

US EPA ARCHIVE DOCUMENT



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

497E  
**CASSELL FILE**

JUL 12 1993

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

**SUBJECT:** Section 18: ID# 93AZ0007. Emergency Exemption for Use of CONFIDOR 2 Flowable (Imidacloprid) on Broccoli, Cauliflower, and Cabbage in Arizona

Tox. Chem. No.: 497E  
PC No.: 129099  
Barcode No.: D192379  
Submission No.: S441955

**FROM:** Sheryl K. Reilly, Ph.D. *Sheryl K. Reilly 7/2/93*  
Review Section II, Toxicology Branch I  
Health Effects Division (H7509C)

**TO:** Rebecca Cool, Manager, PM Team 41  
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**THRU:** Myron S. Ottley, Ph.D. *MSO/Cy 7/6/93*  
Review Section IV, Toxicology Branch I  
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**I. CONCLUSIONS**

The toxicology data requirements for imidacloprid (CONFIDOR 2 Flowable Systemic Insecticide) are complete for the issuance of a Section 18 emergency exemption by the State of Arizona for the temporary use of imidacloprid to control Sweet Potato Whitefly on broccoli, cauliflower, and cabbage between August 10, 1993 and May 15, 1994. Toxicology Branch I has no objection to the issuance of this exemption.

The margins of exposure (MOEs) for acute exposure were greater than 100. The MOEs were calculated assuming 100% dermal absorption



in humans, which is unlikely to occur, especially when protective clothing is worn, as per the requirements of the Worker Protection Standards.

Imidacloprid is a "Group E" carcinogen, so there is no cancer risk associated with exposure to this chemical.

## **II. ACTION REQUESTED**

In a letter dated June 1, 1993, the Arizona Department of Agriculture requested an emergency exemption under Section 18 for the use of imidacloprid to control Sweet Potato Whitefly (Bemisia tabaci) on broccoli, cauliflower, and cabbage, between August 10, 1993 and May 15, 1994. The broccoli, cauliflower, and cabbage growers have no registered pesticides that will satisfactorily control these pests when they become numerous.

This is the first request made by Arizona for emergency use of imidacloprid on broccoli, cauliflower or cabbage. CONFIDOR 2 Flowable Systemic Insecticide (Miles) is the formulation for the active ingredient imidacloprid.

The total estimated acreage to be treated in Arizona is 16,600 (7,000 acres for broccoli, 6100 acres for cauliflower, and 3500 acres for cabbage). A maximum of 1 application per crop per season (2 crops per year) will be made, by ground equipment, at a rate of 2.5 to 5 dry oz. a.i. (10-20 fl oz. of the formulation) imidacloprid per acre, for a total of 8,300 lbs a.i. The preharvest interval will be at least 20 days.

## **III. TOXICOLOGY BRANCH I COMMENTS**

The toxicology data base for imidacloprid is sufficient to support the proposed Section 18 exemption. Refer to the draft toxicology profile for technical imidacloprid (NTN 33893), attached.

## **IV. RISK/EXPOSURE ASSESSMENT**

This action was submitted to OREB (Occupational and Residential Exposure Branch; subordinate data package D192506/S441955) for determination of exposure estimates (see attached memo from Bruce F. Kitchens to Sheryl K. Reilly, Ph.D., dated July 1, 1993). Acute MOEs were based on these exposure estimates, and the rabbit maternal and developmental NOEL of 24 mg/kg/d (HED Doc. #009960). Cancer risk is not quantitated, since imidacloprid is a group E carcinogen, and there is no Q<sub>1</sub>\* for this chemical.

Formulas used in calculations:

Acute MOE (Actual) =

$$\text{NOEL (24 mg/kg BW/d)} \div \text{Exposure (mg/kg BW/d)}$$

OPERATION*	EXPOSURE (mg/kg/d)	ACUTE MOE	PROTECTIVE CLOTHING SCENARIO
Applicator GB <sup>™</sup> Open	0.0059	4068	long pants, short sleeves
Applicator GB Closed	0.0031	7742	none (total deposition)
Mix/Load GB Open	0.0068	3529	long pants, long sleeves, gloves
Mix/Load GB Closed	0.0081	2963	gloves only

Minimum clothing requirements are: long-sleeved shirt, long pants, shoes, socks, and chemically resistant gloves for each job function (Worker Protection Standard for Agricultural Pesticides).

GB = ground boom  
Open = open pour  
Closed = closed pour

The acute MOEs for actual exposure are greater than 100 in all operations, even though a dermal absorption of 100% is assumed, because no dermal absorption data is available. Given the protective clothing requirements, the actual MOEs are anticipated to be even greater than calculated for these application scenarios.

## V. SPECIAL TOXICOLOGY ISSUES AND PROBLEMS

1. Labelling. The labelling precautionary statements for CONFIDOR 2 Flowable Systemic Insecticide are governed by toxicity studies on the active ingredient.
2. Carcinogenicity. 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/d and above, and females at 73 mg/kg/d (see attached Toxicology Profile, study # 100652/101931). In a developmental study in rabbits (see attached Tox. Profile, study # 083518), 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. Mutagenicity/genetic toxicity comments. Most of the genotoxicity studies for imidacloprid were negative, although an in vitro chromosome aberration study (human lymphocytes) was positive at cytotoxic concentrations (HED Doc. #099262), and an in vitro sister chromatid exchange mutagenicity study (CHO cells) was positive at cytotoxic doses (HED Doc. 102655).

