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

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JUN 16 1994

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: OCCUPATIONAL EXPOSURE TO THE ACUTE CENTRAL NERVOUS
SYSTEM (CNS) EFFECTS OF AMITRAZ

FROM: Jeff Evans, Biologist 
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TO: Debra Edwards, Chief
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THRU: 
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Please find the OREB review of

DP Barcode: D192360

Pesticide Chemical Code: 106201

EPA Reg. No.: N/A

EPA MRID No.: 424960-02, 424960-03

Review Time: 5 Days

PHED: 1.01



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I. INTRODUCTION:

The Chemical Coordination Branch (CCB) has requested that OREB conduct an occupational exposure assessment addressing the CNS effects of amitraz. HED's Less-Than-Lifetime committee has established a NOEL of 0.25 mg/kg/day for the CNS effects and the use of an 8% dermal absorption factor to estimate a systemic dose for handlers (mixer/loader/applicators) and workers (reentry).

Because of the low NOEL, some margins of exposure (MOE) are less than 100 (the typically accepted number). For reentry workers, MOE's of 100 or more are not feasible or practical. For handlers (M/L/A), the use of closed systems and closed cabs may be the only way to attain MOE's of 100.

OREB questions the value of requiring MOE greater than 100. OREB is not certain whether the occupational concern is for the acute clinical effects of amitraz or, the potential hazard to equipment operators suffering from acute CNS depression. Because of concerns that low MOE's may overestimate risk, OREB requests that HED's appropriate toxicology personnel provide further guidance regarding the consequences of this effect.

II. DETAILED CONSIDERATIONS:

PEARS - Handler Exposure Using the Registrant's Data

Two studies were submitted by the registrant to address pear mixer/loader/applicator exposure when applying the 1.5 lb ai, per acre rate. Handler exposure was measured using passive dosimetry and biological monitoring. Serious questions regarding the validity of the biological monitoring data prevented its use in the RED. Data from the passive dosimetry study were used however, only 6 replicates were provided (15 are required). Each replicate represented a full day of mixing/loading and applying amitraz. The individuals handled 19 to 20 pounds ai per day. Because the replicates consist of the combined functions and exposure of a mixer/loader/applicator, they could not be merged with data in PHED which separates the mixer/loader function from the applicator function.

In the dermal passive dosimetry study, dermal patches were used to measure exposure inside and outside the handlers clothing. All handlers wore long-sleeved shirts and pants. Two of the six handlers also wore disposable coveralls. All handlers wore gloves during mixing/loading and application activities.

The mean unit exposure from this study (MRID 424960-03) is 4.13 mg/lb ai handled. Assuming the maximum rate of 1.5 lb ai per acre (typically used) and 17 acres treated per day, the average daily exposure (ADE) is 1.5 mg/kg/day. Corrected for

dermal absorption (8%), the ADE is 0.12 mg/kg/day. The MOE is 2.

PEARS - Handler Exposure Using Surrogate Data

In order to fully assess the exposure potential for handlers treating pears with amitraz, data from the Pesticide Handlers Exposure Database (PHED) were used. The database was used to 1) provide separate exposure estimates for mixer/loaders and for applicators and, 2) estimate exposure for the separate functions using closed mixing/loading systems and closed cabs.

Mixer/loader - Open Bag, Wettable Powder

Dermal exposure - wearing protective coveralls and gloves = 0.2 mg/lb ai handled

$$\frac{1.5 \text{ lb ai/A} \times 17 \text{ acres} \times 0.2 \times 8\%}{70 \text{ kg}} = 0.0058 \text{ mg/kg/day}$$

Inhalation exposure - no respirator = 0.0037 mg/lb ai handled

$$\frac{1.5 \text{ lb ai/A} \times 17 \text{ acres} \times 0.0037}{70 \text{ kg}} = 0.0013 \text{ mg/kg/day}$$

Combined exposure = 0.007 mg/kg/day

MOE = 36

Mixer/loader - Water Soluble Pack, Wettable Powder

Dermal exposure - total deposition = 0.02 mg/lb ai handled

$$\frac{1.5 \text{ lb ai/A} \times 17 \text{ acres} \times 0.02 \times 8\%}{70 \text{ kg}} = 0.00058 \text{ mg/kg/day}$$

Inhalation exposure - no respirator = 0.0003 mg/lb ai handled

$$\frac{1.5 \text{ lb ai/acre} \times 17 \text{ acres} \times 0.0003}{70 \text{ kg}} = 0.0001 \text{ mg/kg/day}$$

Combined exposure = 0.0007 mg/kg/day

MOE = 357

Applicator - Open Cab

Dermal exposure - wearing protective coveralls and gloves =
1.8 mg/lb ai handled

$$\frac{1.5 \text{ lb ai/A} \times 17 \text{ acres} \times 1.8 \times 8\%}{70 \text{ kg}} = 0.052 \text{ mg/kg/day}$$

Inhalation exposure - no respirator = 0.0037 mg/lb ai
handled

$$\frac{1.5 \text{ lb ai/A} \times 17 \text{ acres} \times 0.0042}{70 \text{ kg}} = 0.0015 \text{ mg/kg/day}$$

Combined exposure = 0.053 mg/kg/day

MOE = 5

Applicator - Closed Cab

Dermal exposure - total deposition = 0.02 mg/lb ai handled

$$\frac{1.5 \text{ lb ai/A} \times 17 \text{ acres} \times 0.02 \times 8\%}{70 \text{ kg}} = 0.00058 \text{ mg/kg/day}$$

Inhalation exposure - no respirator = 0.0003 mg/lb ai
handled

$$\frac{1.5 \text{ lb ai/acre} \times 17 \text{ acres} \times 0.0003}{70 \text{ kg}} = 0.0001 \text{ mg/kg/day}$$

Combined exposure = 0.0007 mg/kg/day

MOE = 357

PEAR - Worker Reentry

The following table presents amitraz-derived dislodgeable residues on pear foliage following two applications (14 days apart) of the wettable powder formulation. The average daily exposure (ADE) was calculated assuming an 8 hour work day, a dermal absorption rate of 8%, and a transfer coefficient of 10,000 cm²/hr. This generic transfer coefficient was used because concurrent dermal exposure data were not conducted by the registrant. This was the transfer coefficient used in the previous assessment addressing chronic (cancer) concerns.

