2-14-96

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

FILE

FEB 14 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: California Section 18 Request (96CA0019) to Use Imidacloprid on Spinach to Control Aphids.

FROM: George Tompkins, Ph.D, Entomologist
Special Review and Registration Section II

TO: Yung Yang, Ph.D., Toxicologist
Toxicology Branch II
Health Effects Division (7509C)

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

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

Please find below, the OREB review of:

DP Baracode: D222379

Pesticide Chemical Code: 129099

EPA Reg. No.: 3125-457

PHED:: Yes, Version 1.1

I. INTRODUCTION

A. Background:

The California Department of Pesticide Regulation requests a Section 18 Specific Exemption to use imidacloprid on spinach to control green peach aphid (Myzus persicae) in Imperial and Riverside counties. Imidacloprid (Provado 1.6 Flowable) is a systemic insecticide registered for use on ornamentals, cotton, mangoes, potatoes, and apples. Provado 1.6 Flowable is formulated as a flowable with 17.4% active ingredient.

This emergency exemption is not intended to circumvent the Section 3 registration requirements, but to alleviate a critical pest problem where registered alternatives are not effective. An unprecedented warm fall and early winter have increased populations of green peach aphids infesting the spinach crop. Because the registered alternatives provide inadequate control and the cancellation of Phosdrin as a clean up spray, the aphid populations have severely affected the quality and marketability of the spinach crop. Spinach is grown for fresh market and processing. Treatments will be made up to seven days of harvest to approximately 460 acres of unharvested crop.

Information from a previous report (DP Barcode D213915, dated 13 April 1995) indicated that the tox endpoint of concern is a maternal and developmental NOEL of 24 mg/kg/day. The tox categories for the technical product were listed as: category II for acute oral toxicity, and category IV for acute dermal and inhalation toxicity and primary dermal and eye irritaion. The end use product tox categories were listed as: category III for acute oral and dermal toxicity and primary eye irritation, and category IV for acute inhalation toxicity and primary dermal irritation. Both the technical and end use grade products of Imidacloprid were not listed as a dermal sensitizer.

B. Purpose:

Registration Division has requested OREB to determine if there are any worker exposure concerns associated with the proposed use pattern.

II. DETAILED CONSIDERATIONS:

A. Proposed Program:

Table One describes the California section 18 request.

TABLE ONE SECTION 18 DETAILS

Crop	Spinach
Pest	green peach aphid
Application method	ground or aerial as a foliar spray
Application rate	0.047 lb ai/A
Minimum final spray volume	ground- 20 gal/acre air- 5 gal/acre
Number of applications	5 foliar sprays/year
Maximum acreage	460 acres
Manufacturer	Bayer, Corp.
Average farm size	37.9 acres[1]
Use period	8 January 1996-30 March 1996

[1] Average farm size estimate obtained from the U.S. Department of Commerce, 1992 Census of Agriculture, Vol. 1, Part 5 (California), p 408, Table 29.

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]	70 acres
Mixer/loader unit of exposure PHED, open pour[2]	43.57 ug/lb ai
Applicator unit of exposure	26.29 ug/lb ai

[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 20 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 spinach to control green peach aphids (see Table 3).

TABLE 3 IMIDACLOPRID WORKER EXPOSURE	
	Daily Exposure ug/kg/day
Mixer/loader[1]	2.389
Applicator	1.442

[1] For calculations please see Appendix I

The product label states that the following Personal Protective Equipment (PPE) be worn: long-sleeved shirt and long pants, shoes plus 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 coincides with WPS since imidacloprid is a tox category IV compound for the technical grade.

cc: G. Tompkins
Chemical File: IMIDACLOPRID (129099)

Appendix I. CALCULATIONS

Total ai handled per day:

0.047 lb ai/acre X 70 acres/day = 3.29 lb ai/day

Mixer/loader daily exposure (DE):

43.57 ug/lb ai X 3.29 lb ai/day/60 kg = 2.389 ug/kg/day

Applicator daily exposure:

