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File

12/10/96

DP Barcode : D231732
PC Code No : 128857
EEB Out : DEC 10 1996

To: Robert Forrest PM 41
Product Manager

From: Norman Cook, Acting Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 97FL0001
Chemical Name : MYCLOBUTANIL
Type Product : FUNGICIDE
Product Name : NOVA 40W
Company Name : FLORIDA DEPT OF AGR
Purpose : Request by Florida to use myclobutanil under an emergency exemption to control powdery mildew on strawberries
Action Code : 510 Date Due : 12-16-96
Reviewer : Allen Vaughan Date In EEB: 12-3-96

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

2014104

DP BARCODE: D231732

CASE: 288188 DATA PACKAGE RECORD DATE: 11/26/96
SUBMISSION: S514196 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: EMERGENCY EXEMP ACTION: 510 SEC18-OC F/F USE
RANKING : 0 POINTS ()
CHEMICALS: 128857 Myclobutanil (ANSI) %

ID#: 97FL0001
COMPANY:
PRODUCT MANAGER: 41 ROB FORREST 703-308-8417 ROOM: CS1 6G
PM TEAM REVIEWER: STEPHEN SCHAIBLE 703-308-8337 ROOM: CS1 6W35
RECEIVED DATE: 11/07/96 DUE OUT DATE: 12/27/96

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 231732 EXPEDITE: N DATE SENT: 11/26/96 DATE RET.: / /
CHEMICAL: 128857 Myclobutanil (ANSI)
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 12/16/96
DIV : EFED	11/27/96	/ /	NEGOT DATE: / /
BRAN: EEB	12/13/96	/ /	PROJ DATE: / /
SECT:	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Please review this section 18 request from Florida to use myclobutanil on strawberries to control powdery mildew. Please indicate if exposure to non-target organisms is a concern, including for Federally-listed species. If I can be of help, please give me a call.

Steve Schaible (308-8337)

* * * 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
231544	RCAB/PIRAT	11/26/96	12/16/96	Y	N	Y
231710	BAB	11/25/96	12/15/96	Y	N	Y
231729	EAB	11/26/96	12/16/96	Y	N	Y
231733	EFGB	11/26/96	12/16/96	Y	N	Y

ECOLOGICAL EFFECTS BRANCH REVIEW

Chemical: Myclobutanil (Nova 40W)

100 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

The Florida Department of Agriculture has applied for an emergency exemption for Nova 40W (myclobutanil) fungicide to control powdery mildew on strawberries. This is the first time this use has been requested under an emergency exemption in Florida. No new data were submitted with this request.

100.2 Formulation Information

Myclobutanil:a-butyl-a-(4-chlorophenyl)-1H-1,2,4-triazole-1-propane-nitrile. 40%
Inert Ingredients 60%

100.3 Application Methods, Directions, Rates (from label)

Applications should begin at first sign of disease development and continue on a 14 to 21 day schedule. Application rate is 2.5 to 5 oz product (0.0625 to 0.125 lb ai)/A, to a maximum of 0.75 lb ai per crop. Application may be made by ground only. All applicable directions, restrictions and precautions on the EPA registered label are to be followed.

100.4 Target Organisms

Powdery mildew (*Sphaerotheca macularis*).

100.5 Precautionary Labeling

Section 18 Label

A Section 18 label was not provided.

Product Label

For terrestrial uses, do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters. Do not apply when weather conditions favor drift or runoff from areas treated.

101 Hazard Assessment

101.1 Discussion

The proposed exemption would allow use of myclobutanil on 6000 acres of strawberries, statewide. Proposed exemption period is one year from date of approval.

101.2 Likelihood of Adverse Effects on Nontarget Organisms

Environmental Fate Data:

- Stable to hydrolysis at pH 5, 7, and 9
- Stable to photolysis in water
- Photolytic soil half-life = 143 days
- Aerobic soil half-life = 66 days
- Anaerobic soil half-life = no degradation at 62 days
- solubility = 142 ppm
- Leaching: myclobutanil is moderately mobile (K_ds = 1.46 - 9.77 for adsorption and 0.47 - 4.18 for desorption in 5 soils). K_{oc} = 112. The degradate is considered highly mobile.
- Bioaccumulation: Fish bioaccumulation study was waived. Myclobutanil is not expected to bioaccumulate.

The major route of dissipation is believed to be diffusion and dilution; myclobutanil appears to be resistant to most environmental breakdown processes.

Toxicity Data
Terrestrial Species

BIRDS: Ecological effects avian toxicity data for myclobutanil are as follows:

Species	Study Type	% a.i.	Results	Status
Bobwhite	Acute oral LD_{50}	84.5	510 mg/kg	Core
Bobwhite	Dietary LC_{50}	84.5	>5000 ppm	Core
Mallard	Dietary LC_{50}	84.5	>5000 ppm	Core
Bobwhite	Reproduction	94.2	NOEC=260ppm	Supplemental
Mallard	Reproduction	94.2	NOEC=260ppm	Supplemental

Myclobutanil is slightly toxic to birds on an acute basis, and practically non-toxic to birds on a sub-acute (dietary) basis.