6. Dermal Penetration. There are no available dermal penetration data for imidacloprid.

# V. TOXICOLOGY PROFILE

Technical NTN 33893

Guideline	Study; Company; Date; MRID #; Category; Classification	Study Results
81-1	<p>Acute oral LD50 Species: rat Bayer AG Instit. Fur Tox. Germ Study#: T 2033060 MRID: 420553-31</p> <p>Date: 12/15/89 CORE - ACCEPTABLE DOC#s: 009375</p>	<p>Male Sprague-Dawley rats dosed at: 0, 50, 100, 250, 315, 400, 450, 500 &amp; 1800 mg/kg. Females dosed: 0, 100, 250, 315, 400, 475, 500, and 1800 mg/kg. LD50 (M) = 424 mg/kg (calculated). F &gt; 450, &lt; 475 mg/kg (estimated).</p> <p>Toxicity category <u>II</u></p>
81-2	<p>Acute Dermal LD50 Species: rat Mobay Chem. Study#: T 5033063 MRID: 420553-32</p> <p>Date: 11/15/89 CORE - ACCEPTABLE DOC#s: 009375</p>	<p>Sprague-Dawley rats dosed at 0 and 5000 mg/kg.n LD50 &gt; 5000 mg/kg (limit test). Necropsy Observations: None</p> <p>Toxicity category <u>IV</u></p>
81-3	<p>Acute inhalation LC50 Species: rat Bayer AG Instit. Fur Tox. Germ Study#: 16777 MRID: 420553-33 422881-01</p> <p>Date: 06/06/88 CORE - ACCEPTABLE DOC#s: 009375</p> <p>New Document DER Attached</p>	<p>Wistar rats dosed at 69 mg/m3 aerosol, 1220, 2577, and 5323 dust. Controls received conditioned air or 20,000 uL Lutrol vehicle. LC50 &gt; 5323 mg/m3 (Tentative).</p> <p>upgraded</p> <p>Toxicity category <u>IV</u></p>
81-4	<p>Primary eye irritation Species: rabbit Bayer AG Instit. Fur Tox. Germ Study#: T 8025515 MRID: 420553-34</p> <p>Date: 02/25/89 CORE - ACCEPTABLE DOC#s: 009375</p>	<p>NZW rabbits given 0.1 mL of test substance in one eye. TIS: Primary Irrit. Index = 0. Non-irritating. Minimal redness (1 animal) &amp; swelling (1 animal) observed 1 hr. post-dosing; was completely gone at 24 hrs.</p> <p>Toxicity category <u>IV</u></p>
81-5	<p>Primary dermal irritation Species: rabbit Bayer AG Instit. Fur Tox. Germ Study#: T 8025515 MRID: 420553-35</p> <p>Date: 02/25/88 CORE - ACCEPTABLE DOC#s: 009375</p>	<p>4 hr dermal exposure to NZWrabbits at 500 mg/kg. PIS = 0.0 (non-irritating).</p> <p>Toxicity category <u>IV</u></p>

Technical (Co.T.)

Guideline	Study Identification	Study Results
81-6	Dermal sensitization Species: guinea pig Bayer AG Instit. Fur Tox. Germ Study#: T 902561 MRID. 420553-36  Date: 03/15/88 CORE - ACCEPTABLE DOC#: 009375	Not a sensitizer to DHPW guinea pigs.

## NTN 33893 Technical

Guideline	Study Identification	Study Results
82-2	<p>21-day Repeated Dose Dermal            Species: Rabbit            Bayer AG Dept. of Toxicology            Study #: T 7029592            MRID: 422563-29</p> <p>Date: June 11, 1990            Core: Minimum            DOC#s: DER Attached</p>	<p>NTN 33893 Technical was administered at 1000 mg/kg to shorn backs of 5 male and 5 female New Zealand White rabbits for 6 hours/day, 5 days/week for 3 weeks.</p> <p>NOEL    Systemic:        1000 mg/kg/day                      Dermal:            1000 mg/kg/day</p> <p>LOEL    Systemic:        &gt; 1000 mg/kg/day                      Dermal:            &gt; 1000 mg/kg/day</p>
83-1b	<p>Chronic            Species: Dog            RCC, Research &amp; Consulting Co.            Study #: 100015            MRID: 422730-02</p> <p>Date: Oct. 19, 1989            Core: Minimum            DOC #s: DER Attached</p>	<p>NTN 33893 Technical was administered in the diet to 4 male and 4 female Beagle dogs per group at 0, 200, and 1250 (increased to 2500 from week 17 onwards) ppm for 52 weeks.</p> <p>NOEL:    1250 ppm (41 mg/kg/d)</p> <p>LOEL:    2500 (72 mg/kg/d) Increased Cytochrome P-450 levels in males and females. Considered a threshold dose. 5000 ppm caused 50% mortality in rangefinding study.</p>
83-1a, 83-2a	<p>Chronic/Onco            Species: Rat            Bayer AG            Study #: 100652                      101931            MRIDs: 422563-31                      422563-32</p> <p>Dates:    July 14, 1989,                      Aug 19, 1991            Core: Minimum            DOC #s: DER Attached</p>	<p>NTN 33893 Technical was administered in the diet to 50 male and 50 female Bor 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.</p> <p>NOEL:    <u>Chronic Effects</u>: 100 ppm (5.7 mg/kg/d in males, 7.6 mg/kg/d in females)</p> <p>LOEL:    <u>Chronic Effects</u>: 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.  <u>Oncogenicity</u>: No apparent treatment-related effect at any dose.</p>
83-3	<p>Developmental Toxicity            Species: Rabbit            RCC, Research &amp; Consulting Co.            Study #: 083518            MRID: 422563-38</p> <p>Date: Jan. 8, 1992            Core: Minimum            DOC #s: DER Attached</p>	<p>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.</p> <p>Maternal</p> <p>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.</p> <p>Developmental</p> <p>NOEL    24 mg/kg/d            LOEL    72 mg/kg/d. Decrease body weight, increased skeletal abnormalities.</p>



