US ERA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JAN 6 1991

JAN 6 1994

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 18: ID# 94MI0002. Emergency Exemption for Use

of ADMIRE 2 Flowable (Imidacloprid) on Potatoes in

Michigan

Tox. Chem. No.:

497E

PC No.:

129099

Barcode No.:

D197468

Submission No.:

S454691

TO:

Rebecca Cool, Manager, PM Team 41

Libby Pemberton, Reviewer, PM Team 41

Emergency Response and Minor Use Section/Registration

Support Branch

Registration Division (7505C)

FROM:

Sheryl K. Reilly, Ph.D. Stenk Kleek

Review Section II, Toxicology Branch I

Health Effects Division (7509C)

THRU:

Myron S. Ottley, Ph.D.

Review Section IV, Toxicology Branch I

Health Effects Division (7509C)

and

Joycelyn E. Stewart, Ph.D.

Section Head

Review Section II, Toxicology Branch I

Health Effects Division (H7509C)

I. CONCLUSIONS

The toxicology data requirements are complete for the issuance of a Section 18 emergency exemption by the State of Michigan for the temporary use of imidacloprid (ADMIRE 2 Flowable) to control pesticide-resistant Colorado potato beetles on potatoes. The margins of exposure (MOEs) for acute exposure are greater than 100. Imidacloprid is a "Group E" carcinogen, so there is no cancer risk associated with exposure to this chemical.

Toxicology Branch I has no objection to the issuance of this exemption.

II. ACTION REQUESTED

In a letter dated December 1, 1993, the Michigan Department of Agriculture requested an emergency exemption under Section 18 for the use of imidacloprid to control Colorado potato beetle (CPB, Leptinotarsa decemberata) on potatoes. This is the first request made by Michigan for this use. Most of the CPB populations in southern and central Michigan are resistant to all available synthetic insecticides. Alternative products for control of highly-resistant CPB include cryolite and BT products, however, BT products are only useful against very young larvae, and CPB control with cryolite is less than optimal.

ADMIRE 2 Flowable (Miles, Inc.) is the formulation for the active ingredient. The pesticide will be used once per growing season, as an at-planting soil systemic treatment for CPB. The maximum estimated acreage to be treated in Michigan is 30,000. The rate of application will be 0.9-1.3 fl. oz. of ADMIRE 2 Flowable per 1000 feet of row (6.39-9.23 g a.i./1000 row feet). This is equivalent to 13.8 to 20 fl. oz. of formulated product per acre, with 34 inches between rows (0.216 to 0.313 lb. a.i./acre).

III. TOXICOLOGY BRANCH I COMMENTS -

The toxicology data base for imidacloprid is sufficient to support the proposed Section 18 exemption.

IV. RISK/EXPOSURE ASSESSMENT

This action was submitted to OREB (Occupational and Residential Exposure Branch; subordinate data package D197683) for determination of exposure estimates (see attached memo from

to S. Reilly, dated December , 1993). Acute MOEs were based on these exposure estimates, and the rabbit maternal and developmental NOEL of 24 mg/kg/d (see Toxicology Profile, below). Calculations were based on a dermal absorption of 100%, because no dermal absorption data is available for imidacloprid. Cancer risk is not quantitated, since imidacloprid is a group E carcinogen, and there is no Q_1* for this chemical.

Formula used in calculations:

Acute MOE = NOEL (24 mg/kg BW/d) ÷ Exposure (mg/kg BW/d)

OPERATION.	EXPOSURE (mg/kg/d)	ACUTE MOE	
Mixer/Loaders, open pour	0.012	2,000	
Applicator, open cab	0.011	2,182	

Minimum clothing requirements for Applicators are long pants, short-sleeved shirt, and no gloves; Mixer/Loader exposure is based on wearing long pants, long sleeves, and gloves (Worker Protection Standard for Agricultural Pesticides).

