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REVIEW NO.

EEB REVIEW

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TYPE PRODUCT(S) Fungicide

DATA ACCESSION NOS. _____

PRODUCT MANAGER NO. S. Lewis (21)

PRODUCT NAME(S) Myclobutanil (Rally, Nova)

COMPANY NAME Rohm and Haas Company

SUBMISSION PURPOSE Proposed registration for use on stone
fruits: apricots, cherries, nectarines,
peaches, plums, and prunes

SHAUGHNESSEY NO.	CHEMICAL AND FORMULATION	% AI
<u>128857</u>	<u>Myclobutanil</u>	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

EEB REVIEW

Chemical: Myclobutanil (Rally, Nova)

100 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

The registrant (Rohm and Haas Company) proposes to amend the labels for the myclobutanil end use products, Rally and Nova, to include use on stone fruits (apricots, cherries, nectarines, peaches, plums, and prunes). No new data were submitted with this request.

100.2 Formulation Information

Active Ingredient:

Myclobutanil	40%
Inert Ingredients	60%

100.3 Application Methods, Directions, Rates

Rate of application is 0.0625 to 0.15 lb ai per acre, to be applied at 7 to 14 day intervals beginning at about 5% bloom. Maximum amount to be applied per acre per season is 1.4 lb ai. Application is by ground equipment only. For additional information, please see attached label.

100.4 Target Organisms

Target organisms include blossom blight (Monilinia spp.), powdery mildew (Podosphaera spp.), shothole (Stigmina sp.), leaf spot (Coccomyces sp.), rusty spot (Sphaerotheca sp.), and rust (Tranzschelia sp.).

100.5 Precautionary Labeling

Environmental Hazards

Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not apply when weather conditions favor drift or runoff from areas treated.

101 Hazard Assessment

101.1 Discussion

The proposed label amendment would allow application of myclobutanil (Nova, Rally) to stone fruits. Application would be by ground equipment only, at a maximum rate of 0.15 lb ai per acre.

Application may be made at 7 to 14 day intervals, up to a total of 1.4 lb ai per acre per season.

Environmental fate data characterize myclobutanil as stable to hydrolysis and photolysis in water. Soil metabolism studies provide a half-life of 61-71 days.

101.2 Likelihood of Adverse Effects on Nontarget Organisms

Terrestrial Organisms

Data from avian single-dose oral and dietary studies indicate that myclobutanil is slightly toxic to practically nontoxic to birds (bobwhite LD50 = 510 mg/kg; bobwhite and mallard dietary LC50's > 5000 ppm). Avian reproduction tests showed no adverse effects at 60 ppm (highest level tested) for bobwhite and mallard.

Myclobutanil is slightly toxic to mammals, with LD50's of 1600 and 2290 mg/kg for male and female rats, respectively. The systemic and reproductive NOEL's for rats were 50 and 200 ppm, respectively, in a two-generation reproduction test.

Following application at the maximum rate (0.15 lb ai/acre), maximum residues on terrestrial food items (forage, insects) would be in the range of 8.6 ppm. This is well below any acute hazard trigger for terrestrial nontargets. Thus, acute hazard to birds and mammals is not anticipated from the proposed use.

Because the limited environmental fate data indicate a potential for myclobutanil to persist in the environment, chronic hazard must be addressed. Using fate data and application information, EEB has calculated average and maximum residues to be expected following multiple applications at 0.15 lb ai/acre (see attached). Average residues on forage and insects would be lower than any of the chronic hazard triggers for birds and mammals. Maximum residue (51.27 ppm, following 9 applications), only slightly exceeds the systemic NOEL for mammals, and does not exceed reproductive NOEL's for birds or mammals. Thus, chronic hazard to birds and mammals is not expected.

Application to blooming stone fruits will result in exposure of bees to the pesticide. No hazard is expected, however, since myclobutanil tested practically nontoxic to honey bees in an acute study.

Aquatic Organisms

Myclobutanil is moderately toxic to fish (rainbow trout LC50 = 4.2 ppm; bluegill LC50 = 2.4 ppm) and slightly toxic to aquatic invertebrates (daphnid LC50 = 11 ppm). A fish early life stage test with fathead minnow provided an MATC > 2.2 ppm and < 4.0 ppm.

An aquatic half-life is not available for myclobutanil, but fate data show that the chemical is stable to photolysis and hydrolysis in water. Since a maximum of 1.4 lb ai may be applied per acre per season, an aquatic EEC was calculated using this amount. The resultant EEC (see attached) is 42.7 ppb. This estimate is well below any acute or chronic hazard triggers for aquatic organisms.

No data are available on the toxicity of myclobutanil to nontarget aquatic plants. Data are required from a Tier 1 aquatic plant growth study with algae (Selenastrum sp.).