**NTN 33893 Technical — Mutagenicity Study Evaluation**  
**DERs to be submitted with subsequent action**

Study Type (MRID No.)	Title (Report No.)	Reported Results	TB Evaluation
Gene mutation- Ames (422563-41)	"NTN 33893 Reverse Mutation Assay (Salmonella typhimurium and Escherichia coli)," Report No. 101276	Negative for inducing reverse mutation in bacteria exposed to doses up to 5000 <u>ug</u> /plate.	ACCEPTABLE
Gene mutation- mamm. cell (422563-42)	"NTN 33893 Mutagenicity Study for the Detection of Induced Forward Mutations in the CHO-HGPRT Assay in Vitro," Report No. 098584	Negative for inducing forward mutation in CHO (mammalian) cells treated up to 1222 <u>ug</u> /ml	ACCEPTABLE
Gene mutation- Ames (422563-43)	"NTN 33893 Salmonella/Microsome Test to Evaluate for Point Mutagenic Effects," Report No. 098570	Negative up to 12,500 <u>ug</u> /plate	ACCEPTABLE
Chromosome Ab. <u>in vivo</u> (422563-44)	"NTN 33893 In Vivo Cytogenetic Study of the Bone Marrow In Chinese Hamster to Evaluate for Induced Clastogenic Effects" Report No. 100021	Negative for chromosome breakage up to 2000 <u>mg</u> /kg	ACCEPTABLE
Chromosome Ab. <u>in vitro</u> (422563-45)	"NTN 33893 In Vitro Cytogenetic Study with Human Lymphocytes for the Detection of Induced Clastogenic Effects," Report No. 099262	<u>Positive</u> at 500 <u>ug</u> /ml -S9 and 1300 <u>ug</u> /ml +S9, both toxic doses	ACCEPTABLE
SCE <u>in vivo</u> (422563-46)	"NTN 33893 Sister Chromatid Exchange in Bone Marrow of Chinese Hamster in Vivo," Report No. 099257	Negative up to 2000 <u>ug</u> /kg	ACCEPTABLE
Chromosome Ab.- Mouse MT (422563-47)	"NTN 33893 Micronucleus Test on the Mouse to Evaluate for Clastogenic Effects," Report No. 102652	Negative, but only tested up to 80 <u>mg</u> /kg, a non-toxic dose	UNACCEPTABLE
Chromosome Ab. <u>in vivo</u> (422563-48)	"Mouse Germ-Cell Cytogenetic Assay with NTN 33893," Report No. 102654	Negative, but only tested up to 80 <u>mg</u> /kg	UNACCEPTABLE
Other genotoxicity (422563-49)	"Clastogenic Evaluation of NTN 33893 in an In Vitro Cytogenetic Assay Measuring Sister Chromatid Exchange in Chinese Hamster Ovary (CHO) Cells," Report No. 102655	<u>Positive</u> at 500 <u>mg</u> /ml -S9 and 2000 <u>mg</u> /ml +S9, both toxic doses	ACCEPTABLE
Other genotoxicity (472563-50)	"Sister Chromatid Exchange Assay in Chinese Hamster Ovary Cells," Report No. 099676	Negative, but only tested up to 400 <u>ug</u> /ml/-S9, 1250 <u>ug</u> /ml/ +S9	ACCEPTABLE
DNA repair (411563-51)	"NTN 33893 Rec-assay with Spores in the Bacterial System" Report No. 101275	Negative up to 5000 <u>ug</u>	ACCEPTABLE
DNA repair (422563-52)	"Mutagenicity Test on NTN 33893 In the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay," Report No. 098573	Negative up to 750 <u>ug</u> /ml, a toxic dose	ACCEPTABLE
Other genotoxicity (422563-53)	"NTN 33893 Test on S. Cerevisiae D7 to Evaluate for Induction of Mitotic Recombination," Report No. 102653	Negative for crossing-over in yeast up to 10,000 <u>ug</u>	ACCEPTABLE

**NTN 33893 75% Formulation**

Guideline	Study Identification	Study Results																								
83-1	<p>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</p>	<p>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.</p> <p>LD50    Male    2591 mg/kg (calculated)                      Female   1858 mg/kg (calculated)</p> <p>Toxicity Category: III</p>																								
81-2	<p>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</p>	<p>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.</p> <p>LD50 &gt; 2000 mg/kg</p> <p>Toxicity Category: III</p>																								
81-3	<p>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</p>	<p>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.</p> <p>LC50    Male:   2650 mg/m3 (calculated)                      Female:   2750 mg/m3 (calculated)</p> <p>NOEL    &lt; 2110 mg/m3                      LOEL    2110 mg/m3</p> <p>Toxicity Category: III</p>																								
81-4	<p>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</p>	<p>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.</p> <table border="0"> <tr> <td>TIS:</td> <td>TIME</td> <td>1hr</td> <td>24hr</td> <td>48hr</td> <td>72hr</td> <td>7d</td> <td>14d</td> </tr> <tr> <td></td> <td>-----</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td>IRRIT. SCORE</td> <td>2.5</td> <td>1.1</td> <td>1</td> <td>0.1</td> <td>0</td> <td>0</td> </tr> </table> <p>Toxicity Category: III</p>	TIS:	TIME	1hr	24hr	48hr	72hr	7d	14d		-----								IRRIT. SCORE	2.5	1.1	1	0.1	0	0
TIS:	TIME	1hr	24hr	48hr	72hr	7d	14d																			
	-----																									
	IRRIT. SCORE	2.5	1.1	1	0.1	0	0																			
81-5	<p>Primary Dermal Irritation                      Species: Rabbit                      Mobay Corp.                      Study #: 91-335-JG                      MRID: 422563-20                      Date: August 15, 1991                      Core: Minimum                      DOC #: DER to be submitted with subsequent action</p>	<p>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.</p> <p>PIS:    1.08    Mild irritation at 72 hr.</p> <p>Toxicity Category: IV</p>																								
81-6	<p>Dermal Sensitization                      Species: guinea pig                      Mobay Corp.                      Study #: 91-324-JC                      MRID: 422563-22                      Date: August 23, 1991                      Core: Minimum                      DOC #: DER to be submitted with subsequent action</p>	<p>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 guinea pigs.</p> <p>Conclusion:    Not a Sensitizer</p>																								