V. SPECIAL TOXICOLOGY ISSUES AND PROBLEMS

- 1. <u>Labelling</u>. The labelling precautionary statements for ADMIRE 2 Flowable are governed by toxicity studies on the active ingredient.
- 2. <u>Carcinogenicity</u>. There is no cancer risk associated with exposure to this chemical, because the HED RfD Review Committee has determined that the test compound is a "Group E" carcinogen.
- 3. RfD. The RfD/Quality Assurance Peer Review Committee met on April 22, 1993 to assess the reference dose for this chemical. The Committee recommended that an RfD of 0.057 should be established, based upon a NOEL of 5.7 mg/kg/d in a chronic toxicity study in rats. An uncertainty factor of 100 was used to account for interspecies extrapolation and intraspecies variability.
- 4. Non-carcinogenic risk assessment. In a chronic/oncogenicity study, male rats exhibited increased thyroid lesions at 16.9 mg/kg/day and above, and females at 73 mg/kg/day (see attached Toxicology Profile, study # 100652/101931). In a developmental study in rabbits, 72 mg/kg/d of technical imidacloprid (administered on days 6-19 of gestation) increased the number of resorptions and abortions in the dams, and increased skeletal abnormalities and decreased body weight in the pups.
- 5. <u>Mutagenicity/genetic toxicity comments</u>. Most of the genotoxicity studies for imidacloprid were negative, although an in vitro chromosome aberration study (human lymphocytes) was positive at cytotoxic concentrations (Tox. Doc. #099262), and an in vitro sister chromatid exchange mutagenicity study (CHO cells) was positive at cytotoxic doses (Tox. Doc. 102655).
- 6. <u>Dermal Penetration</u>. There are no available dermal penetration data for imidacloprid.

TOXICOLOGY PROFILE

Technical NTN 33893

Guideline

Study; Company;

Date: MRID #: Category; Classification

Study Results

81-1

Acute oral LD50

Species: rat Bayer AG Instit. Fur Tox. Germ

Study#: T 2033060

MRID: 420553-31

Date: 12/15/89 CORE - ACCEPTABLE DOC#s: 009375

Male Sprague-Dawley rats dosed at: 0, 50, 100, 250, 315, 400, 450, 50 1800 mg/kg. Females dosed: 0, 100, 250, 315, 400, 475, 500, and 1800 mg/kg. LD50 (M) = 424 mg/kg (calculated). F > 450, < 475 mg/kg (estimated).

Foxicity category I

81-2

Acute Dermal LD50

Species: rat

Mobey Chem.

Study#: T 5033063 MRID: 420553-32

Date: 11/15/89

CORE - ACCEPTABLE

DOC#s: 009375

Sprague-Dawley rats dosed at 0 and 5000 mg/kg.n LD50 > 5000 mg/kg (limit test). Necropsy Observations: None

Toxicity category IV

81-3

Acute inhelation LC50

Species: rat

Bayer AG Instit. Fur Tox. Germ Study#: 16777

HRID: 420553-33 4 22 - 01

Date: 06/06/88

CORE - - ACCEPTABLE DOCES: 009375

New Document BERATTACHER

Wister rats dosed at 69 mg/m3 serosol, 1220, 2577, and 5323 dust. Contro received conditioned air or 20,000 uL Lutrol vehicle. LC50 > 5323 mg/m3 (Tentative).

upgraded

Toxicity rategory TV

81-4

Primary eye irritation

Species: rabbit

Seyer AG Instit. Fur Tox. Germ

Study#: T 8025515

MRID: 420553-34

Date: 02/25/89

CORE - ACCEPTABLE

DOC#s: 009375

NZW rabbits given 0.1 mL of test substance in one eye. TIS: Primary Irrit. Index = 0. Non-irritating. Minimal redness (1 anima & swelling (1 animal) observed 1 hr. post-dosing; was completely gone

