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

OCT 17 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: WORKER EXPOSURE ASSESSMENT FOR THE USE OF INDAR 2F (FENBUCONAZOLE) ON BANANAS

TO: Albin Kocialski, Section Head
Chemical Coordination Branch
Health Effects Division (7509C)

FROM: Arthur O. Schlosser, Chemist
Special Review and Registration Section II

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

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

Please find below review of:

DP Barcode: D205486 and D207317

Pesticide Chemical Code: 129011

EPA Reg. No.: 707-231

EPA MRID No.: None

PHED: YES- Extended Version 1.01 PHED (Data Analyses Attached)

I INTRODUCTION:

A. Background:

Chemical Coordination Branch (CCB) has requested an exposure assessment for the use of the fungicide product Indar 2F containing the active ingredient, fenbuconazole, on bananas. Assessments for less-than-lifetime as well as lifetime exposures (LADE) are requested. For the use on bananas, INDAR 2F is applied at 6.0 fluid oz.(0.09 lb. active) per acre using either ground or aerial application equipment. Applications may be repeated as required at 14-21 day intervals for up to 8 times per year (0.72 lb ai/acre). Specific health effect concerns are identified in a Toxicology Endpoint Selection Document which accompanied the bean sheet. They are as follows: Developmental NOEL = 30 mg/kg/day: Abnormal liver histopathology at the LOEL of 5.1 mg/kg/day. Fenbuconazole has been classified as a Group C possible human carcinogen and quantification of the human risk has been recommended. Dermal absorption: 12.35% of a 0.125 mg/kg dermal dose was recovered in the urine, feces, carcass and skin (combined).

Label Precautionary Statements-
Personal Protective Equipment (PPE)
Applicators and other handlers must wear:
Long-sleeved shirt and long pants
Shoes plus socks

In Addition to the required PPE, the following PPE is recommended:
Waterproof gloves
Protective eyewear
Chemical-resistant headgear for overhead exposure

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

The registrant, Rohm and Haas, submitted additional information on application practices, plot sizes and PPE in a correspondence of August 30, 1994 (DP Barcode: D207317).

II DETAILED CONSIDERATIONS:

OREB uses the assumptions given below and the Pesticide Handlers Exposure Database, Version 1.01 (PHED) to develop the exposure assessments for the use of fenbuconazole on bananas. The PHED data used to estimate exposures for the air-blast applicator do not completely meet OREB criteria for number of replicates for all body parts. However, they may be considered to support a conditional registration depending on the related risks that are determined.

Use of Indar 2E on bananas will be in Hawaii and Puerto Rico.

A typical banana plot is 12 acres in Hawaii and 5 acres in Puerto Rico. Treatment in Hawaii is mostly by air-blast sprayer and in Puerto Rico by backpack equipment. It is reported that very little or no application of fenbuconazole to bananas would be done aerially although this method appears on the proposed label.

Worker body weight is assumed to be 60 Kg for developmental effects and 70 Kg for other effects including carcinogenicity.

Unit dermal exposure for a mixer/loader, open pour, wearing long-sleeved shirt, long pants and gloves is 26.3 µg/lb ai handled.

Unit inhalation exposure for a mixer/loader, open pour is 0.38 µg/lb ai handled.

Unit dermal exposure for an air-blast applicator in an open cab wearing long-sleeved shirt, long pants and gloves is 554 µg/lb ai applied.

Unit inhalation exposure for an air-blast applicator in an open cab is 4.47 µg/lb ai applied.

Estimates for exposure from air-blast application are based on the assumption of a 12 acre plot in Hawaii being treated with the maximum application rate of 0.09 lb ai/acre. Eight applications are made per year.

OREB does not have adequate data to support registration for the backpack spray application of fenbuconazole to bananas.

Aerial application of fungicides to bananas is not practiced.

There appears to be potential for post-application exposure to harvest workers, however, OREB has no data to assess this exposure for the use on bananas.

III CONCLUSIONS/RECOMMENDATIONS

OREB estimates exposure values shown in Table I for the application of the protective fungicide, Indar 2F, containing the active ingredient, fenbuconazole, to bananas. No corrections have been made for dermal absorption which is reported to be 12.35%
The PHED data used to estimate exposures for the air-blast applicator do not completely meet OREB criteria for number of replicates for all body parts. However, they may be considered to support a conditional registration depending on the related risks that are determined. Estimates are for short term and intermediate term (90 days) exposures to mixer/loaders (open pour) and applicators using open cab air-blast ground equipment. Eight

applications per year are assumed to be made to bananas at 0.09 lb ai/acre per application.