**NTN 33893 240 F.S.**

Guideline	Study Identification	Study Results																								
83-1	<p>Acute Oral LD50                      Species: Rat                      Mobay Corp.                      Study #: 89-012-DV                      MRID: 422563-13                      Date: Feb. 26, 1990                      Core: Minimum                      DOC #: DER to be submitted with subsequent action</p>	<p>NTN 33893 240 F.S. was administered once by gavage to Sprague-Dawley rats (5/sex/dose) at 0, 1030, 2100, 3595 and 4870 mg/kg for males, and 0, 2100, 3595 and 4870 mg/kg for females. Animals were observed for 14 days.</p> <p>LD50    Male    &gt;4870 mg/kg                      Female   4143 mg/kg (calculated)</p> <p>Toxicity Category: III</p>																								
81-2	<p>Acute Dermal LD50                      Species: Rat                      Mobay Corp.                      Study #: 89-025-EB                      MRID: 422563-15                      Date: February 22, 1990                      Core: Minimum                      DOC #: DER to be submitted with subsequent action</p>	<p>NTN 33893 240 F.S. was administered once dermally for 24 hr to New Zealand White rabbits (5/sex/dose) at 0 and 2000 mg/kg. Animals were observed for 14 days.</p> <p>LD50 &gt; 2000 mg/kg</p> <p>Toxicity Category: III</p>																								
81-3	<p>Acute Inhalation                      Species: Rat                      Mobay Corp.                      Study #: 89-042-EG                      MRID: 422563-17                      Date: February 27, 1990                      Core: Minimum                      DOC #: DER to be submitted with subsequent action</p>	<p>NTN 33893 240 F.S. was administered as a liquid aerosol by inhalation once for 4 hr to Sprague-Dawley rats (6/sex/dose) at 0, 5060, and 5330 mg/m<sup>3</sup>. Animals were observed for 14 days.</p> <p>LC50    -&gt;5330 mg/m<sup>3</sup></p> <p>NOEL    &lt;5060 mg/m<sup>3</sup>                      LOEL    5060 mg/m<sup>3</sup></p> <p>Toxicity Category: IV</p>																								
81-4	<p>Eye Irritation                      Species: Rabbit                      Mobay Corp.                      Study #: 89-335-DZ                      MRID: 422563-19                      Date: January 15, 1990                      Core: Minimum                      DOC #: DER to be submitted with subsequent action</p>	<p>NTN 33893 240 F.S. was introduced into the conjunctival sac of the one eye of 6 New Zealand White rabbits (3/sex) at 0.1 ml. The other eye of each animal served as control. Animals were observed for 14 days.</p> <table border="0"> <tr> <td>TIS:</td> <td>TIME</td> <td>1hr</td> <td>24hr</td> <td>48hr</td> <td>72hr</td> <td>7d</td> <td>14d</td> </tr> <tr> <td></td> <td>-----</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td>IRRIT. SCORE</td> <td>1.0</td> <td>0.3</td> <td>0.2</td> <td>0.0</td> <td>0</td> <td>0</td> </tr> </table> <p>Toxicity Category: III</p>	TIS:	TIME	1hr	24hr	48hr	72hr	7d	14d		-----								IRRIT. SCORE	1.0	0.3	0.2	0.0	0	0
TIS:	TIME	1hr	24hr	48hr	72hr	7d	14d																			
	-----																									
	IRRIT. SCORE	1.0	0.3	0.2	0.0	0	0																			
81-5	<p>Primary Dermal Irritation                      Species: Rabbit                      Mobay Corp.                      Study #: 89-325-DU                      MRID: 422563-21                      Date: January 15, 1990                      Core: Minimum                      DOC #: DER to be submitted with subsequent action</p>	<p>NTN 33893 240 F.S. was administered for 4 hr once dermally to shaved backs of six New Zealand White Rabbits (3/sex) at 500 mg/animal, and observed for 7 days.</p> <p>PIS:    0.0    Non-irritating.</p> <p>Toxicity Category: IV</p>																								
81-6	<p>Dermal Sensitization                      Species: Guinea pig                      Mobay Corp.                      Study #: 89-324-DO                      MRID: 422563-23                      Date: February 22, 1990                      Core: Minimum                      DOC #: DER to be submitted with subsequent action</p>	<p>NTN 33893 240 F.S. 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 guinea pigs.</p> <p>Conclusion:        Not a Sensitizer</p>																								