Texicity category IV

81-5

Primary dermal irritation

Species: rabbit

Bayer AG Instit. Fur Tox. Germ

Study#: T 8025515

MRID: 420553-35

Date: 02/25/88

CORE - ACCEPTABLE DOC#s: 009375

4 hr dermal exposure to NZWrabbits at 500 mg/kg. PIS = 0.0 (non-

toxicity category II

NTN 33893 Technical

	ne Study Identificatio	n Study Results
82-2	21-day Repeated Dose Derma Species: Rabbit Bayer AG Dept. of Toxicology	NTN 33893 Technical was administered at 1000
	MRID: 422563-29 Date: June 11, 1990	NOEL Systemic: 1000 mg/kg/day Dermal: 1000 mg/kg/day
	Core: Minimum DOC#s: DER Attached	Dermal: > 1000 mg/kg/day > 1000 mg/kg/day
83-1b	Chronic Species: Dog RCC, Research & Consulting Co Study #: 100015 MRID: 422730-02 Date: Oct. 19,1989 Core: Minimum	NOEL: 1250 ppm (41 mg/kg/d) LOEL: 2500 (72 mg/kg/d)
83-1a, 83-2a	DOC #s: DER Attached Chronic/Onco	caused 50% mortality in rangefinding study
3-3	Species: Rat Bayer AG Study #: 100652 101931 MRIDs: 422563-31 422563-32 Dates: July 14, 1989, Aug 19, 1991 Core: Minimum DOC #s: DER Attached	NTN 33893 Technical was administered in the diet to 50 male and 50 female 8or WISW (SPF Cpb) rats per group at 0, 100, 300, 900 and 1800 ppm for 104 weeks. The 1800 ppm dose group tested in a separate study with its own concurrent controls. NOEL: Chronic Effects: 100 ppm (5.7 mg/kg/d in males, 7.6 mg/kg/d in females) LOEL: Chronic Effects: 300 ppm Increased thyroid lesions in males at 300 ppm (16.9 mg/kg/d) and above and in females at 900 ppm (73 mg/kg/d) and above; Decr. body wt. gain in females at 300 ppm (24.9 mg/kg/d) and above; weight changes in liver, kidney, lung, heart, spleen, adrenals, brain and gonads in males and/or females at 900 ppm (51.3 mg/kg/d in males, 73.0 mg/kg/d in females) or 1800 ppm. Oncogenicity: No apparent treatment-related effect at any dose.
	Developmental Toxicity Species: Rabbit RCC, Research & Consulting Co. Study #: 083518 MRID: 422563-38	NTN 33893 Technical was administered to 16 pregnant Chinchilla / rabbits per group at 0, 8, 24, and 72 mg/kg/d during gestation days 6 through 19. Maternal NOEL 24 mg/kg/d
	Date: Jan. 8, 1992 Core: Minimum DOC #s: DER Attached	NOEL 24 mg/kg/d LOEL 72 mg/kg/d. Decreased food consumption; at 72 mg/kg/d: decreased body weight, increased resorption, increased abortion, and death.
* * *]1	Developmental NOEL 24 mg/kg/d LOEL 72 mg/kg/d. Decrease body weight, increased skeletal abnormalities.