26.29 ug/lb ai X 3.29 lb ai/day/60 kg = 1.442 ug/kg/day

YSNG(BEAD) Estimate of Spray time/day by Various Application Methods

02/06/96

Site: SPINACH.18 Chem: PROVADO Hrs/Day: 8.0 hr.
Appl. method: GROUND Speed: 4.0 (increment: 1) mph
Tank capacity(TC): 350 (Increment: 10) gal Length of run(LR): 2000 ft.
Swath width(SW): 26 (Increment: 5) ft. Water station(WS): 0 yd.
Finish spray(FS): 20 (Increment: 5) gal/a. 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				time in mins
FS	20	25	30	35	- 20	25	30	35	- 20	25	30	35	<- Finish spray
26	70	66	62	59	82	76	71	66	92	85	78	73	<- Acre treated
SW 26	337	316	297	281	314	291	272	255	293	270	250	233	<- Spray time
26	127	149	168	186	148	172	192	210	166	191	213	231	<- Refill time
26	14	13	13	12	17	16	14	14	19	17	16	15	<- Ferry/turn time
FS	20	25	30	35	- 20	25	30	35	- 20	25	30	35	<- Finish spray
31	80	74	69	65	92	85	79	73	103	94	86	80	<- Acre treated
SW 31	321	298	279	261	296	272	252	235	275	251	230	213	<- Spray time
31	144	168	188	206	167	192	213	231	186	212	234	252	<- Refill time
31	14	13	12	11	16	15	13	12	18	16	15	14	<- Ferry/turn time

Make life easier, hit "PrtSc" to get a hard copy, than hit any key to continue

DP BARCODE: D222379

CASE: 287306 DATA PACKAGE RECORD DATE: 01/
SUBMISSION: S499164 BEAN SHEET Page 1 c

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: EMERGENCY EXEMP ACTION: 510 SEC18-OC F/F USE
RANKING : 75 POINTS (A)
CHEMICALS: 129099 Imidacloprid

ID#: 96CA0019
COMPANY:
PRODUCT MANAGER: 41 MEREDITH JOHNSON 703-308-8417 ROOM: CS1 6
PM TEAM REVIEWER: MARGARITA COLLANTES 703-308-8347 ROOM: CS1 6
RECEIVED DATE: 01/24/96 DUE OUT DATE: 03/14/96

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 222379 EXPEDITE: N DATE SENT: 01/30/96 DATE RET.: /
CHEMICAL: 129099 Imidacloprid
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: Y

FEB 19

ASSIGNED TO	DATE IN	DATE OUT
DIV : HED	1/31/96	/ /
BRAN: OREB	/ /	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 02/19/96
NEGOT DATE: / /
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the attached specific exemption request from California for the use of imidacloprid on spinach to control green peach aphids. This is the first year this use has been requested. Indicate whether there are any wowker exposure concerns aassociatedm with the proposed use pattern. thanks, Margarita 308-3847.

* * * 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	L
222371	BAB	01/30/96	02/19/96	Y	N	
222376	EAB	01/30/96	02/19/96	Y	N	
222378	TB-2	01/30/96	02/19/96	Y	N	
222380	TSCB	01/30/96	02/19/96	Y	N	
222381	EEB	01/30/96	02/19/96	Y	N	
222384	EFGB	01/30/96	02/19/96	Y	N	
222385	RCAB/RS	01/30/96	02/19/96	Y	N	

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SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Lognormal	2.73	7.512	132.3469	2.6969	65
NECK.FRONT	Lognormal	.6	1.2992	145.02	.4231	57
NECK.BACK	Lognormal	.374	.9149	163.1763	.2797	58
UPPER ARMS	Lognormal	1.6005	2.1825	70.1627	1.7757	22
CHEST	Lognormal	2.13	6.035	177.1118	2.5459	69
BACK	Lognormal	2.485	6.2191	185.3982	2.7358	54
FOREARMS	Lognormal	.968	3.9983	253.9129	1.3669	46
THIGHS	Lognormal	1.146	3.8766	160.7543	1.658	27
LOWER LEGS	Lognormal	1.428	3.3088	115.758	1.6452	41
FEET	Lognormal	12.1175	30.2392	168.5319	5.2741	6
HANDS	Lognormal	27.2804	60.7863	158.0358	25.3605	14
TOTAL DERM:	45.7618	52.8594	126.3719		45.7618	