TABLE I - Estimated Worker Exposures for the Treatment of Bananas with the Fungicide, INDAR 2F, containing Fenbuconazole with Air-Blast Ground Equipment

	Mixer/Loader		Applicator	
Exposure Type	Dermal exposure	Inhalation exposure	Dermal exposure	Inhalation exposure
Daily exposure * (mg/kg/day)	4.8×10^{-4}	7.0×10^{-6}	1.0×10^{-2}	8.2×10^{-5}
Annual exposure (mg/kg/year)	3.3×10^{-3}	4.8×10^{-5}	7.0×10^{-2}	5.6×10^{-4}
ADE (mg/kg/day)	9.0×10^{-6}	1.3×10^{-7}	1.9×10^{-4}	1.5×10^{-6}
LADE (mg/kg/day)	4.5×10^{-6}	6.5×10^{-8}	9.5×10^{-5}	7.5×10^{-7}

(1) * Daily exposure based on 60 kg body weight for developmental effects. Other exposure values are based on 70 kg body weight.

(2) Mixer/loaders (open pour loading) wear long-sleeve shirt, long pants and gloves.

(3) Applicators (open cab) wear long-sleeve shirt, long pants and gloves.

There appears to be potential for post-application exposure to harvest workers, however, OREB has no data to assess this exposure for the use on bananas.

OREB does not have adequate data to support registration for the backpack spray application of fenbuconazole to bananas.

The PHED data used to estimate exposure to the air-blast applicator do not fully meet OREB criteria for the number of replicates (15) for all body parts. The registrant should be requested to provide these data to fully support registration.

4

APPENDIX

GROUND APPLICATION-

Assume a banana plot of 12 acres in Hawaii: 12 acres x 0.09 lb ai/acre = 1.1 lbs ai/day. Assume 8 applications/year.

Air Blast Equipment

Mixer loader-

Daily dermal exposure = Unit exposure x lbs ai handled/day
= 26.3 μg/lb ai x 1.1 lbs ai/day = 28.9 μg/day

28.9 μg/day ÷ 60 Kg = 0.48 μg/kg/day for developmental effects
0.48 μg/kg/day ÷ 1000 μg/mg = 0.00048 mg/kg/day = $4.8.0 \times 10^{-4}$ mg/kg/day

28.9 μg/day ÷ 70 Kg = 0.41 μg/kg/day for non-developmental effects

Daily inhalation exposure = Unit exposure x lbs ai handled/day
= 0.38 μg/lb ai x 1.1 lbs ai/day = 0.42 μg/day

0.42 μg/day ÷ 60 Kg = 0.007 μg/kg/day for developmental effects
0.007 μg/kg/day ÷ 1000 μg/mg = 0.000007 mg/kg/day = 7.0×10^{-6} mg/kg/day

0.42 μg/day ÷ 70 Kg = 0.006 μg/kg/day for non-developmental effects

Annual dermal exposure = 8 applications per year x daily dermal exposure

0.48 μg/kg/day x 8 = 3.8 μg/kg/year for developmental effects
0.41 μg/kg/day x 8 = 3.3 μg/kg/year for non-developmental effects
3.3 μg/kg/year ÷ 1000 μg/mg = 0.0033 mg/kg/year = 3.3×10^{-3} mg/kg/year

Annual inhalation exposure = 8 x daily inhalation exposure

0.007 μg/kg/day x 8 = 0.056 μg/kg/year for developmental effects
0.006 μg/kg/day x 8 = 0.048 μg/kg/year for non-developmental effects
0.048 μg/kg/year ÷ 1000 μg/mg = 0.000048 mg/kg/year = 4.8×10^{-5} mg/kg/year

ADE = Average Daily Exposure = Annual exposure (mg/kg/year) ÷ 365 days/year. (Body weight assumed as 70 Kg).

ADE (dermal) = 3.3×10^{-3} mg/kg/year ÷ 365 days/year = 9.0×10^{-6} mg/kg/day

ADE (inhalation) = 4.8×10^{-5} mg/kg/year ÷ 365 days/year = 1.3×10^{-7} mg/kg/day

LADE = Lifetime Average Daily Exposure = ADE x 35 years worked ÷ 70 years assumed lifetime

LADE (dermal) = 9.0×10^{-6} mg/kg/day x 35/70
= 4.5×10^{-6} mg/kg/day.

