

US EPA ARCHIVE DOCUMENT



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

MAR 25 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 18: ID# 94WA0012. Emergency Exemption for Use
of ADMIRE 2 Flowable (Imidacloprid) on Hops in Washington

Tox. Chem. No.: 497E
PC No.: 129099
Barcode No.: D200395
Submission No.: S459670

TO: Rebecca Cool, 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 3/17/94*
Review Section I, Toxicology Branch I
Health Effects Division (H7509C)

THRU: Myron S. Ottley, Ph.D. *Myron Ottley 3/17/94*
Review Section IV, Toxicology Branch I
Health Effects Division (H7509C)
and
Roger Gardner, Section Head
Review Section I, Toxicology Branch I *R. Gardner 3/25/94*
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 Washington for the temporary use of imidacloprid (ADMIRE 2 Flowable) to control aphids on hops. 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 February 24, 1994, the Washington Department



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of Agriculture requested an emergency exemption under Section 18 for the use of imidacloprid to control aphids on hops. This is the first request made by Washington for this use. ADMIRE 2 Flowable (Miles, Inc.) is the formulation for the active ingredient. The pesticide will be used three times per growing season. The maximum estimated acreage to be treated in Washington is 30,000. The rate of application will be 6.4 fl. oz. of ADMIRE 2 Flowable per acre (0.1 lb ai per acre). At the maximum rate and maximum number of applications, a total of 4,500 gallons of formulated product (9,000 lbs. ai) will be applied.

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 J. Tice to W. Dykstra, dated March 17, 1994). Therefore, the OREB exposure estimates and the rabbit maternal and developmental NOEL of 24 mg/kg/d (see One Liners, below) were used to determine the Acute MOEs. 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 Q₁* for this chemical.

Formula used in calculations:

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

OPERATION*	EXPOSURE (mg/kg/d)	ACUTE MOE
Mixer/Loaders, open pour	0.015	1,600
Applicator, air blast	0.011	2,182

* 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 ADMIRE 2 Flowable 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 mg/kg/day 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. 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 (Tox. Doc. #099262), and an in vitro sister chromatid exchange mutagenicity study (CHO cells) was positive at cytotoxic doses (Tox. Doc. 102655).
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

MAR 17 1994


OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES


MEMORANDUM

SUBJECT: Section 18, Washington State Request to Use Imidacloprid on Hops

FROM: John Tice 
Occupational and Residential Exposure Branch
Health Effects Division (H-7509-C)

TO: Bill Dykstra, Ph.D, D.A.B.T.
Toxicology Branch I
Health Effects Division (H-7509-C)

THRU: Mark I. Dow, Ph.D., Section Head 
Special Review and Registration Section II
Occupational and Residential Exposure Branch
Health Effects Division (H-7509-C)

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

Please find below, the OREB review of:

DP Barcode: D-200394

Pesticide Chemical Code: 129099, Imidacloprid

EPA Reg. No.: 3125-UEE, Admire 2 Flowable

EPA MRID No.: N/A

PHED: PHED version 1.01 used for exposure estimates
mixer/loader exposures from run # 7
Air-blast (long-sleeves, pants and gloves) run # 2

REFERRED TO TOX II FOR RISK ASSESSMENT



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I. INTRODUCTION:

Background/Purpose

The State of Washington has requested an emergency exemption to use Admire 2 F, (imidacloprid) to control mites and aphids on hops. The State of Washington has 30,000 acres of hops that they feel will need treatment.

II. DETAILED CONSIDERATIONS:

A. Use

Imidacloprid will be applied by ground as a foliar spray at the rate of 6.4 oz product per acre or 0.10 lb ai per acre. A maximum of three applications may be applied per season with a maximum application of 19.2 fl. oz. of product or 0.3 lb ai/acre. Hops are normally grown in rows with 7 ft. centers on trellises that stand approximately 14-18 feet tall. Insecticides are generally applied via ground, air-blast equipment with no less than 100 gallons of water per acre and preferably 400 gallons of water applied per acre for maximum coverage. In discussions with an expert in hops production¹, it is estimated that the maximum acreage that could be sprayed in one day is 20 acres (spraying 20 A would require > 12 hrs.).

B. Toxicology concerns

The tox endpoint of concern is maternal/developmental toxicity with a NOEL of 24 mg/kg/day. Imidacloprid is a tox category III chemical for oral toxicity, dermal and eye irritation; and a tox category IV for inhalation and primary dermal toxicity.

C. Prior exposure reviews

Other exposure evaluations have been performed for hops with the same application rate and same PPE required. The table below provides the estimates of worker exposure.