95% C.I. on Mean: Dermal: [-1931.098, 2183.8418]

Number of Records: 76
Data File: APPLICATOR Subset Name: GBM1.APPL

ADD INHALATION CHANGE HEAD LB AI TO KG AI EXIT

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Subset Specifications for GBM1.APPL

With Dermal Grade Uncovered Equal to "A" "B" "C"
Subset originated from GBM.APPL
With Application Method Equal to 2 and
With Cab Type Equal to 1 2 and
With Total lb ai Applied Less than or Equal to 45
Subset originated from APPL.FILE

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SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Lognormal	4.29	13.226	208.3079	4.1171	42
NECK.FRONT	Lognormal	1.035	1.8471	118.3098	.8787	35
NECK.BACK	Other	.605	1.2555	136.3919	.5476	37
UPPER ARMS	Lognormal	2.1825	2.4735	64.7301	2.0787	12
CHEST	Lognormal	2.84	8.2343	159.999	3.3885	41
BACK	Lognormal	2.84	7.5849	170.6074	3.3293	41
FOREARMS	Lognormal	1.21	5.1745	224.5144	1.9573	34
THIGHS	Lognormal	.764	6.0301	303.6086	1.097	14
LOWER LEGS	Lognormal	1.428	2.9115	129.5999	1.4092	30
FEET	Lognormal	12.1175	30.2392	168.5319	5.2741	6
HANDS	Lognormal	9.9266	47.2829	185.9778	5.218	18
TOTAL DERM:	29.3529	39.2386	126.2595		29.2955	

95% C.I. on Mean: Dermal: [-1751.35, 2003.869]

Number of Records: 47

Data File: APPLICATOR Subset Name: GBM2.APPL

ADD INHALATION | CHANGE HEAD | LB AI TO KG AI | EXIT

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Subset Specifications for GBM2.APPL

With Hand Grade Equal to "A" "B" "C"
Subset originated from GBM.APPL
With Application Method Equal to 2 and
With Cab Type Equal to 1 2 and
With Total lb ai Applied Less than or Equal to 45
Subset originated from APPL.FILE

SUMMARY STATISTICS FOR INHALATION EXPOSURES

	DISTRIB. TYPE	NANOGRAMS PER LB AI SPRAYED Median	Mean	Coef of Var	Geo. Mean	Obs.
EXPOSURE	Lognormal	1035.7895	2101.2639	146.9486	666.9355	15

95% C.I. on Geo. Mean: [18.6574, 23840.613]
Number of Records: 15
Data File: APPLICATOR Subset Name: GBM3.APPL

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Subset Specifications for GBM3.APPL

With Airborne Grade Equal to "A" "B"
Subset originated from GBM.APPL
With Application Method Equal to 2 and
With Cab Type Equal to 1 2 and
With Total lb ai Applied Less than or Equal to 45
Subset originated from APPL.FILE

EXPOSURE

***Based on a Long Sleeve Shirt, Long Pants and Gloves Clothing Scenario**

Dermal Exposure = 25.6193 µg/lb ai Sprayed

Inhalation Exposure = 0.6669 µg/lb ai Sprayed

TOTAL EXPOSURE = 26.2862 µg/lb ai Sprayed
(Combined Dermal and Inhalation)

PHED version 1.1

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DP Barcode:
D 222379

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves **LIQUID-OPEN M/L**

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Other	2.99	128.9568	493.8357	4.0992	121
NECK.FRONT	Lognormal	1.695	23.2318	360.9199	1.74	103
NECK.BACK	Lognormal	.341	15.7106	381.706	.5427	109
UPPER ARMS	Other	.582	157.6735	903.2036	1.4925	90
CHEST	Other	3.905	19.2219	262.7404	3.4337	89
BACK	Other	.8875	11.009	221.7177	1.8891	88
FOREARMS	Other	.6655	4.4266	211.9821	.8927	84
THIGHS	Lognormal	3.82	16.8134	196.8466	4.0237	71
LOWER LEGS	Other	.952	38.271	819.5203	1.1162	81
FEET	Lognormal	5.371	346.998	180.1404	19.5296	25
HANDS	Lognormal	3.5883	34.7596	316.3227	3.5782	80
TOTAL DERM:	39.3962	24.7973	797.0722		42.3376	