NTM 33893 2.5% Granular

Guideline	Study Identification	Study Results																
81-1	Acute oral LD50 Species: rat Mobay Chem. Study#: 89-012-DY MRID: 420553-24  Date: 02/26/90 CORE - ACCEPTABLE DOC#: 009375	LD50 > 4820 mg/kg (5000 mg/kg nominal, limit test) Necropsy Observations: None.  Toxicity category IV																
81-2	Acute Dermal LD50 Species: rabbit Mobay Chem. Study#: 89-025-DS MRID: 420553-25  Date: 01/15/90 CORE - ACCEPTABLE DOC#: 009375	NZW rabbits dose at 0 and 2000 mg/kg. LD50 > 2000 mg/kg. Necropsy: None  Toxicity category III																
81-3	Acute inhalation LC50 Species: rat Mobay Chem. Study#: 89-042-DX MRID: 420553-26  Date: 02/26/90 CORE - ACCEPTABLE DOC#: 009375 DER ATTACHED	Sprague-Dawley rats dosed at 0 and 5092 mg/m <sup>3</sup> . LC50 > 5092 mg/m <sup>3</sup> (95% C.L. intervals) Tentative. Necropsy: None Data submission is incomplete. Verification of particle size & distribution in exposure chamber not possible. See deficiencies section. Upgraded. Toxicity category IV																
81-4	Primary eye irritation Species: rabbit Mobay Chem. Study#: 89-335-DT MRID: 420553-27  Date: 01/15/90 CORE - ACCEPTABLE DOC#: 009375	NZW rabbits received 0.1 mL of pulverized test substance/animal. Reversible irritation by 14 days. <table border="1"><thead><tr><th>TIS</th><th>Time</th><th>1 hr</th><th>24 hr</th><th>48 hr</th><th>72 hr</th><th>7 d</th><th>14 d</th></tr></thead><tbody><tr><td>Iris Irrit Score</td><td></td><td>2.3</td><td>1.2</td><td>1.0</td><td>0.5</td><td>0.2</td><td>0.0</td></tr></tbody></table> Toxicity Category II	TIS	Time	1 hr	24 hr	48 hr	72 hr	7 d	14 d	Iris Irrit Score		2.3	1.2	1.0	0.5	0.2	0.0
TIS	Time	1 hr	24 hr	48 hr	72 hr	7 d	14 d											
Iris Irrit Score		2.3	1.2	1.0	0.5	0.2	0.0											
81-5	Primary dermal irritation Species: rabbit Mobay Chem. Study#: 89-325-ED MRID: 420553-28  Date: 12/11/90 CORE - ACCEPTABLE DOC#: 009375	4 hr dermal exposure to NZW rabbits at 50 mg/animal & observed for 72 hrs. PIS = 0.0. Nonirritating.  Toxicity Category IV																

2.5% granular (cont.)

Guideline	Study Identification	Study Results
81-6	Dermal sensitization Species: guinea pig Mobay Chem. Study#: 89-324-DN MRID: 420553-29  Date: 12/11/90 CORE - ACCEPTABLE DOC#s: 009375	Not a sensitizer to Hartley guinea pigs.

NTN 33893 0.62% Granular

Guideline	Study Identification	Study Results
81-1	<p>Acute oral LD50 Species: rat Mobay Chem. MRID#: 420553-23</p> <p>Date: 09/30/91 DOC#: 009375</p>	<p>Study waived. Use data from study #89-012-DY (MRID 420553-24).</p> <p style="text-align: center;"><i>Toxicity Category IV</i></p>
81-2	<p>Acute Dermal LD50 Species: Mobay Chem. MRID#: 420553-23</p> <p>Date: 09/30/91 DOC#: 009375</p>	<p>Study waived. Use data from study #89-025-DS (MRID 420553-25).</p> <p style="text-align: center;"><i>Toxicity Category III</i></p>
81-4	<p>Primary eye irritation Species: rabbit Mobay Chem. MRID#: 420553-23</p> <p>Date: 09/30/91 DOC#: 009375</p>	<p>Study waived. Use data from study #89-335-DT (MRID 420553-27)</p> <p style="text-align: center;"><i>Toxicity Category II</i></p>
81-5	<p>Primary dermal irritation Species: Mobay Chem. MRID#: 420553-23</p> <p>Date: 09/30/91 DOC#: 009375</p>	<p>Study waived. Use data from study #89-325-ED (MRID 420553-28)</p> <p style="text-align: center;"><i>Toxicity Category II</i></p>
81-6	<p>Dermal sensitization Species: Mobay Chem. MRID#: 420553-23</p> <p>Date: 09/30/91 DOC#: 009375</p>	<p>Study waived. Use data from study #89-324-DN (MRID 420553-29) Not a sensitizer.</p>



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

JUL 1 1993

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: SECTION 18 REQUEST FROM ARIZONA TO USE THE ACTIVE  
INGREDIENT IMIDACLOPRID (CONFIDOR 2 FLOWABLE) ON  
BROCCOLI, CAULIFLOWER, CABBAGE, AND HEAD & LEAF LETTUCE  
TO CONTROL SWEETPOTATO WHITEFLIES

FROM: Bruce F. Kitchens, Chemist *Bruce F. Kitchens*

TO: Sheryl K. Reilly, Ph.D  
Toxicology Branch I  
Health Effects Division (H7509C)

THRU: Mark I. Dow, Ph.D., Section Head *Mark I. Dow*  
Special Review and Registration Section II  
Larry C. Dorsey, Chief *Larry C. Dorsey*  
Occupational and Residential Exposure Branch  
Health Effects Division (H7509C)

Please find below, the OREB review of:

DP Barcode: D192506, D192507

Pesticide Chemical Code: 129099

EPA Reg. No.: 93AZ0007, 93AZ0005

EPA MRID No.: N/A

Review Time: 2 days

PHED: YES:Version 1.01, Run #19



I. INTRODUCTION:

Arizona requests two section 18 specific exemptions for the use of the active ingredient imidacloprid, trade name Confidor 2 Flowable. Confidor 2 Flowable is a systemic insecticide that will be used to control the sweet potato whitefly on broccoli, cauliflower, and cabbage in the first section 18 (93AZ0007) and head & leaf lettuce in the second section 18 (93AZ0005). Miles, Inc. manufactures Confidor 2 Flowable.