¹ Personal communications with Dr. Wyatt Cone, Washington State University (IAREC), Prosser, WA (509) 786-2226.

WORKER EXPOSURES TO IMIDACLOPRID USING PHED SURROGATE DATA

OPERATION	UNIT EXPOSURE <i>μg/lb handled</i>	GROSS EXPOSURE² 20 ACRES <i>(μg a.i.)</i>	DAILY EXPOSURE³ (20 ACRES) <i>μg/kg</i>
M/L OPEN LOAD	448.5	897.0	15.0
GROUND A.B. 20 ACRES	325.9	651.8	10.9
M/L/A GROUND	774.4	1,548.8	25.8

III. CONCLUSIONS:

Daily exposure estimates for a mixer/loader/applicator spraying 20 acres of hops at 0.1 lb ai per acre is 25.8 μg/kg/day.

The minimum PPE required include long-sleeved shirt, long pants, shoes with socks, and chemical resistant gloves. Other PPE including chemical resistant headgear, coveralls or rain-suit and dust mist respirator may also be used.

cc: Correspondence File
Imidacloprid File (129099)

² Exposure resulting from handling 2 lbs ai; enough to spray 20 acres @ 0.1 lbs ai/acre.

³ Daily exposure estimate for handling 2 lbs ai. Estimates calculated using the following formula:

$$\frac{\text{Unit Exposure} * (2 \text{ lbs ai})}{60 \text{ kg. bw.}} = \text{Daily Exposure}$$

D. Detailed exposure calculations

Exposure calculations are based on the following assumptions:

- Average worker has the mass of 60 kg,
- mixer/loader and applicator can be the same person (see combined exposure),
- respiratory exposure is negligible compared to dermal exposure,
- dermal exposure is not adjusted for dermal absorption,
- standard work clothing is worn which includes protective gloves, long sleeved shirts, long pants, shoes, socks, and hat,
- in one day a single person will mix/load and spray a maximum of 20 acres at 0.1 lbs ai per acre.
- the maximum application rate is used during each of three applications (0.1 lb ai/acre times 3 applications = 0.3 lbs ai/acre per year.)

The following table summarizes daily and annual exposures for mixer/loader, applicator, and mixer/loader/applicator, using an open pour loading system.

DP BARCODE: D200395

CASE: 285477
SUBMISSION: S459670

DATA PACKAGE RECORD
BEAN SHEET

DATE: 03/11/94
Page 1 of 1

*** CASE/SUBMISSION INFORMATION ***

CASE TYPE: EMERGENCY EXEMP ACTION: 500 SECT18 SPC EXE NC F/F USE
RANKING : 75 POINTS (A)
CHEMICALS: 129099 Imidacloprid

ID#: 94WA0012

COMPANY:

PRODUCT MANAGER: 41 REBECCA COOL 703-308-8417 ROOM: CS1
PM TEAM REVIEWER: MARGARITA COLLANTES 703-308-8641 ROOM: CS1 6THFL
RECEIVED DATE: 03/04/94 DUE OUT DATE: 04/23/94

*** DATA PACKAGE INFORMATION ***

DP BARCODE: 200395 EXPEDITE: N DATE SENT: 03/11/94 DATE RET.: / /

CHEMICAL: 129099 Imidacloprid

DP TYPE: 001 Submission Related Data Package

CSF: Y LABEL: N

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 03/31/94
DIV : HEB	3/14/94	/ /	NEGOT DATE: / /
BRAN: TB-#1	/ /	/ /	PROJ DATE: / /
SECT:	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

*** DATA REVIEW INSTRUCTIONS ***

The Washington State Department of Agriculture submitted a request for a specific exemption for the use of imidacloprid on Hops to control aphids. This is the first year this use has been requested. Last year Washington requested the use of bifenthrin and were denied due to delaney. Since than bifenthrin has been classified as a raw agricultural commodity and no longer falls under delaney. According to IR-4, bifenthrin could be registered this use season. The applicant claims bifenthrin does not allow widespread implementation of integrated pest management programs. Please review the attached package. Thanks, Margarita 308-8347.

*** DATA PACKAGE EVALUATION ***

No evaluation is written for this data package

*** ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION ***

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
200390	BAB	03/11/94	03/31/94	Y	Y	N
200391	EAB	03/11/94	03/31/94	Y	Y	N
200392	EEB	03/11/94	03/31/94	Y	Y	N
200393	EFGB	03/11/94	03/31/94	Y	Y	N