95% C.I. on Mean: Dermal: [-12060.5932, 13654.7376]

Number of Records: 137
Data File: MIXER/LOADER Subset Name: LIQ1.OPN.MLOD

ADD INHALATION CHANGE HEAD LB AI TO KG AI EXIT

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Subset Specifications for LIQ1.OPN.MLOD

With Dermal Grade Uncovered Equal to "A" "B"
Subset originated from LIQ.OPN.MLOD
With Liquid Type Equal to 1 2 3 4 5 and
With Mixing Procedures Equal to 1
Subset originated from MLOD.FILE

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SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

SCENARIO: Long pants, long sleeves, gloves

PATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs.
HEAD (ALL)	Lognormal	1.885	144.2756	493.6915	3.2991	96
NECK.FRONT	Lognormal	1.2675	22.6456	409.0843	1.0823	82
NECK.BACK	Lognormal	.2255	16.0728	418.1281	.3845	84
UPPER ARMS	Other	.582	211.2486	781.2068	1.8065	67
CHEST	Other	5.68	22.1621	251.7974	4.2547	70
BACK	Other	.71	15.265	208.1592	2.2097	69
FOREARMS	Other	.726	5.8497	182.5683	1.172	61
THIGHS	Lognormal	3.82	16.6769	197.9019	3.8973	67
LOWER LEGS	Other	.714	42.9788	773.9239	1.1099	72
FEET	Lognormal	5.371	346.998	180.1404	19.5296	25
HANDS	Lognormal	11.5385	58.2033	228.9173	6.7068	59
TOTAL DERM:	43.3116	32.5195	902.3764		45.4524	

95% C.I. on Mean: Dermal: [-14732.9298, 16537.6826]

Number of Records: 112
Data File: MIXER/LOADER Subset Name: LIQ2.OPN.MLOD

ADD INHALATION | CHANGE HEAD | LB AI TO KG AI | EXIT

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Subset Specifications for LIQ2.OPN.MLOD

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

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SUMMARY STATISTICS FOR INHALATION EXPOSURES

	DISTRIB. TYPE	NANOGRAMS PER LB AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs.
EXPOSURE	Other	1041.6667	3519.5428	233.2266	598.9849	85

95% C.I. on Geo. Mean: [8.0354, 44650.2369]
Number of Records: 92
Data File: MIXER/LOADER Subset Name: LIQ3.OPN.MLOD

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Subset Specifications for LIQ3.OPN.MLOD

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

EXPOSURE
Based on a long sleeve shirt, long pants and glove clothing scenario

Dermal Exposure = 42.5248 µg/lb ai M/L

Inhalation Exposure = 1.0416 µg/lb ai M/L

TOTAL EXPOSURE = 43.5664 µg/lb ai M/L
(Combined dermal and inhalation)

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SUMMARY STATISTICS FOR INHALATION EXPOSURES

	DISTRIB. TYPE	NANOGRAMS PER LB AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs.
EXPOSURE	Other	1041.6667	3519.5428	233.2266	598.9849	85

95% C.I. on Geo. Mean: [8.0354, 44650.2369]
Number of Records: 92
Data File: MIXER/LOADER Subset Name: LIQ3.OPN.MLOD

<< Specifications >> Page 1 of 1

Subset Specifications for LIQ3.OPN.MLOD

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

EXPOSURE

Based on a long sleeve shirt, long pants and glove clothing scenario

Dermal Exposure = 42.5248 µg/lb ai M/L

Inhalation Exposure = 1.0416 µg/lb ai M/L

TOTAL EXPOSURE = 43.5664 µg/lb ai M/L
(Combined dermal and inhalation)

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