Days After Treatment (DAT)	Residues ($\mu\text{g}/\text{cm}^2$)	Systemic Dose ADE mg/kg/day	MOE
0	0.66	0.06	4
1	0.69	0.063	4
2	0.67	0.061	4
5	0.62	0.057	4
7	0.8	0.073	3
14	0.6	0.06	4
21	0.64	0.059	4
28	0.23	0.02	13
35	0.27	0.025	10

As shown in the table above, MOE's of 100 or more are not feasible for reentry workers. Although it is possible that harvesting may occur 30 to 60 days after the last treatment, current labelling indicates a preharvest interval (PHI) of 14 days. In addition, reentry activities are not limited to harvesting. Thinning and limb spreading activities may occur much closer to the applications. Scouting activities are covered by the WPS.

LIVESTOCK - SPRAY/DIP APPLICATIONS - Handlers

The ADE's for handlers using amitraz to treat livestock range from 0.00011 mg/kg/day to 0.0011 mg/kg/day. These numbers reflect the 8% dermal absorption rate and were taken from OREB's previous exposure assessment. The respective MOE's are 2272 to 227.

COTTON - HANDLERS

The exposure assessment for cotton was conducted using PHED and addresses the high rate of 1 lb ai/acre. It is assumed that ground boom applicator can treat 100 acres per day and aerial applicators can treat 350 acres per day. For the aerial applications, the mixer/loader and application functions are assumed to be conducted by separate individuals. For the ground boom application, these functions may be performed by the same or by separate individuals.

Mixer/loader - Ground-boom, Open Pour, Liquid Formulation

Dermal exposure - wearing protective coveralls and gloves = 0.113 mg/lb ai handled

$$\frac{1 \text{ lb ai/A} \times 100 \text{ acres} \times 0.113 \times 8\%}{70 \text{ kg}} = 0.013 \text{ mg/kg/day}$$

Inhalation exposure - no respirator = 0.0037 mg/lb ai handled

$$\frac{1 \text{ lb ai/A} \times 100 \text{ acres} \times 0.0004}{70 \text{ kg}} = 0.00057 \text{ mg/kg/day}$$

Combined exposure = 0.0136 mg/kg/day

MOE = 18

MOE's for the lower rates are 38 (0.5 lb/A), 79 (0.25 lb/A), and 145 (0.125 lb/A). If MOE's of 100 or more for mixer/loaders are desired they can only handle @ 20 lb ai/day. Otherwise closed mixing and loading systems are required. The MOE for mixer/loaders using closed system and the PPE suggested in the following scenario is 416

Mixer/loader - Aerial Application Support, Closed System, Liquids

Dermal exposure - long-sleeved shirt, long pants, coveralls, and gloves = 0.0046 mg/lb ai handled

$$\frac{1 \text{ lb ai/A} \times 350 \text{ acres} \times 0.0046 \times 8\%}{70 \text{ kg}} = 0.0018 \text{ mg/kg/day}$$

Inhalation exposure - no respirator = 0.00006 mg/lb ai handled

$$\frac{1 \text{ lb ai/acre} \times 350 \text{ acres} \times 0.00006}{70 \text{ kg}} = 0.0003 \text{ mg/kg/day}$$

Combined exposure = 0.0021 mg/kg/day

MOE = 119

Applicator - Open Cab

Dermal exposure - long sleeve shirt, long pants, and gloves
= 0.014 mg/lb ai handled

$$\frac{1 \text{ lb ai/A} \times 100 \text{ acres} \times 0.014 \times 8\%}{70 \text{ kg}} = 0.0016 \text{ mg/kg/day}$$

Inhalation exposure - no respirator = 0.0004 mg/lb ai
handled

$$\frac{1 \text{ lb ai/A} \times 100 \text{ acres} \times 0.0004}{70 \text{ kg}} = 0.0006 \text{ mg/kg/day}$$

Combined exposure = 0.0022 mg/kg/day

MOE = 113

If the mixer/loader is also the applicator, closed system
mixing/loading is required.

Applicator - Pilot

Dermal exposure - total deposition = 0.004 mg/lb ai handled

$$\frac{1 \text{ lb ai/A} \times 350 \text{ acres} \times 0.004 \times 8\%}{70 \text{ kg}} = 0.0016 \text{ mg/kg/day}$$

Inhalation exposure - no respirator = 0.0002 mg/lb ai
handled

$$\frac{1 \text{ lb ai/acre} \times 350 \text{ acres} \times 0.0002}{70 \text{ kg}} = 0.001 \text{ mg/kg/day}$$

Combined exposure = 0.0026 mg/kg/day

MOE = 96

OREB recommends that the pilot wear chemical resistant
gloves when entering and exiting the aircraft.

cc: J. Evans, OREB
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Chemical File (106201)