NTN 33893 75% Formulation

83-1	ine Study Identification	Study Results
	Acute Oral LD50 Species: Rat Mobay Corp. Study #: 91-012-JJ MRiD: 422563-12 Date: August 27, 1991 Core: Minimum DOC #: DER to be submitted with subsequent action	NTN 33893 75% Formulation was administered once by gavage to Sprague-Dawley rats (5/sex/dose) at 0, 1063, 2180, and 3170 mg/kg for males, and 0, 1063, 2180, 2750, and 3170 mg/kg for females. Animals were observed for 14 days. LD50 Male 2591 mg/kg (calculated) Female 1858 mg/kg (calculated)
81-2	Acute Dermal LD50 Species: Rat Mobay Corp. Study #: 91-022-JH MRID: 422563-14 Date: August 21, 1991 Core: Minimum DOC #: DER to be submitted with subsequent action	Toxicity Category: III NTN 33893 75% Formulation was administered once dermally for 24 hr to Sprague-Dawley rats (5/sex/dose) at 0 and 2000 mg/kg. Animals were observed for 14 days. LD50 > 2000 mg/kg Toxicity Category: III
81-3	Acute Inhalation Species: Rat Mobay Corp. Study #: 91-042-JZ MRID: 422563-16 Date: September 25, 1991 Core: Minimum DOC #: DER to be submitted with subsequent action	NTN 33893 75% Formulation was administered as a liquid aerosol by inhalation once for 4 hr to Sprague-Dawley rats (6/sex/dose) at 0.2110, 2810, and 2990 mg/m3. Animals were observed for 14 days. LC50 Male: 2650 mg/m3 (calculated) Female: 2750 mg/m3 (calculated) NOEL <2110 mg/m3 LOEL 2110 mg/m3
81-4	Eye Irritation Species: Rabbit Mobay Corp. Study #: 91-335-JK MRID: 422563-18 Date: June 25, 1992 Core: Minimum DOC #: DER to be submitted with subsequent action	Toxicity Category: III NTN 33893 75% Formulation was introduced into the conjunctival sac of the left eye of 6 male New Zealand White rabbits at 0.1 ml (44-46 mg). The right eye of each animal served as control. Animals were observed for 14 days. TIS: TIME 1hr 24hr 48hr 72hr 7d 14d IRRIT. SCORE 2.5 1.1 1 0.1 0 0
31-5	Primary Dermal Irritation Species: Rebbit Mobay Corp. Study #: 91-335-JG MRID: 422563-20 Dete: August 15, 1991 Core: Minimum DOC #: DER to be submitted with subsequent action	Toxicity Category: III NTN 33893 75% Formulation was administered for 4 hr once dermally to shaved backs of six male New Zealand White rabbits at 500 mg/animal, and observed for 7 days. PIS: 1.08 Mild irritation at 72 hr. Toxicity Category: IV
1-6	Dermal Sensitization Species: guinea pig Mobay Corp. Study #: 91-324-JC	NTN 33893 75% Formulation was administered, in 3 6-hr topical induction applications followed by one 24-hr topical challenge 14 days later, to shaved backs of 15 Hartley albino guines pigs. Conclusion: Not a Sensitizer

Date: 12/11/90 CORE - ACCEPTABLE DOC#s: 009375

Guidelin	e Study Identification	Study Results
81-1	Acute oral LD50 Species: rat	LD50 > 4820 mg/kg (5000 mg/kg nominal, limit test) Necropsy Observations: None
	Mobay Chem. Study#: 89-012-04 MRID: 420553-24	
	Date: 02/26/90 CORE - ACCEPTABLE DOC#s: 009375	Toxicity category IV
81-2	Acute Dermal LD50 Species: rebbit	NZW rabbits dose at 0 and 2000 mg/kg.
	Mobay Chem. Study#: 89-025-05 MRID: 420553-25	LD50 > 2000 mg/kg. Necropsy: None Toxicity (410,000 III
	Date: 01/15/90 CORE - ACCEPTABLE DOC#s: 009375	
81-3)	<u>.</u>	
	Acute inhalation LC50 Species: rat Mobay Chem. Study#: 89-042-DX MRID: 420553-26	Sprague-Dawley rats dosed at 0 and 5092 mg/m3. LC50 > 5092 mg/m3 (95% C.L. intervals) Tentative. Necropsy: None distribution in exposure chamber not possible. See deficiencies sections.
	Pate: 02/26/90 CORE - ACCEPTABLE OC#s: 009375 DER ATTACHED	Toxicity category IV
Mo Mo	rimmary eye irritation secies: rabbit bay Chem.	MZW rabbits received 0.1 mL of pulverized test substance/animal. TIS Time 1 he 2
PAR	ID: 420553-27	Iris Irrit Score 2.3 1.2 1.0 0.5 0.2 0.0
00	te: 01/15/90 ME - ACCEPTABLE CMe: 009375	Texicity Category II
-5 Pri	many dermal irritation	
Mot	ncies: rabbit May Chem. May: 89-325-ED D: 420553-28	4 hr dermal exposure to NZW rabbits at 50 mg/animal & observed for 72 hrs. PIS = 0.0. Nonirritating.
		Toxicit. Cotesary TI