101.3 Endangered Species Considerations

The endangered species triggers are as follows:

Birds: 500 ppm (LC50 5000 ppm/10)

Mammals: 145 ppm (LC50 1454 ppm/10)

Fish: 120 ppb (LC50 2.4 ppm/20)

Aquatic Invertebrates: 550 ppb (LC50 11 ppm/20)

Mammal LC50 is derived from LD50 of 1600 mg/kg, divided by 1.1 (extrapolated to a 1-day LC50 for the least shrew, which eats 1.1 times its weight per day).

Estimated residues on terrestrial food items do not exceed the triggers for endangered species of birds and mammals. Also, the reproductive NOEL's for birds and mammals have not been exceeded. Aquatic EEC does not approach endangered species triggers for freshwater fish and aquatic invertebrates. Based on this information, proposed use on stone fruits is not expected to present hazard to any endangered species.

101.4 Adequacy of Toxicity Data

The existing database is adequate to assess hazards to nontargets, with the exception of nontarget aquatic plants.

101.5 Adequacy of Labeling

Current labeling for environmental hazards is adequate. No changes are recommended at this time.

103 Conclusions

EEB has reviewed the proposed amendments to add use on stone fruits to the labels for the myclobutanil end use products Rally and Nova. Based on ecotoxicity data and use information, EEB concludes that use on stone fruits will provide for minimal adverse effects on nontarget organisms. However, hazard assessment for nontarget

aquatic plants is deferred, pending receipt of data from an aquatic plant growth study with Selenastrum sp. This use is not expected to affect any endangered species.

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USE DIRECTIONS FOR STONE FRUITS

NOVA 40W is a systemic, protectant and curative fungicide. Best control of diseases being evaluated is achieved when the fungicide is applied on a 7 to 10 day protectant application schedule.

Crop	Disease	Rate of RH-3866 40W		Use Recommendations	Restrictions
		Oz./100 gals.	Oz./Acre		
Apricots	Blossom Blight (Monilinia spp.)	1.25 to 2.0 (0.5 to 0.8 active)	2.5 to 6.0 (1.0 to 2.4 active)	Begin applications at red bud stage (about 5% bloom). If conditions are favorable for disease development, apply again at full bloom and at petal fall.	Do not apply more than 3.5 pounds (1.4 pounds active) NOVA 40W fungicide per acre per season. Application by ground equipment only. Do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock.
	Powdery Mildew (Podosphaera sp.)			Follow blossom blight schedule making additional applications at shuck split, shuck fall and 10 to 14 days later.	
	Shothole (Stigmella sp.)			Follow blossom blight schedule making additional applications at 10 to 14 day intervals as long as needed.	
Cherries	Blossom Blight	1.25 to 2.0 (0.5 to 0.8 active)	2.5 to 6.0 (1.0 to 2.4 active)	Refer to Apricots.	Refer to Apricots.
	Powdery Mildew (Podosphaera sp.)			Follow blossom blight schedule making additional applications at shuck split, shuck fall and 10 to 14 days later.	
	Leaf Spot (Coccomyces sp.)			Follow blossom blight schedule and continue applications at 10 to 14 days intervals to within 14 days of harvest. Make an additional application 14 to 21 days after harvest.	
Nectarines	Blossom Blight Shothole	1.25 to 2.0 (0.5 to 0.8 active)	2.5 to 6.0 (1.0 to 2.4 active)	Refer to Apricots.	
Peaches	Blossom Blight Powdery Mildew	1.25 to 2.0 (0.5 to 0.8 active)	2.5 to 6.0 (1.0 to 2.4 active)	Refer to Apricots.	
	Rusty Spot (Sphaerotheca sp.)			Follow blossom blight schedule making additional applications at shuck split, shuck fall and 10 to 14 days later.	
Plums Prunes	Blossom Blight Powdery Mildew Shothole	1.25 to 2.0 (0.5 to 0.8 active)	2.5 to 6.0 (1.0 to 2.4 active)	Refer to Apricots.	Refer to Apricots. For use on fresh market plums and prunes only.
	Rust (Tranzscheia sp.)			Follow blossom blight schedule making additional applications on a 10 to 14 day schedule as necessary.	

USE DIRECTIONS FOR STONE FRUITS

RALLY 40W is a systemic, protectant and curative fungicide. Best control of diseases being evaluated is achieved when the fungicide is applied on a 7 to 10 day protectant application schedule.