LADE (inhalation) = 1.3×10^{-7} mg/kg/day x 35/70
= 6.5×10^{-8} mg/kg/day.

Applicator-

Daily dermal exposure = Unit exposure x lbs ai applied/day
= 554 µg/lb ai x 1.1 lbs ai/day = 610 µg/day

610 µg/day ÷ 60 Kg = 10 µg/kg/day for developmental effects
10 µg/kg/day ÷ 1000 µg/mg = 0.01 mg/kg/day = 1.0×10^{-2} mg/kg/day

610 µg/day ÷ 70 Kg = 8.7 µg/kg/day for non-developmental effects

Daily inhalation exposure = Unit exposure x lbs ai applied/day
= 4.47 µg/lb ai x 1.1 lbs ai/day = 4.9 µg/day

4.9 µg/day ÷ 60 Kg = 0.082 µg/kg/day for developmental effects
0.082 µg/kg/day ÷ 1000 µg/mg = 0.000082 mg/kg/day = 8.2×10^{-5} mg/kg/day

4.9 µg/day ÷ 70 Kg = 0.070 µg/kg/day for non-developmental effects

Annual dermal exposure = 8 applications per year x daily dermal exposure

10 µg/kg/day x 8 = 80 µg/kg/year for developmental effects
8.7 µg/kg/day x 8 = 70 µg/kg/year for non-developmental effects
70 µg/kg/year ÷ 1000 µg/mg = 0.07 mg/kg/year = 7.0×10^{-2} mg/kg/year

Annual inhalation exposure = 8 x daily inhalation exposure

0.082 µg/kg/day x 8 = 0.66 µg/kg/year for developmental effects
0.070 µg/kg/day x 8 = 0.56 µg/kg/year for non-developmental effects
0.56 µg/kg/year ÷ 1000 µg/mg = 0.00056 mg/kg/year = 5.6×10^{-4} mg/kg/year

ADE = Average Daily Exposure = Annual exposure (mg/kg/year) ÷ 365 days/year. (Body weight assumed as 70 Kg).

ADE (dermal) = 70 µg/kg/year ÷ 365 days/year = 0.19 µg/kg/day
0.19 µg/kg/day ÷ 1000 µg/mg = 0.00019 mg/kg/day = 1.9×10^{-4} mg/kg/day

ADE (inhalation) = 0.56 µg/kg/year ÷ 365 days/year
= 0.0015 µg/kg/day

0.0015 μg/kg/day ÷ 1000 μg/mg = 1.5×10^{-6} mg/kg/day

LADE = Lifetime Average Daily Exposure = ADE x 35 years worked ÷ 70 years assumed lifetime

LADE (dermal) = 1.9×10^{-4} mg/kg/day x 35/70
= 9.5×10^{-5} mg/kg/day.

LADE (inhalation) = 1.5×10^{-6} mg/kg/day x 35/70
= 7.5×10^{-7} mg/kg/day.

Attachments:

CC: A.Schlosser, OREB
Chemical file- fenbuconazole/129011
Correspondence

Cynthia Giles-Parker

DATA ANALYSIS SECTION: File/Subset Selection

Name: AIR.OPEN.DER.AB.APPL

<< Specifications >> Page 1 of 1

Subset Specifications for AIR.OPEN.DER.AB.APPL

With Dermal Grade Uncovered Greater than or Equal to "B"
Subset originated from AIR.OPEN.APPL
With Application Method Equal to 1 and
With Cab Type Equal to 1
Subset originated from APPL.FILE

Use Home, End, Page Up and Page Down keys to view specifications.
<F9> - Return to Subset Operations Menu

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	401.7	955.3585	134.5565	278.989	34
NECK.FRONT	Lognormal	27.2175	46.2335	126.9004	19.378	30
NECK.BACK	Lognormal	14.421	33.7328	140.7372	12.9185	34
UPPER ARMS	Lognormal	219.8505	219.8505	69.1664	191.7626	2
CHEST	Lognormal	8.875	54.2361	127.2239	13.9252	9
BACK	Lognormal	30.53	26.2306	113.0874	8.3712	9
FOREARMS						0
THIGHS	Lognormal	34.38	112.3626	171.2492	21.0294	7
LOWER LEGS	Lognormal	4.998	7.514	138.1714	2.9585	7
FEET						0
HANDS	Lognormal	10.6667	9.0733	90.7817	4.9943	27
TOTAL DERM:	554.3267	752.6387	1464.5919		554.3267	
INHALATION:	Lognormal	5.3857	10.0253	199.591	4.5792	36
COMBINED:	558.9059	758.0244	1474.6172		558.9059	