The maximum application rate is 0.313 lbs a.i./A (5.0 dry oz. ai/A) for Confidor 2 Flowable in both section 18 requests. Pesticide application is via ground equipment for both requests. From this point in this memo both requests will be treated as one single document since the maximum application rates are the same for both requests. Where there are differences between the section 18s it will be noted. There is a maximum number of 2 applications per year. The total acreage to be treated for 93AZ0007 is 16,600 acres with a maximum of 8300 lbs a.i. The total acreage to be treated for 93AZ0005 is 55,000 acres with a maximum of 27,750 lbs a.i. Spray season begins August 10, 1993 and ends May 15, 1994. Confidor 2 Flowable will be used in the following Arizona counties:

LaPaz	Pinal
Maricopa	Yuma
Pima	

The tox endpoints of concern are maternal and developmental toxicity with NOELs of 24 mg/kg/day.

A. Background:

OREB estimated worker exposure in a recent section 18 request from Arizona (D191574 6/14/93) for the use of Confidor 2 Flowable on cotton. Exposure estimates derived from PHED will serve as background for this section 18.

B. Purpose:

This document estimates worker exposure for the proposed uses of imidacloprid in Arizona on broccoli, cauliflower, cabbage, and head & leaf lettuce to control the sweet potato whitefly. OREB estimates exposure for the following:

<b>Applicator:</b>	<u>Groundboom</u>	open cab & closed cab
<b>Mixer/loader:</b>	<u>Groundboom</u>	open loading & closed loading



II. DETAILED CONSIDERATIONS:

OREB will use the following assumptions to estimate worker exposure:

TABLE 1. ASSUMPTIONS

Mixer loader weighs.....	60 kg
Applicator weighs.....	60 kg
Application rate.....	0.313 lb ai/A
Max No. Applications.....	2
App. GB open cab exposure.....	22.5 µg/lb ai
App. GB closed cab exposure.....	11.7 µg/lb ai
Mixer/loader open exposure.....	25.9 µg/lb ai
Mixer/loader closed exposure.....	30.9 µg/lb ai
Adjustment for Dermal absorption...	None

CROP	AVG FARM SIZE	AVG ACRES PER DAY
Broccoli	158	50
Cabbage	37	50
Cauliflower	230	50
Lettuce	497	50

1. 1987 Agricultural Census: Arizona

Calculations:

**Applicator - Groundboom Open Cab**

AI sprayed per day:

$$50 \text{ acres/day} \times 0.313 \text{ lb ai/A} = 15.7 \text{ lb ai/day}$$

Exposure then becomes:

$$15.7 \text{ lb ai/day} \times 22.5 \text{ µg/lb ai} \div 60 \text{ kg} = 5.9 \text{ µg/kg/day}$$

Calculations: (con't)

**Applicator - Groundboom Closed**

Amount of active ingredient sprayed per day remains the same as calculated for groundboom open cab.

Exposure then becomes:

$$15.7 \text{ lb ai/day} \times 11.7 \text{ } \mu\text{g/lb ai} \div 60 \text{ kg} = 3.1 \text{ } \mu\text{g/kg/day}$$

**Mixer/loader - Groundboom open pour**

AI handled per day:

$$50 \text{ acres/day} \times 0.313 \text{ lb ai/A} = 15.7 \text{ lb ai/day}$$

Exposure then becomes:

$$15.7 \text{ lb ai/day} \times 25.9 \text{ } \mu\text{g/lb ai} \div 60 \text{ kg} = 6.8 \text{ } \mu\text{g/kg/day}$$

**Mixer/loader - Groundboom closed pour**

The amount of active ingredient handled per day remains the same as calculated for M/L - groundboom open pour.

Exposure then becomes:

$$15.7 \text{ lb ai/day} \times 30.9 \text{ } \mu\text{g/lb ai} \div 60 \text{ kg} = 8.1 \text{ } \mu\text{g/kg/day}$$

### III. CONCLUSIONS:

OREB concludes that the following worker exposures may result from the use of Confidor 2 Flowable on broccoli, cabbage, cauliflower, and head & leaf lettuce. Inhalation exposures are included in these estimates. See Appendix A for PHED runs.

TABLE 3. ESTIMATED IMIDACLOPRID WORKER EXPOSURES		
JOB FUNCTION	EXPOSURE $\mu\text{g}/\text{kg}/\text{day}$	CLOTHING SCENARIO
Applicator GB open	5.9	long pants, short sleeves
Applicator GB closed	3.1	no clothes (total deposition)
Mix/load GB open	6.8	long pants, long sleeves, gloves
Mix/load GB closed	8.1	no clothes, gloves

Note that the clothing scenario for each exposure estimate represents the best data set available in PHED.

The exposure estimates apply to all of the individual crops. In this case the application method and the application rates are the same for each crop. One exception is the total acreage treated per day for cabbage. The exposure estimates presented are slightly higher than what the actual estimates for cabbage treated at the lower acres/day.

The label attached to this action did not specify what personal protective equipment (PPE) should be employed when handling Confidor 2 Flowable. The Worker Protection Standards (WPS) indicate that the signal word dictates the PPE in the absence of label specified PPE. Since the signal word is "Caution" the following PPE should be used:

- long sleeved shirt and long pants
- shoes and socks
- chemical resistant gloves

### IV. REFERENCES:

cc: B. Kitchens  
Chemical File: IMIDACLOPRID  
Circulation  
Correspondence

**APPENDIX A.**  
**PHED RUNS**

Run #19  
6/3/93

APPLICATOR EXPOSURE

GROUNDBOOM/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:

EXPOSURE	DISTRIB.	NANOGRAMS PER LB AI SPRAYED				Obs.
	TYPE	Median	Mean	Coef of Var	Geo. Mean	
	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

SCENARIO: Long pants, short sleeves

PATCH LOCATION	DISTRIB.	MICROGRAMS PER LB AI SPRAYED				Obs.
	TYPE	Median	Mean	Coef of Var	Geo. Mean	
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	186.9849	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						0
<b>TOTAL DERM:</b>		<b>9.7339</b>				

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  
Cab Type Equal to 1 and  
Subset originated from APPL.FILE

