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

Application method #497E — ground boom as a foliar spray 7/20/95

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **Section 18: ID# 95FL0008.** Emergency Exemption for Use of Provado 1.6F (Imidacloprid) on Leafy Vegetables in Florida

Tox. Chem. No.:	497E
PC No.:	129059
Barcode No.:	D213914
Submission No.:	S484569

TO: Andrea Beard, Manager, PM Team 41
Margarita Collantes, Reviewer, PM Team 41
Emergency Response and Minor Use Section/Registration Support Branch
Registration Division (H7505C)

FROM: William Dykstra, Ph.D. William Dykstra 4/19/95
Review Section I, Toxicology Branch I
Health Effects Division (H7509C)

THRU: John Doherty, Ph.D. 4/20/95
Review Section IV, Toxicology Branch I
Health Effects Division (H7509C)
and
Roger Gardner, Section Head Roger Gardner 4/20/95
Review Section I, Toxicology Branch I
Health Effects Division (H7509C) 4/20/95

I. CONCLUSIONS

The toxicology data requirements are complete for the issuance of a Section 18 emergency exemption by the State of Florida for the temporary use of imidacloprid (Provado 1.6F) to control aphids on leafy vegetables. The margins of exposure (MOEs) for short term exposure are greater than 100. Imidacloprid is a "Group E" carcinogen, so there is no cancer risk associated with exposure to this chemical.

For acute dietary exposure, a toxicological NOEL of 24 mg/kg/day based on the increased resorptions and abortions in the rabbit developmental study should be used.

Toxicology Branch I has no objection to the issuance of this

exemption.

II. ACTION REQUESTED

In letters dated March 14 and 29, 1995, the Florida Department of Agriculture requested an emergency exemption under Section 18 for the use of imidacloprid to control aphids on leafy vegetables. This is the first request made by Florida for this use.

Provado 1.6F (Miles, Inc.) is the formulation for the active ingredient. The pesticide will be used five times per growing season. The maximum estimated acreage to be treated in Florida is 31,670. The rate of application will be 3.75 fl. oz. of Provado 1.6F per acre (0.047 lb ai) at 5 day intervals. This is equivalent to 4,639 gallons of formulated product (7,423 lbs ai) for the entire Section 18.

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) for determination of exposure estimates (see attached memo from T. Manville to W. Dykstra, dated April 13, 1995). Therefore, the OREB exposure estimates and the rabbit maternal and developmental NOEL of 24 mg/kg/day (see previously submitted One Liners) were used to determine the Short term MOEs. Calculations were based on a dermal absorption of 100%, because no dermal absorption data is available for imidacloprid. However, dermal exposure is considered negligible, since a 21 day dermal study in rabbits has a systemic NOEL of 1000 mg/kg/day (HDT).

Formula used in calculations:

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

OPERATION*	EXPOSURE (mg/kg/d)	SHORT TERM MOE
Mixer/Loader	0.0027	8,889
Applicator	0.00086	27,906

* Minimum clothing requirements for Applicators are long pants, long-sleeved shirt, and chemical resistant 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. Labelling. The labelling precautionary statements for Provado 1.6F are governed by toxicity studies on the active ingredient. Provado 1.6F has the following Tox Categories: Tox III for acute oral, dermal, and primary eye irritation and TOX IV for acute inhalation and primary dermal irritation. Provado 1.6F is not a skin sensitizer.

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 mg/kg/day should be established, based upon a NOEL of 5.7 mg/kg/day 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 one-liners). In a developmental study in rabbits, 72 mg/kg/day 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. The NOEL was 24 mg/kg/day.

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, and an in vitro sister chromatid exchange mutagenicity study (CHO cells) was positive at cytotoxic doses.

6. Dermal Penetration. There are no available dermal penetration data for imidacloprid. However, a 21 day dermal toxicity study in rabbits has a systemic NOEL of 1000 mg/kg/day (HDT).