Toxicity Category I

81-1	Acute oral LD50 Species: rat Mobay Chem. MRID#: 420553-23 Date: 09/30/91 DOC#s: 009375 Acute Dermet LD50 Species: Mobay Chem.	Study Results Study waived. Use data from study #89-012-DY (MRID 420553) Toxicity Category IV
	Species: rat Mobay Chem. MRID#: 420553-23 Date: 09/30/91 DOC#s: 009375 Acute Dermal LD50 Species:	Toxicity Category IV
	Species: rat Mobay Chem. MRID#: 420553-23 Date: 09/30/91 DOC#s: 009375 Acute Dermal LD50 Species:	Toxicity Category IV
81-2	Date: 09/30/91 DOC#s: 009375 Acute Dermel LD50 Species:	
81-2	DOC#s: 009375 Acute Dermet LD50 Species:	
81-2	Acute Dermal LD50 Species:	
81-2	Species:	
81-2	Species:	
	Mobey Chem	Study waived the
	MRID#: 420553-23	Study waived. Use data from study #89-025-DS (MRID 420553-2
•		
	Date: 09/30/91	Toxicity Category III
Í	DOC#s: 009375	10210119 001909
,	,	
		•
81-4	Primary eye irritation	1
- 1	Mobey Chem	Study waived. Use data from study #89-335-DT (MRID 420553-2
- 1	MRID#: 420553-23	· ·
- 1	Date: 09/30/91	Toxicity Category II
- I	POC#s: 009375	
	· ·	
S	rimery dermal irritation pecies:	Study waived. Use data from study #89-325-ED (MRID 420553-28)
H	obey Chem. RID#: 420553-23	
.	*	Toxicity Category II
D4	ate: 09/30/91	
00	Cile: 009375	
6 De	rmal sensitization	Lama
Sp Mo	ecies: bey Cham	Study waived. Use data from study #89-324-DN (MRID 420553-29)
MR	10#: 420553-23	
Dat	te: 09/30/91	
i	#s: 009375	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 27 1993

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMO		

EXPOSURE ESTIMATE FOR THE PROPOSED USE OF IMIDACLOPRID ON SUBJECT:

POTATOES TO CONTROL THE COLORADO POTATO BEETLE

FROM:

Bruce F. Kitchens, Chemist

Freed

TO:

Sheryl K. Reilly, Toxicologist

Toxicology Branch I

Health Effects Division (7509C)

THRU:

PHED:

Mark I. Dow, Ph.D., Section Head

Section II Special Review and Registration

Larry C. Dorsey, Chief ///// Lync J V/NC Occupational and Residential Exposure Branch

Health Effects Division (7509C)

Please find below, the OREB review of:

Yes Version 1.01 Run # 19

DP Barcode: D197683 Pesticide Chemical Code: 129099 EPA Reg. No.: 94MI0002 EPA MRID No.: N/A Review Time: 4-days

I. INTRODUCTION:

A. Background:

Michigan requests a section 18 specific exemption to use the formulation Admire 2 Flowable (a.i. imidacloprid) to control the Colorado Potato Beetle (CPB) on potatoes. Michigan states that an emergency situation exists because of the CPB's resistance to almost all synthetic insecticides and an extreme build up in the CPB population levels. Michigan believes that severe economic losses will result from failure to control the CPB.

Imidacloprid is a systemic insecticide used to control a broad spectrum of insects. Admire 2 Flowable is formulated at 2 lbs ai/gal. For this section 18 use, Admire 2 Flowable is applied at the rate of 0.216 - 0.313 lbs ai/acre. The maximum amount of formulation applied per acre per season is 0.3 lbs. The maximum number of applications is one (1). A total of 9,375 lbs active ingredient is needed to treat 30,000 acres. The application method is in furrow at planting via ground equipment. This section 18 use period is from March 15, 1994 through June 15, 1994. Use sites for Admire 2 Flowable are the central and southern part of the Lower Peninsula.