MAMMALS: Mammalian toxicity data for myclobutanil is as follows:

Species	Test type	% a.i.	Results	Status
rat	acute oral	91.9	LD_{50}=1360 g/kg	core
rat	2-gen. repro.	84.5	Repro NOEL = 200 ppm, LOEL = 1000 ppm	core

rat	2-gen repro.	84.5	systemic NOEL = 50 ppm, LOEL = 200 ppm	core

Myclobutanil is slightly toxic to mammals on an acute basis.

Aquatic Species

Aquatic toxicity data for myclobutanil is as follows:

Species	Test type	% a.i.	Results	Status
Bluegill sunfish	96-hr acute	84.5	LC_{50}=2.4 ppm	core
Rainbow trout	96-hr acute	84.5	LC_{50}=4.2 ppm	core
Daphnid	48-hr acute	84.5	EC_{50}= 11 ppm	core
Sheepshead minnow	96-hr acute	93	LC_{50} = 4.7 ppm	core
Eastern oyster	96-hr acute	93	EC_{50}= 0.68 ppm	supplemental
Mysid	96-hr acute	93	LC_{50}=0.24 ppm	core
Fathead minnow	Early life stage		NOEC = 0.98 ppm, LOEC = 2.2 ppm	supplemental

Myclobutanil is moderately toxic to freshwater fish and invertebrates, moderately toxic to marine fish, and highly toxic to marine invertebrates on an acute basis.

Exposure Data and Risk Quotients (RQs)

Acute terrestrial exposure estimates were made using the Kenaga nomograph. Values were derived based on the maximum label rate per acre per application (0.125 lb a.i./A). Values were also calculated for 6 applications at 0.125 lb ai/A on a 14-day application interval using the FATE program. Values presented below are the maximum estimated residues for various vegetation types. RQ values were derived by dividing the estimated exposure by the LC_{50} value. RQs greater than 0.5 exceed the Agency's Level-of-Concern (LOC) for high risk; values greater than 0.2 indicate a risk which may be reduced if mitigation measures are instituted; values greater than 0.1

exceed the LOC for endangered species.

Chronic risk was assessed using the residues generated by the FATE program and comparing them to the available avian reproduction data. An RQ greater than 1 exceeds the Agency's LOC for high risk. The printout for the FATE program is attached at the end of this review.

Vegetation Type	Max. Kenaga value (0.125 lb ai/A)	Acute RQ	Max. FATE EEC (6 appl., total of 0.75 lb ai/A)	Chronic RQ
Short Grass	30 ppm	0.01	125 ppm	0.48
Long Grass	14 ppm	0.00		
Leaves/leafy crops	15.5 ppm	0.00		
Forage/Insects	7.5 ppm	0.00		

There were no LOC exceedances for avian species from the proposed use of myclobutanil. This use is not expected to cause concern for avian species.

Terrestrial Species-Mammals

Acute: Based on acute LD_{50} values, mammals are less sensitive than birds to myclobutanil. Since acute risk to birds is not expected from the proposed use of myclobutanil, acute risk to mammals is not expected.

Chronic: Maximum residues calculated via the FATE program are lower than reproductive NOECs for mammalian species. Therefore, reproductive risk is not expected from the proposed use of myclobutanil.

Aquatic Organisms

Exposure estimates (EECs) and RQs

The aquatic EECs presented below were generated using the GENEEC computer program developed by EFGWB. This program uses a variety of environmental fate parameters in conjunction with the application rate to estimate the exposure to aquatic organisms from runoff. The maximum total application rate (0.75 lb a.i./A) was used in this program, since little degradation would occur during the 14-day application interval for multiple applications. The printout from this program is attached at the end of this review.

Acute RQs were derived by dividing the instantaneous EEC by the LC or EC_{50} value for each species. The Agency's LOC for high-risk is exceeded if the RQ value is greater than 0.5. Values of 0.2 and higher indicate risk that may be reduced if mitigation measures are instituted, and values greater than 0.05 exceed the LOC for endangered species.

Chronic RQs were derived by dividing the appropriate EEC by

the NOEC obtained in chronic tests. The 21-day EEC is used for aquatic invertebrates, and the 56-day EEC is used for fish (using the early life-stage NOEC). Note that there is no acceptable chronic data available for invertebrates, so the chronic invertebrate RQ could not be generated for this risk assessment.

	EEC (ppb)	RQ
Instantaneous	22.3	Bluegill: 0.01 Trout: 0.01 Daphnid: 0.00 Shpshd. minnow: 0.00 Oyster: 0.03 Mysid: 0.09[1]
56-day	17.4	Fathead minnow: 0.02

[1]Exceeds the endangered species LOC

No high-risk LOCs were exceeded for the proposed use of myclobutanil. The mysid RQ exceeds the LOC for endangered species; however, as there are no endangered species of marine/estuarine invertebrates, this is not a concern.

Plants
Tier II Testing
Terrestrial
Tier II terrestrial plant testing is unavailable for myclobutanil.