95% C.I. on Mean: Dermal: [-14492.2056, 17421.3894]
95% C.I. on Geo. Mean: Inhalation: [.4353, 48.1683]
Inhalation Rate : 25 Liters/Minute Number of Records: 36
Data File: APPLICATOR Subset Name: AIR.OPEN.DER.AB.APPL

ADD INHALATION CHANGE HEAD LB AI TO KG AI EXIT

*** Press 'P' to print this report ***

8

DATA ANALYSIS SECTION: File/Subset Selection

Name: AIR.OPEN.INH.AB.APPL

<< Specifications >> Page 1 of 1
Subset Specifications for AIR.OPEN.INH.AB.APPL

With Airborne Grade Greater than or Equal to "B"
Subset originated from AIR.OPEN.APPL
With Application Method Equal to 1 and,
With Cab Type Equal to 1
Subset originated from APPL.FILE

Use Home, End, Page Up and Page Down keys to view specifications.
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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	398.32	915.8781	136.2502	270.823	37
NECK.FRONT	Lognormal	27.12	43.9886	128.4631	19.0921	33
NECK.BACK	Lognormal	13.475	32.0353	143.1973	12.6846	37
UPPER ARMS	Lognormal	219.8505	219.8505	69.1664	191.7626	2
CHEST	Lognormal	6.39	41.2983	153.3768	7.9089	12
BACK	Lognormal	16.33	34.6125	150.8524	7.9864	12
FOREARMS						0
THIGHS	Lognormal	10.505	79.1122	209.8071	8.9354	10
LOWER LEGS	Lognormal	4.403	6.2832	140.091	2.7104	10
FEET						0
HANDS	Lognormal	10.6667	9.0733	90.7817	4.9943	27
TOTAL DERM:	526.8977	707.0602	1382.132		526.8977	
INHALATION:	Lognormal	5.1333	9.5262	202.4543	4.4689	39
COMBINED:	531.3666	712.1935	1391.6582		531.3666	

95% C.I. on Mean: Dermal: [-13432.2806, 16196.5446]

95% C.I. on Geo. Mean: Inhalation: [2.4605, 43.3698]

Inhalation Rate : 25 Liters/Minute
Number of Records: 39
Data File: APPLICATOR

Subset Name: AIR.OPEN.INH.AB.APPL

DATA ANALYSIS SECTION: File/Subset Selection

Name: ALL.LIQ.OPEN.INH.AB.MLOD

<< Specifications >> Page 1 of 1
Subset Specifications for ALL.LIQ.OPEN.INH.AB.MLOD

With Airborne Grade Greater than or Equal to "B"
Subset originated from ALL.LIQ.OPEN.MLOD
With Liquid Type Greater than or Equal to 1 and
With Mixing Procedures Equal to 1
Subset originated from MLOD.FILE

Use Home, End, Page Up and Page Down keys to view specifications.
<F9> - Return to Subset Operations Menu

DATA ANALYSIS SECTION: File/Subset Selection

Name: ALL.LIQ.OPEN.DER.AB.MLOD

<< Specifications >> Page 1 of 1
Subset Specifications for ALL.LIQ.OPEN.DER.AB.MLOD

With Dermal Grade Uncovered Greater than or Equal to "B"
Subset originated from ALL.LIQ.OPEN.MLOD
With Liquid Type Greater than or Equal to 1 and
With Mixing Procedures Equal to 1
Subset originated from MLOD.FILE

Use Home, End, Page Up and Page Down keys to view specifications.
<F9> - Return to Subset Operations Menu

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	2.73	27.0229	267.7237	2.8546	91
NECK.FRONT	Lognormal	.9675	7.7799	253.1356	.9628	82
NECK.BACK	Lognormal	.2805	5.0742	277.7935	.3228	88
UPPER ARMS	Normal	1.8915	3.301	101.9388	1.5413	32
CHEST	Lognormal	5.68	12.0463	159.4589	4.1503	30
BACK	Other	1.065	8.9599	323.0918	1.7381	46
FOREARMS	Lognormal	1.936	2.3708	143.8417	1.1349	32
THIGHS	Lognormal	6.112	11.6001	178.1062	4.007	30
LOWER LEGS	Other	.833	3.002	146.8155	1.1817	44
FEET						0
HANDS	Lognormal	5.05	44.9154	261.59	5.3641	79
TOTAL DERM:	23.9955	26.5455	126.0725		23.2576	
INHALATION:	Lognormal	.7004	1.8775	142.482	.3843	64
COMBINED:	24.3798	27.2459	127.95		23.6419	