The tox endpoint of concern is maternal/developmental toxicity with a NOEL of 24 mg/kg/day in the rabbit. Imidacloprid is a tox category II chemical for oral toxicity and tox category III for dermal toxicity.

B. Purpose:

This review evaluates mixer/loader/applicator exposure from the specified section 18 use of imidacloprid on potatoes to control the Colorado Potato Beetle.

II. <u>DETAILED CONSIDERATIONS</u>:

OREB uses the following assumptions to calculate estimated worker exposure:

II. DETAILED CONSIDERATIONS: (con't)

TABLE 1. ASSUMPTIONS

Mixer loader weighs 60 kg	
Applicator weighs 60 kg	*
Acres treated/day 901.	
Avg. farm size 500 acr	es².
Application rate 0.313 1	
Maximum # applications 1	; ,
App. GB open cab exposure 22.5 μ g	/lb ai
Mixer/loader open pour exposure 25.9 μg	/lb ai
Adjustment for Dermal Exposure None	

Calculations:

Active Ingredient Handled per Day: 90 acre/day x 0.313 lb ai/A =

28.2 lb ai/day

Applicator Exposure is:

28.2 lb ai/day x 22.5 μ g/lb ai ÷ 60 kg = 10.6 μ g/kg/day

Mixer/loader Exposure is:

28.2 lb ai/day x 25.9 μ g/lb ai ÷ 60 kg = 12.2 μ g/kg/day

III. CONCLUSIONS:

OREB concludes that the following exposures may occur from the use of imidacloprid on potatoes to control the Colorado Potato Beetle.

> Applicator open cab 10.6 μ g/kg/day Mixer/loader open pour 12.2 μg/kg/day

Applicator exposure is based on the wearing of long pants, short sleeves, and no gloves. Mixer/loader exposure is based on the wearing of long pants, long sleeves, and gloves. These PPE are in agreement with the PPE required by the Worker Protection Standards (WPS).

IV. REFERENCES:

- 1. OREB Memorandum: "Evaluate Emergency Exemption Section 18 From the State of Michigan For the Use of TRIGARD 75 WP (CYROMAZINE) To Control the Colorado Potato Beetle (CPB) in Potatoes", DP Barcode D176382, June 19, 1992.
- 2. Michigan section 18 application, page 4, 1994.

cc: B. Kitchens
Chemical File: Imidacloprid
Circulation
Correspondence

APPENDIX A. PHED RUNS

APPLICATOR EXPOSURE

ROUNDBOOM/OPEN CAB

Total Exposure for workers wearing long pants, short sleeves, no gloves:

Inhalation: 0.37 ug/lb ai Dermal/body: 9.73 ug/lb ai

Hands: 12.35 ug/lb ai Total: 22.45 ug/lb ai

INHALATION EXPOSURE:

DISTRIB. NANOGRAMS PER LB AI SPRAYED

TYPE Median Mean Coef of Var Geo. Mean Obs.

EXPOSURE Lognormal 483.3333 665.933 88.5362 373.5249 13

Number of Records: 13
Data File: APPLICATOR

Subset Name: GB.OP.AIR.APPL

Subset Specifications for GB.OP.AIR.APPL With Airborne Grade Equal to "A" "B" Subset originated from GB.OP.APPL With Application Method Equal to 2 3 and With Cab Type Equal to 1 and Subset originated from APPL.FILE