EXPOSURE

SCENARIO: no gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI SPRAYED				Obs.
		Median	Mean	Coef of Var	Geo. Mean	
HANDS	Lognormal	6.4599	55.3427	169.62	12.3523	22

Number of Records: 30  
Data File: APPLICATOR

Subset Name: GB.OP.HDABC.APPL

Subset Specifications for GB.OP.HDABC.APPL

With Hand Grade Equal to "A" "B" "C"  
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

GROUNDBOOM APPLICATION/CLOSED CAB

Total Exposure for workers wearing no clothing, no gloves:  
Inhalation: 0.09 ug/lb ai  
Dermal/body: 4.29 ug/lb ai  
Hands: 7.34 ug/lb ai  
Total: 11.72 ug/lb ai

Total Exposure for workers wearing long pants, short sleeves, no gloves:  
Inhalation: 0.09 ug/lb ai  
Dermal/body: 0.42 ug/lb ai  
Hands: 7.34 ug/lb ai  
Total: 7.85 ug/lb ai

INHALATION EXPOSURES

EXPOSURE	DISTRIB. TYPE	NANOGRAMS PER LB AI SPRAYED				Obs.
		Median	Mean	Coef of Var	Geo. Mean	
	Lognormal	36.1635	362.2118	154.0302	██████████	23

Number of Records: 23  
Data File: APPLICATOR

Subset Name: GB.CLSD.AIR.APPL

Subset Specifications for GB.CLSD.AIR.APPL

With Airborne Grade 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

DERMAL EXPOSURES

SCENARIO: No clothing (total deposition)

PATCH LOCATION	DISTRIB. TYPE	Median	MICROGRAMS PER LB AI SPRAYED			Obs.
			Mean	Coef of Var	Geo. Mean	
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	Lognormal	.476	2.0771	248.5196	.6046	11
FEET						0
TOTAL DERM:		<b>4.2916</b>				

Number of Records: 11  
Data File: APPLICATOR

Subset Name: GB.CLSD.DRMA\_D.APPL

SCENARIO: Long pants, short sleeves

PATCH LOCATION	DISTRIB. TYPE	Median	MICROGRAMS PER LB AI SPRAYED			Obs.
			Mean	Coef of Var	Geo. Mean	
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						0
CHEST						0
BACK						0
FOREARMS	Other	.121	.209	68.9474	.1766	11
THIGHS						0
LOWER LEGS						0
FEET						0
TOTAL DERM:		<b>4.2916</b>				

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

SCENARIO: no gloves

PATCH LOCATION	DISTRIB. TYPE	Median	MICROGRAMS PER LB AI SPRAYED			Obs.
			Mean	Coef of Var	Geo. Mean	
HANDS	Lognormal	8.3966	43.6448	206.8178		12

Number of Records: 14  
Data File: APPLICATOR

Subset Name: GB.CLSD.HDA\_D.APPL

Subset Specifications for GB.CLSD.HDA D.APPL  
 Hand Grade 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

AERIAL APPLICATION

Total Exposure for workers wearing long pants, short sleeves, no gloves:  
 Inhalation: 0.19 ug/lb ai  
 Dermal/body: 2.51 ug/lb ai  
 Hands: 3.08 ug/lb ai  
Total: 5.78 ug/lb ai

INHALATION EXPOSURE

EXPOSURE	DISTRIB. TYPE	Median	NANOGRAMS PER LB AI SPRAYED			Obs.
			Mean	Coef of Var	Geo. Mean	
	Lognormal	156.3625	543.7511	226.6519	192.4707	25

Number of Records: 25  
 Data File: APPLICATOR

Subset Name: AER.AIR.APPL

Subset Specifications for AER.AIR.APPL  
 Airborne Grade Equal to "A" "B" "C"  
 Subset originated from AERIAL.APPL  
 With Application Method Equal to 5 6  
 Subset originated from APPL.FILE

DERMAL EXPOSURES

SCENARIO: Long pants, short sleeves

PATCH LOCATION	DISTRIB. TYPE	Median	MICROGRAMS PER LB AI SPRAYED			Obs.
			Mean	Coef of Var	Geo. Mean	
HEAD (ALL)	Other	.39	1.2734	178.0587	.4735	44
NECK.FRONT	Other	.045	.0982	151.3238	.0479	44
NECK.BACK	Other	.0275	.0584	166.7808	.0304	36
UPPER ARMS	Other	.291	.291	0	.291	6
CHEST	Other	.355	.3905	28.758	.3805	10
BACK	Other	.355	.355	0	.355	10
FOREARMS	Other	.4235	1.0499	214.5347	.3641	34
THIGHS	Other	.382	.382	0	.382	6
LOWER LEGS	Other	.238	.238	0	.238	6
FEET						0
<b>TOTAL DERM:</b>		<b>2.507</b>				

Number of Records: 44  
 Data File: APPLICATOR

Subset Name: AE.DMA\_C.APPL

Subset Specifications for AE.DMA\_C.APPL  
 Dermal Grade Uncovered Equal to "A" "B" "C"  
 Subset originated from AERIAL.APPL  
 With Application Method Equal to 5 6  
 Subset originated from APPL.FILE



F EXPOSURE

SCENARIO: no gloves

PATCH	DISTRIB.	Median	Mean	Coef of Var	Geo. Mean	Obs.
LOCATION	TYPE					
HANDS	Lognormal	2.2666	12.7278	206.1244	3.0849	22

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

Hand/body: 21.1 ug/lb ai

Hands\*: 4.34 ug/lb ai

Total Exposure: 25.88 ug/lb ai

\*Combined geometric mean of two hand estimates.

