1994 memo.)

C. Ratios of Poisoning - U.S. Poison Control Data

Active registrations of methidathion are for agricultural use exclusively. Ratios of the number of occupational Poison Control Center exposures to the reported pounds of the chemical used³ were calculated. The results for methidathion and the median for the 15 agricultural chemicals included in the analysis are presented in the Table 3 below.

Table 3: Ratios of Methidathion Poisonings (PCC Data, 1985-1992) to Reported Use^a

| Pesticide | Exposure Per Use | Poisonings Per Use | Health Care Referral Per Use | Hospital Admitted Cases Per Use |
|--------------|--------------------|----------------------|------------------------------|---------------------------------|
| Methidathion | .052* ³ | .032* ^{3,5} | .037* ⁴ | .005 |
| Median | .033 | .013 | .027 | .004 |

^a Extracted from Table 9 in the December 5, 1994 memo from Jerome Blondell to Joshua First * Top 33% of chemicals are ranked with a superscript of 1 to 5

D. Exposure in Children

A separate analysis of the number of exposures in children five years of age and under from 1985-1992 was conducted. For methidathion, there were 3 incidents; all involved exposure to methidathion alone.

II. California Data - 1982 through 1993

Detailed descriptions of 59 cases submitted to the California Pesticide Illness Surveillance Program were reviewed. In these incidents, methidathion was either used alone or with one other chemical (dicofol, dimethoate or xylene) but methidathion was judged to be responsible for the health effects. (Only cases with a definite, probable or possible relationship were reviewed.) Table 5 presents the types of illness reported by year.

Table 4: Types of Illnesses Reported as a Result of Methidathion Exposure in California, 1982-1993^{a,b}

| Year | No. of Cases | Illness Type | | | |
|------|--------------|--------------|-----|------|----------|
| | | Systemic | Eye | Skin | Eye/Skin |
| 1982 | 7 | 4 | 2 | - | 1 |
| 1983 | 3 | 2 | 1 | - | - |

³ Gianessi, L.P., Puffer, C.A. Insecticide Use in U.S. Crop Production. Resources for the Future, Washington, D.C., 1992.

| | | | | | |
|-------|-----|----|----|---|---|
| 1984 | 4 | 2 | 1 | 1 | - |
| 1985 | 2 | 1 | - | - | 1 |
| 1986 | 17* | 15 | 2 | - | - |
| 1987 | 2 | 2 | - | - | - |
| 1988 | 3 | 2 | 1 | - | - |
| 1989 | 6 | 5 | 3 | - | - |
| 1990 | 6 | 3 | - | 3 | - |
| 1991 | 3 | 2 | 1 | - | - |
| 1993 | 6 | 5 | - | - | 1 |
| Total | 59 | 43 | 11 | 4 | 3 |

a Multiple illnesses may be reported for each case.

b There were no incident reports for 1992 involving use of methidathion alone.

* Includes fourteen grape pickers who were exposed when methidathion was applied to nearby field. Foliage from vineyard revealed residues. All pickers were taken to a doctor for evaluation and cholinesterase testing. Results in comments section for 11 workers state that serum and RBC cholinesterase were within normal range.

The data were also tabulated by type of illnesses reported for individual activity categories; see Table 5 below.

Table 5: Illnesses by Activity Categories for Methidathion Exposure in California, 1982-1993^a

| Activity Category | Illness Category | | | | |
|-------------------|------------------|-----|------|----------|-------|
| | Systemic | Eye | Skin | Eye/Skin | Total |
| Drift | 21* | 3 | - | 1 | 25 |
| Applicator | 10 | 3 | 1 | 2 | 16 |
| Other | 7 | - | 1 | - | 8 |
| Mixer/Loader | 2 | 4 | 1 | - | 7 |
| Residue | 3 | 1 | 1 | - | 5 |

Drift = anyone exposed in the course of application who was not involved in making the application; termed as coincidental prior to 1989; Applicator = workers involved in all forms of pesticide applications (ground, hand, other);

Other = all activity categories not otherwise identified; Mixer/Loader = mixes and loads pesticides; Residue = exposure to residual pesticide (field, structural, other)

* Includes fourteen grape pickers who were exposed when methidathion was applied to a nearby field.

Accidents, such as hoses breaking or pressure building up in cans, were responsible for 5 exposures. The comments sections of the reports noted that workers were not wearing personal protective equipment in two cases. A Notice of Violation was issued in three cases for safety reasons.

IV. NPTN

Methidathion was not on the list of the top 200 chemicals for which NPTN received calls from 1984-1991, inclusively.