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WASHINGTON, D.C. 20460

APR 18 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: FLORIDA SECTION 18 REQUEST (95FL0008) TO USE IMIDACLOPRID ON LEAFY VEGETABLES TO CONTROL APHIDS

FROM: Tina Manville, Biologist
Special Review and Registration Section II
Tina Manville

TO: William Dykstra, Ph.D., Toxicologist
Toxicology Branch I
Health Effects Division (7509C)

THRU: Mark I. Dow, Ph.D., Section Head
Special Review and Registration Section II
Mark I Dow

Larry C. Dorsey, Chief
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Please find below, the OREB review of:

DP Barcode: D213915

Pesticide Chemical Code: 129099

EPA Reg. No.: 3125-457

EPA MRID No.: N/A

Review Time: 2 DAY

PHED: Yes, Version 1.1, M/L OPN.LIQ.MLOD, Applicator

BRUCE1.APPL

I. INTRODUCTION:

A. Background:

Florida requests a Section 18 Specific Exemption to use imidacloprid on the Brassica leafy vegetable grouping (cabbage, chinese cabbage, and kale) and the non-Brassica leafy vegetable grouping (lettuce, escarole/endive, spinach, parsley) to control aphids. Imidacloprid, trade name Provado 1.6 Flowable, is a systemic insecticide registered for use on ornamentals, cotton, mangoes, apples, and potatoes. A tolerance was established in 4/5/95 for residues on leafy-Brassica group vegetables and lettuce. Provado 1.6 Flowable is formulated as a flowable compound with 17.4% active ingredient.

On March 15, 1995, Florida asked for a similar Section 18 exemption, which it is now asking to continue since the crops covered in the first request will be harvested on May 30th. The aphid problem shows no sign of disappearing and Florida would like a year of imidacloprid use. Florida states that recently there has been a shift in the population of the predominant aphid species, with the turnip aphid (Hyadaphis erysimi) becoming dominant and that there are no registered pesticides that can adequately control it.

The tox endpoint of concern is a maternal and developmental NOEL of 24 mg/kg/day. The tox categories for the technical product are: category II for acute oral toxicity, and category IV for acute dermal and inhalation toxicity and primary dermal and eye irritation. The end-use product tox categories (for a 21.4% flowable formulation, with the same inerts) are: category III for acute oral and dermal toxicity, and primary eye irritation, and category IV for acute inhalation toxicity and primary dermal irritation. Imidacloprid is not a dermal sensitizer for the both technical and end-use grade products (personal communication with William Dykstra, Ph.D., TB I, 4/11/95).

B. Purpose:

Registration Division has requested OREB to provide an estimate of worker exposure to imidacloprid as it is used on leafy vegetables to control aphids.

II. DETAILED CONSIDERATIONS:

A. Proposed Program:

Table One describes the Florida section 18 request.

TABLE ONE SECTION 18 DETAILS	
Crop	leafy vegetables[1]
Pest	turnip aphid
Application method	ground boom as a foliar spray
Application rate	0.047 lb ai/A
No. of applications	5/crop, multiple leafy crops/year
Maximum acreage	31,670 acres
Manufacturer	Miles, Inc.
Average farm size	100 acres[2]
Use period	May 31 1995 - May 31 1996

1. Leafy vegetables of the Brassica group (cabbage, chinese cabbage, kale) and non-Brassica group (lettuce, escarole/endive, spinach, parsley).

2. Florida states it is not uncommon for farmers to plant several leafy vegetable crops within a 100 acre area. OREB believes it is possible for a farmer in Florida to have leafy vegetable acreage of more than 100 acres, since the average lettuce acreage per farmer that grows lettuce is 131 acres and the average chinese cabbage acreage is 113 acres. A farmer could plant both these crops plus other leafy vegetable crops giving an area well over 100 acres. (Agricultural Statistics 1992, Vol. 1, Part 9, Ch. 2, Table 29: Vegetables, Sweet Corn and Melons Harvested for Sale: 1992.)