DERMAL EXPOSURE

_CENARIO: Long pants, short sleeves

PATCH	DISTRIB.		MICROGRAMS	PER LB AI SP	RAYED	۸
LOCATION	TYPE	Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Lognormal	2.73	13.9146	247.9999	2.825	57
NECK.FRONT	Lognormal	.3	1.65	244.8909	.3045	55
NECK.BACK	Lognormal	.1595	1.2397	246.9468	.2015	54
UPPER ARMS	Other	.291	.291	0	.291	6
CHEST	Other	.71	6.8697	205.236	1.5676	37
BACK	Other	2.13	9.4075		1.7338	22
FOREARMS	Lognormal	2.783	9.5993	171.8344	2.6519	57
THIGHS	Other	.382	1.0641	165.5202	.5749	14
LOWER LEGS	Other	.238	1.615	232.805	.4201	14
FEET	•		2.023	. 232.003	. 4201	0
TOTAL DERM:	9.7339					

Number of Records: 57
Data File: APPLICATOR

Subset Name: G.OP.DERMA D.APPL

Subset Specifications for G.OP.DERMA D.APPL

With Dermal Grade Uncovered Equal to "A" "B" "C" "D"
Subset originated from GB.OP.APPL
With Application Method Equal to 2 3 and
"ith Cab Type Equal to 1 and
abset originated from APPL.FILE

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DERMAL EXPOSURES

JENARIO: No	clothing (total depositi	on)	**************************************		
PATCH	DISTRIB.		MICROGRAMS	PER LB AI SP	RAYED	
LOCATION	TYPE	Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Lognormal	.13	.3664	116.4028	.2468	11
NECK. FRONT	Lognormal	.015	.0832	219.1106	.0319	11
NECK.BACK	Normal	.011	.025	98.4	.0182	11
UPPER ARMS	Lognormal	.582	.8201	85.1847	.6039	11
CHEST	Lognormal	.355	1.9686	219.1405	.7551	11
BACK	Normal	.355	.8068	98.5622	.5877	11
FOREARMS	Other	.121	.209	68.9474	.1766	11
THIGHS	Lognormal	.764	2.483	184.2489	1.0965	8
LOWER LEGS FEET	Lognormal	.476	2.0771	248.5196	.6046	11
TOTAL DERM:	4 5544	•			•	0
TOTUT DEKW!	4.2916					

Number of Records: 11
Data File: APPLICATOR

Subset Name: GB.CLSD.DRMA_D.APPL

SCENARIO: LO PATCH LOCATION HEAD (ALL) NECK.FRONT NECK.BACK UPPER ARMS HEST LACK	ong pants, sho DISTRIB. TYPE Lognormal Lognormal Normal	Median .13 .015 .011	MICROGRAMS Mean .3664 .0832 .025	PER LB AI SP Coef of Var 116.4028 219.1106 98.4	RAYED Geo. Mean .2468 .0319 .0182	Obs. 11 11 11 0
FOREARMS THIGHS LOWER LEGS FEET	Other	.121	209	68.9474	.1766	0 11 0 0
TOTAL DERM:	0.4247	9				0

Number of Records: 11 Data File: APPLICATOR

Subset Name: GB.CLSD.DRMA_D.APPL

Subset Specifications for GB.CLSD.DRMA D.APPL
With Dermal Grade Uncovered Equal to "A" "B" "C" "D"
Subset originated from GB.CLSD.APPL
With Application Method Equal to 2 3 and
With Cab Type Equal to 3 4
Subset originated from APPL.FILE

HAND EXPOSURE

Number of Records: 14
Data File: APPLICATOR Subset Name: GB.CLSD.HDA_D.APPL

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HAND EXPOSURE

CENARIO: no gloves

DISTRIB. MICROGRAMS PER LB AI SPRAYED PATCH

TYPE LOCATION Median -Coef of Var Geo. Mean Obs. 2.2666 12.7278 206.1244 -HANDS Lognormal 3.0849 2:

Number of Records: 28

Data File: APPLICATOR Subset Name: AER.HDA C.APPL

Subset Specifications for AER. HDA C. APPL

With Hand Grade Equal to "A" "B" "C" Subset originated from AERIAL.APPL With Application Method Equal to 5 6 Subset originated from APPL.FILE

MIXER/LOADER EXPOSURE

OPEN MIX/LIQUIDS

Total Exposure for workers wearing long pants, long sleeves, gloves:

Inhalation: 0.44 ug/lb ai ermal/body: 21.1 ug/lb ai dands*: 4.34 ug/lb ai

Total Exposure: 25.88 ug/lb ai

*Combined geometric mean of two hand estimates.