V. LITERATURE REPORTS OF HUMAN POISONINGS

Gallo and Lawryk summarized the findings of human ingestion of methidathion.⁴ One man took 0.04 mg/kg/day of methidathion for 17 days and 0.08 mg/kg/day for 8 days without any adverse effect on RBC or plasma cholinesterase or on his clinical condition. In another study, groups of four, eight, and eight men received methidathion in capsules at the rate of 0, 0.04, and 0.11 mg/kg/day, respectively, for 6 weeks. There was no effect on any of the clinical or laboratory parameters measured. In an incident which was not identified as accidental or intentional, a 25-year-old farmer swallowed methidathion. He was found unconscious 2 hours later. He recovered after extensive treatment, including 15 days of artificial respiration.

VI. CONCLUSIONS

1. Of the eight Incident Data System reports, only one involved human exposure to methidathion alone. A mixer/loader in California spilled Supracide® on his coveralls, but continued to work before changing clothes. Two days later, he developed ataxia, dizziness and vomiting and was treated for organophosphate poisoning.
2. Methidathion was one of the 28 organophosphate and carbamate chemicals for which Poison Control Center data (from 1985-1992) were requested as part of Data-Call-Ins. The 28 chemicals were ranked using three types of measures: (A) number and percent occupational and non-occupational adult exposures reported to PCCs requiring treatment, hospitalization, displaying symptoms or serious life-threatening effects; (B) California data for handlers and field workers comparing number of agricultural poisonings to reported applications; and (C)

⁴ Gallo, M.A. and Lawryk, N.J. Organic Phosphorus Pesticides. In Hayes, W.L. and Laws, E.R. (eds.) Handbook of Pesticide Toxicology. Volume 2 Classes of Pesticides. New York, Academic Press, 1991.

ratios of poisonings and hospitalization for PCC cases to estimated pounds reported in agriculture for pesticides used primarily in agriculture.

There were a total of 46 methidathion cases in the PCC data base. Of these, 21 cases were occupational exposure; 15 (72%) involved exposure to methidathion alone and 6 (28%) involved exposure to multiple chemicals, including methidathion. There were a total of 25 adult non-occupational exposures; 20 (80%) involved this chemical alone and 5 (20%) were attributed to multiple chemicals.⁵ Only three other chemicals (dicrotophos, profenofos and sulfotepp) had fewer non-occupational cases.

Four measures of occupational and non-occupational hazard were developed to rank chemicals used alone or in combination. Methidathion scored near the median for all of the measures except for percent of cases with life-threatening symptoms. When used in combination with other chemicals, methidathion ranked number one (most hazardous) for this measure. However, this calculation is not reliable because it is based on less than 25 cases. (See Table 1.)

Methidathion, when used alone, ranked number three in the ratio of poisonings per 1,000 applications in field workers using California data. When Poison Control Center data were used, methidathion ranked number three in exposure per use, poisonings per use and health care referral per use. (See Tables 2 and 3.)

Only three cases of methidathion poisoning in children were reported to the Poison Control Centers from 1985 through 1992.

3. Detailed descriptions of incidents reported to the California Pesticide Illness Surveillance Program from 1982 through 1993 were reviewed. There were a total of 59 cases in which methidathion was either used alone or in combination with one other chemical (dicofol, dimethoate or xylene) but methidathion was judged to be responsible for the health effects. The majority of the illnesses were of a systemic type. (See Table 4.) Exposure to drift was the most frequently involved activity category. (See Table 5.) However, 14 of the 21 drift systemic illnesses resulted after exposure to a group of grape pickers. Applicator was the second most frequently exposed category. Accidents, such hoses breaking or pressure building up in cans, were responsible for 5 exposures. The comments sections of the reports noted that workers were not wearing personal protective equipment in two cases. A Notice of Violation was issued in three cases for safety reasons.

4. Methidathion was not on the list of the top 200 chemicals for which NPTN received calls from 1984-1991, inclusively.

⁵ Workers who were indirectly exposed (not handlers) were classified as non-occupational cases.

VI. RECOMMENDATIONS

The number of poisoning cases due to methidathion exposure reported to the Poison Control Centers and the California Pesticide Illness Surveillance Program is small in relation to other organophosphate and carbamate pesticides. However, the chemical is responsible for a significant number of poisonings when compared to the quantity used. Regulatory restrictions to prevent acute poisonings by methidathion should be in accordance with the Acute Worker Risk Strategy for the more toxic chemicals.