95% C.I. on Mean: Dermal: [-920.5988, 1172.7438]

95% C.I. on Geo. Mean: Inhalation: [.0049, 30.0454]

Inhalation Rate : .25 Liters/Minute
Number of Records: 91
Data File: MIXER/LOADER Subset Name: ALL.LIQ.OPEN.INH.AB.MLOD

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	1.69	23.3974	294.0297	2.3038	99
NECK.FRONT	Lognormal	1.215	7.45	256.8148	.9951	87
NECK.BACK	Lognormal	.231	4.7237	289.7115	.2912	93
UPPER ARMS	Other	.291	1.864	113.0848	.8794	37
CHEST	Other	5.68	24.0255	323.1633	2.6898	31
BACK	Other	.71	5.1707	373.4949	1.2121	46
FOREARMS	Lognormal	.726	1.7486	185.7543	.7484	31
THIGHS	Other	1.146	9.3282	223.013	1.8894	31
LOWER LEGS	Other	.476	2.1523	188.4542	.7617	46
FEET	Lognormal	2.358	4.3376	99.7141	3.1109	9
HANDS	Lognormal	3.525	37.1856	308.8411	3.4559	73
TOTAL DERM:	19.2083	18.048	121.3836		18.3377	
INHALATION:	Other	.8333	3.8686	290.4875	.4872	86
COMBINED:	20.0416	18.8813	125.2522		18.8249	

95% C.I. on Mean: Dermal: [-1199.4393, 1442.2065]

95% C.I. on Geo. Mean: Inhalation: [.0044, 53.9287]

Inhalation Rate : 25 Liters/Minute
Number of Records: 104
Data File: MIXER/LOADER

Subset Name: ALL.LIQ.OPEN.DER.AB.MLOD

Total Dermal 19.2083
− Hands 3.4559
15.7524
+ HAND(ABC) 10.5575 Correct for more conservative hand data.
26.3199 ug/lb

DATA ANALYSIS SECTION: File/Subset Selection

Name: ALL.LIQ.OPEN.HAND1.ABC.MLOD

<< Specifications >> Page 1 of 1

Subset Specifications for ALL.LIQ.OPEN.HAND1.ABC.MLOD

With Hand Grade Greater than or Equal to "C" and
With Hand Measuring Method Equal to 1
Subset originated from ALL.LIQ.OPEN.MLOD
With Liquid Type Greater than or Equal to 1 and
With Mixing Procedures Equal to 1
Subset originated from MLOD.FILE

Use Home, End, Page Up and Page Down keys to view specifications.
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New>

SUMMARY STATISTICS FOR CALCULATED DERMAL EXPOSURES

;ENARIO. Long pants, long sleeves, gloves

'ATCH LOCATION	DISTRIB. TYPE	MICROGRAMS PER LB AI MIXED Median	Mean	Coef of Var	Geo. Mean	Obs.
:AD (ALL)	Lognormal	2.86	33.3887	248.6443	4.2565	61
:CK.FRONT	Lognormal	1.32	9.6529	232.2224	1.3232	61
:CK.BACK	Lognormal	.396	7.0474	234.6866	.489	61
'PER ARMS	Other	.291	2.4573	148.2115	.8901	27
IEST	Lognormal	1.065	5.4932	151.5201	1.8692	19
,CK	Other	.71	6.2856	412.8325	1.0579	34
)REARMS	Lognormal	.726	2.7715	149.926	1.1173	21
IIGHS	Lognormal	1.146	4.202	129.1694	1.6435	19
)WER LEGS	Other	.476	2.044	213.1849	.6424	34
:ET						0
,NDS	Lognormal	11.5385	41.2157	181.6296	10.5575	55
)TAL DERM:	22.7332	20.5285	114.5583		23.8466	
IHALATION:	Lognormal	.2315	.8933	139.2141	.1908	39
)MBINED:	22.924	20.76	115.4516		24.0374	

;% C.I. on Mean: Dermal: [-874.1591, 1103.2757]

;% C.I. on Geo. Mean: Inhalation: [.0026, 14.2289]

ihalation Rate : 25 Liters/Minute
umber of Records: 61
ita File: MIXER/LOADER Subset Name: ALL.LIQ.OPEN.HANDI.ABC.MLOD