INHALATION EXPOSURE:

DISTRIB. NANOGRAMS PER LB AI MIXED

Coef of Var Geo. Mean Obs TYPE Median Mean 367.0709 2552.6287 144.4647 443.4466 4(EXPOSURE Lognormal

Number of Records: 40

Subset Name: LIQ.OP.X.AIR.MLOD Data File: MIXER/LOADER

Subset Specifications for LIO.OP.X.AIR.MLOD With Airborne Grade Equal to "A" "B" Subset originated from LIQ.OP.X4081.MLOD Without Study Code Equal to 4081 Subset originated from LIQ.OPEN.MLOD With Mixing Procedures Equal to 1 Subset originated from LIQ.MLOD With Liquid Type Equal to 1 2 3 4 5 Subset originated from MLOD.FILE

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HAND EXPOSURES

CENARIO: gloves

PATCH DISTRIB. MICROGRAMS PER LB AI MIXED

LOCATION TYPE Median Mean Coef of Var Geo. Mean Obs

HANDS Lognormal 19.697 106.6871 118.8365 32.6518 1

Number of Records: 19

Data File: MIXER/LOADER Subset Name: LIQ.OP.X.RNS.MLOD

Subset Specifications for LIO.OP.X.RNS.MLOD
With Hand Grade Equal to "A" "B" "C" and
With Hand Measuring Method Equal to 1
Subset originated from LIQ.OP.X4081.MLOD
Without Study Code Equal to 4081
Subset originated from LIQ.OPEN.MLOD
With Mixing Procedures Equal to 1
Subset originated from LIQ.MLOD
With Liquid Type Equal to 1 2 3 4 5
Subset originated from MLOD.FILE

*Combined Geometric Mean of the two hand estimates: 4.34 ug/lb ai

CLOSED MIX/LIQUIDS

_otal Exposure for workers wearing long pants, long sleeves, gloves:

Inhalation: 0.06 ug/lb ai Dermal/hands: 2.25 ug/lb ai

Hands: 1.33 ug/lb ai

Total Exposure: 3.64 ug/lb ai

Total Exposure for workers wearing no clothing, gloves:

Inhalation: 0.06 ug/lb ai Dermal/body: 29.54 ug/lb ai

Hands: 1.33 ug/lb ai

Total Exposure: 30.93 ug/lb ai

INHALATION EXPOSURES

DISTRIB.

TYPE Median Mean Coef of Var Geo. Mean Obs.

EXPOSURE Lognormal 58.9667 82.8768 92.3632 59.8581 13

Number of Records: 13
Data File: MIXER/LOADER

Data File: MIXER/LOADER Subset Name: LIQ.CL.AIR.MLOD

Subset Specifications for LIO.CL.AIR.MLOD
With Airborne Grade Equal to "A" "B" "C" "D"
Subset originated from LIQ.CLSD.MLOD
With Liquid Type Equal to 1 2 3 4 5 and
th Mixing Procedures Equal to 2 3
Subset originated from MLOD.FILE

page 9 PHED Run #19

Subset Specifications for LIO.CL.HND.MLOD
With Hand Grade Equal to "A" "B" "C" "D"
ubset originated from LIQ.CLSD.MLOD
With Liquid Type Equal to 1 2 3 4 5 and
With Mixing Procedures Equal to 2 3
Subset originated from MLOD.FILE

**Note regarding the data used in this exposure assessment: **

The data cited here do not meet Agency requirements based on the data quality (grades) and number of replicates according to the PHED Data Reporting Guidelines. These data must not be used to support registration or reregistration as they are not acceptable according to current OREB policy.