OREB 's exposure assessment is based on the following assumptions (Table Two):

TABLE TWO ASSUMPTIONS	
Mixer/loader weight	60 kg
Applicator weight	60 kg
Acres treated/day[1]	78 acres
Mixer/loader unit of exposure PHED, open pour[2]	44 µg/lb ai
Applicator unit of exposure PHED, open cab, ground boom[2]	15 µg/lb ai
Adjustment for dermal absorption	None

1. Provided by Dr. Yuen-shaung Ng, Biological and Economic Analysis Division (BEAD) (see attachment). This estimate is based on the assumption that Provado will be mixed with 10 gallons of water per acre.

2. PHED run with normal work clothing of long pants, long-sleeved shirt, and gloves.

III. CONCLUSIONS:

OREB concludes that the following worker exposure results from the section 18 use of imidacloprid on leafy vegetables to control aphids (see Table 3).

TABLE 3 IMIDACLOPRID WORKER EXPOSURE

	Daily Exposure µg/kg/day
Mixer/loader	2.7
Applicator	0.86

For calculations please see appendix.

The product label states that the following Personal Protective Equipment (PPE) be worn: long-sleeved shirt, long pants, shoes and socks, and water-proof gloves. This is in compliance with the Worker Protection Standard (WPS), since Provado 1.6 Flowable is a tox category III compound. The OREB exposure assessment is based on PHED exposure data generated with the same PPE as listed on the label.

According to the product label the Restricted-Entry Interval (REI) is 12 hours. This is in agreement with WPS since imidacloprid is a tox category IV compound for the technical grade.

cc: T. Manville
Chemical File: **IMIDACLOPRID (129099)**
Correspondence

CALCULATIONS

Total ai handled per day:

0.047 lb ai/acre X 78 acres/day = 3.7 lb ai/day

Mixer/loader daily exposure (DE) :

44 μg/lb ai X 3.7 lb ai/day ÷ 60 kg = **2.7 μg/kg/day**

Applicator daily exposure :

14 μg/lb ai X 3.7 lb ai/day ÷ 60 kg = **0.86 μg/kg/day**

YSNG(BEAD) Estimate of Acres Treated by Various Application Methods

04/11/95

Site: LEAFY VEG FIELD Chem: IMIDACLOPRID Hrs/day: 8.0 hr.
Appl. method: GROUND Speed: 4.0 (increment: 1) mph
Tank capacity(TC): 350 (Increment: 25) gal Length of run(LR): 1000 ft.
Swath width(SW): 26 (Increment: 3) ft. Water station(WS): 200 yd.
Finish spray(FS): 10 (Increment: 2) gal. Refill time(RT): 9.0 min
** Recommand: Ground -- RT = 2-3 mins. per 100 gal TC; LR = 1000 ft; **********
WS = varies; Ferry speed = speed * 2.0; Turning time = 0.25 min

350 TC	4.0 mph				5.0 mph				6.0 mph				7.0 mph			
FS	10	12	14	16	10	12	14	16	A 10	12	14	16	10	12	14	16
26	78	75	73	71	92	89	86	83	C 105	101	97	94	117	112	108	103
SW 29	85	82	80	77	101	97	93	90	R 115	110	105	101	128	122	116	111
32	92	89	86	83	109	105	100	97	E 124	118	113	108	137	130	124	118

375 TC	4.0 mph				5.0 mph				6.0 mph				7.0 mph			
FS	10	12	14	16	10	12	14	16	A 10	12	14	16	10	12	14	16
26	78	75	73	71	92	89	86	83	C 106	101	97	94	117	112	108	103
SW 29	85	82	80	77	101	97	93	90	R 115	110	105	101	128	122	116	111
32	93	89	86	83	109	105	101	97	E 124	118	113	108	137	130	124	118

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