INHALATION EXPOSURE:

	DISTRIB.	Median	Mean	Coef of Var	Geo. Mean	Obs.
EXPOSURE	TYPE					
	Lognormal	367.0709	2552.6287	144.4647	443.4466	40

Number of Records: 40

Data File: MIXER/LOADER

Subset Name: LIQ.OP.X.AIR.MLOD

Subset Specifications for LIQ.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

DERMAL EXPOSURE:

SCENARIO: Long pants, long sleeves

PATCH LOCATION	DISTRIB. TYPE	Median	MICROGRAMS PER LB AI MIXED			Obs.
			Mean	Coef of Var	Geo. Mean	
HEAD (ALL)	Other	.52	10.4098	249.4006	1.3465	132
NECK.FRONT	Other	.21	3.2831	440.3917	.2987	120
NECK.BACK	Other	.044	.7621	279.0972	.099	123
UPPER ARMS	Other	3.201	3.3801	105.3578	1.4066	26
CHEST	Other	5.68	20.0883	282.0089	3.6217	75
BACK	Other	5.68	15.8685	181.2339	3.7667	60
FOREARMS	Lognormal	3.63	8.663	125.8167	2.896	42
THIGHS	Other	1.91	8.9917	207.7694	2.2648	39
LOWER LEGS	Other	.952	2.8496	123.7963	1.1634	37
FEET						0
<b>TOTAL DERM:</b>		<b>21.093</b>				

Number of Records: 132

Data File: MIXER/LOADER

Subset Name: LIQ.OP.X.DRM.MLOD

Subset Specifications for LIQ.OP.X.DRM.MLOD

With Dermal Grade Uncovered Equal to "A" "B" "C"

Subset originated from LIQ.OP.X4081.MLOD

Without Study Code Equal to 4081

Subset originated from LIQ.OPEN.MLOD

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

HAND EXPOSURE

SCENARIO: gloves

PATCH LOCATION	DISTRIB. TYPE	Median	MICROGRAMS PER LB AI MIXED			Obs.
			Mean	Coef of Var	Geo. Mean	
HANDS	Lognormal	.0625	96.5471	253.4793	.5764	13

Number of Records: 21

Data File: MIXER/LOADER

Subset Name: LIQ.OP.X.GLV.MLOD

Subset Specifications for LIQ.OP.X.GLV.MLOD

With Hand Grade Equal to "A" "B" and

With Hand Measuring Method Equal to 2

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

EXPOSURES

SCENARIO: gloves

PATCH LOCATION	DISTRIB. TYPE	Median	MICROGRAMS PER LB AI MIXED			Obs.
			Mean	Coef of Var	Geo. Mean	
HANDS	Lognormal	19.697	106.6871	118.8365	32.6518	13

Number of Records: 19

Data File: MIXER/LOADER

Subset Name: LIQ.OP.X.RNS.MLOD

Subset Specifications for LIQ.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

ED MIX/LIQUIDS

Total 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

EXPOSURE	DISTRIB. TYPE	Median	NANOGRAMS PER LB AI MIXED			Obs.
			Mean	Coef of Var	Geo. Mean	
	Lognormal	58.9667	82.8768	92.3632	59.8581	13

Number of Records: 13

Data File: MIXER/LOADER

Subset Name: LIQ.CL.AIR.MLOD

Subset Specifications for LIQ.CL.AIR.MLOD

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

AL EXPOSURES

SCENARIO: Long pants, long sleeves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI MIXED				Obs.
		Median	Mean	Coef of Var	Geo. Mean	
HEAD (ALL)	Lognormal	.52	1.2814	136.9752	.7042	14
NECK.FRONT	Lognormal	.0675	.3632	245.0991	.0881	14
NECK.BACK	Other	.0385	.2239	313.4882	.0454	14
UPPER ARMS						0
CHEST	Other	.71	.71	0	.71	1
BACK	Other	.71	.71	0	.71	1
FOREARMS						0
THIGHS						0
LOWER LEGS						0
FEET						0
<b>TOTAL DERM:</b>	<b>2.2508</b>	<b>2.046</b>	<b>3.2885</b>		<b>2.2577</b>	

Number of Records: 14  
Data File: MIXER/LOADER

Subset Name: LIQ.CL.DERM.MLOD

SCENARIO: No clothing (total deposition)

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI MIXED				Obs.
		Median	Mean	Coef of Var	Geo. Mean	
HEAD (ALL)	Lognormal	.52	1.2814	136.9752	.7042	14
FRONT	Lognormal	.0675	.3632	245.0991	.0881	14
BACK	Other	.0385	.2239	313.4882	.0454	14
UPPER ARMS	Lognormal	1.164	1.8291	136.2091	1.0931	14
CHEST	Lognormal	1.5975	8.5707	245.9309	1.985	14
BACK	Other	1.2425	7.2014	314.6485	1.3949	14
FOREARMS	Lognormal	1.089	22.3159	330.5137	1.8704	14
THIGHS	Lognormal	29.605	153.4821	209.664	20.195	14
LOWER LEGS	Lognormal	1.19	7.6343	166.509	2.3231	13
FEET						0
<b>TOTAL DERM:</b>	<b>29.5399</b>	<b>36.514</b>	<b>202.902</b>		<b>29.6992</b>	

Number of Records: 14  
Data File: MIXER/LOADER

Subset Name: LIQ.CL.DERM.MLOD

Subset Specifications for LIQ.CL.DERM.MLOD

With Dermal Grade Uncovered Equal to "A" "B" "C" "D"  
Subset 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

HAND EXPOSURES

SCENARIO: gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI MIXED				Obs.
		Median	Mean	Coef of Var	Geo. Mean	
HANDS	Lognormal	1.3909	2.9299	112.3247	1.3275	13

Number of Records: 13  
Data File: MIXER/LOADER

Subset Name: LIQ.CL.HND.MLOD

et Specifications for LIQ.CL.HND.MLOD  
Hand Grade Equal to "A" "B" "C" "D"  
Subset 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.