Aquatic
Tier II aquatic plant data is available for *Selenastrum capricornutum* only. The *Selenastrum* EC_{50} value is 0.83 ppm. No adverse effects to aquatic plants are expected, based on this value.

Discussion of RQs/LOC exceedance
A. Effects on terrestrial organisms:
Acute
Based on the acute toxicity data, myclobutanil does not appear to pose an acute risk to avian or mammalian species from the proposed use.

Chronic
The proposed use of myclobutanil does not appear to pose a reproductive concern to birds or mammals.

B. Effects on aquatic organisms:
Acute
Fish: Based on the acute toxicity data, myclobutanil should not pose an acute concern to freshwater or marine/estuarine fish from the proposed use.

Invertebrates: The endangered species LOC was exceeded for

marine/estuarine invertebrates; however, exposure to this class of organisms is not expected from the proposed use. The proposed use of myclobutanil does not pose an acute concern to freshwater aquatic invertebrates.

Chronic
Fish: The proposed use of myclobutanil does not appear to pose a chronic risk to fish.

Invertebrates: Chronic risk to aquatic invertebrates could not be assessed at the present time due to a lack of data.

C. Effects on plants:
Terrestrial: A risk assessment for terrestrial plants could not be completed at this time due to a lack of data.

Aquatic: Based on the single aquatic plant species for which data was available, the proposed use of myclobutanil does not appear to pose a risk to aquatic plants.

101.3 Endangered Species Considerations
Risk to endangered species is not expected from the proposed use.

101.4 Adequacy of Toxicity Data
The available data were adequate to complete a risk assessment for this particular use.

101.5 Adequacy of Labeling
Environmental hazards labeling is adequate for use under this exemption.

102 Conclusions
EEB has reviewed the proposed emergency exemption for the use of myclobutanil on strawberries in Florida. The use of myclobutanil as proposed is not expected to present risk to any nontarget organisms, including endangered species.

Allen W. Vaughan 12-10-96
Allen W. Vaughan, Entomologist
EEB/EFED (7507C)

Daniel Rieder 12-10-96
Daniel D. Rieder, Acting Head, Section 2
EEB/EFED (7507C)

Norman Cook 12-10-96
Norman J. Cook, Acting Chief
EEB/EFED (7507C)

DAILY ACCUMULATED PESTICIDE RESIDUES---MULTP. APPL.

Chemical name ----------	Myclobutanil
Initial concentration (ppm) -----	30
Half-life ----------	61
A number of application --------	6
Application interval ----------	14
Length of simulation (day) -----	90

DAY	RESIDUE (PPM)
0	30
1	29.66104
2	29.3259
3	28.99456
4	28.66696
5	28.34306
6	28.02282
7	27.70619
8	27.39315
9	27.08364
10	26.77763
11	26.47507
12	26.17594
13	25.88018
14	55.58777
15	54.9597
16	54.33872
17	53.72476
18	53.11774
19	52.51757
20	51.92419
21	51.33752
22	50.75746
23	50.18397
24	49.61695
25	49.05634
26	48.50207
27	47.95405
28	77.41223
29	76.53757
30	75.67279
31	74.81778
32	73.97244
33	73.13664
34	72.31029
35	71.49327
36	70.68549
37	69.88683
38	69.0972
39	68.31648
40	67.54459
41	66.78142
42	96.02687
43	94.94189

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 44              93.86916
 45              92.80856
 46              91.75994
 47              90.72316
 48              89.69811
 49              88.68463
 50              87.6826
 51              86.69189
 52              85.71239
 53              84.74394
 54              83.78646
 55              82.83976
 56              111.9038
 57              110.6394
 58              109.3893
 59              108.1534
 60              106.9314
 61              105.7232
 62              104.5286
 63              103.3476
 64              102.1799
 65              101.0254
 66              99.88392
 67              98.75536
 68              97.63954
 69              96.53633
 70              125.4456
 71              124.0282
 72              122.6269
 73              121.2413
 74              119.8715
 75              118.5171
 76              117.178
 77              115.854
 78              114.545
 79              113.2508
 80              111.9712
 81              110.706
 82              109.4552
 83              108.2185
 84              106.9958
 85              105.7868
 86              104.5916
 87              103.4098
 88              102.2414
 89              101.0862
 90              99.94407
Maximum residue  --------------          125.4456
Average residue  --------------          78.95956

Try a different time length (t),different data set(d) or quit(q)? q
Ok
eject
Syntax error
Ok
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RUN No. 1 FOR Myclobutanil INPUT VALUES

RATE (#/AC) ONE	(MULT)	APPLICATIONS NO.	INTERVAL	SOIL KOC	SOLUBILITY (PPM)	% SPRAY DRIFT	INCORP DEPTH(IN)
.125	(.548)	6	14	112.0	142.0	5.0	.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
71.00	0	90.00	90.00-11043.00	.00	89.27

GENERIC EECs (IN PPB)

PEAK GEEC	AVERAGE 4 DAY GEEC	AVERAGE 21 DAY GEEC	AVERAGE 56 DAY GEEC
22.31	21.99	20.29	17.42