Crop	Disease	Rate of RH-3866 40W		Use Recommendations	Restrictions
		Oz./100 gals.	Oz./Acre		
Apricots	Blossom Blight (Monilinia spp.)	1.25 to 2.0 (0.5 to 0.8 active)	2.5 to 6.0 (1.0 to 2.4 active)	Begin applications at red bud stage (about 5% bloom). If conditions are favorable for disease development, apply again at full bloom and at petal fall.	Do not apply more than 3.5 pounds (1.4 pounds active) RALLY 40W fungicide per acre per season. Application by ground equipment only. Do not graze livestock in treated areas or feed cover crops grown in treated areas to livestock.
	Powdery Mildew (Podosphaera sp.)			Follow blossom blight schedule making additional applications at shuck split, shuck fall and 10 to 14 days later.	
	Shothole (Stigmella sp.)			Follow blossom blight schedule making additional applications at 10 to 14 day intervals as long as needed.	
Cherries	Blossom Blight	1.25 to 2.0 (0.5 to 0.8 active)	2.5 to 6.0 (1.0 to 2.4 active)	Refer to Apricots	Refer to Apricots.
	Powdery Mildew Podosphaera sp.)			Follow blossom blight schedule making additional applications at shuck split, shuck fall and 10 to 14 days later.	
	Leaf Spot (Coccomyces sp.)			Follow blossom blight schedule and continue applications at 10 to 14 days intervals to within 14 days of harvest. Make an additional application 14 to 21 days after harvest.	
Nectarines	Blossom Blight Shothole	1.25 to 2.0 (0.5 to 0.8 active)	2.5 to 6.0 (1.0 to 2.4 active)	Refer to Apricots.	Refer to Apricots.
Peaches	Blossom Blight Powdery Mildew	1.25 to 2.0 (0.5 to 0.8 active)	2.5 to 6.0 (1.0 to 2.4 active)	Refer to Apricots.	
	Rusty Spot (Sphaerotheca sp.)			Follow blossom blight schedule making additional applications at shuck split, shuck fall and 10 to 14 days later.	
Plums Prunes	Blossom Blight Powdery Mildew Shothole	1.25 to 2.0 (0.5 to 0.8 active)	2.5 to 6.0 (1.0 to 2.4 active)	Refer to Apricots.	Refer to Apricots. For use on fresh market plums and prunes only.
	Rust (Tranzschelia sp.)			Follow blossom blight schedule making additional applications on a 10 to 14 day schedule as necessary.	

DAILY ACCUMULATED PESTICIDE RESIDUES---MULTP. APPL.

Chemical name -----	myclobutanil
Initial concentration (ppm) -----	8.600001
Half-life -----	61
A number of application -----	9
Application interval -----	10
Length of simulation (day) -----	90

DAY	RESIDUE (PPM)
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0	8.600001
1	8.502831
2	8.406759
3	8.311773
4	8.217861
5	8.12501
6	8.033207
7	7.942443
8	7.852702
9	7.763977
10	16.27625
11	16.09235
12	15.91053
13	15.73076
14	15.55302
15	15.37729
16	15.20355
17	15.03177
18	14.86193
19	14.69401
20	23.12798
21	22.86666
22	22.6083
23	22.35285
24	22.1003
25	21.85059
26	21.60371
27	21.35961
28	21.11827
29	20.87966
30	29.24375
31	28.91333
32	28.58665
33	28.26365
34	27.94431
35	27.62857
36	27.3164
37	27.00776
38	26.70261
39	26.4009
40	34.70261
41	34.31051
42	33.92285
43	33.53956

44	33.1606	
45	32.78593	
46	32.41549	
47	32.04924	
48	31.68712	
49	31.3291	
50	39.57511	
51	39.12797	
52	38.68587	
53	38.24877	
54	37.8166	
55	37.38932	
56	36.96687	
57	36.54919	
58	36.13623	
59	35.72794	
60	43.92426	
61	43.42797	
62	42.93729	
63	42.45215	
64	41.97249	
65	41.49825	
66	41.02937	
67	40.56579	
68	40.10745	
69	39.65429	
70	47.80625	
71	47.26609	
72	46.73204	
73	46.20404	
74	45.68198	
75	45.16584	
76	44.65552	
77	44.15097	
78	43.65212	
79	43.1589	
80	51.27126	
81	50.69196	
82	50.1192	
83	49.55292	
84	48.99303	
85	48.43947	
86	47.89216	
87	47.35105	
88	46.81604	
89	46.28707	
90	45.76409	
Maximum residue	-----	51.27126
Average residue	-----	31.27156

DAILY ACCUMULATED PESTICIDE RESIDUES---MULTP. APPL.

Chemical name	-----	myclobutanil
Initial concentration (ppm)	-----	8.600001
Half-life	-----	61
A number of application	-----	9
Application interval	-----	10

Attachment A

EEC CALCULATION SHEET

I. For un-incorporated ground application

A. Runoff

$$\underline{1.4} \text{ lb(s)} \times \underline{0.05} \text{ (5\% runoff)} \times \underline{10} \text{ (A)} = \underline{0.7} \text{ lb(s)} \text{ (tot. runoff) (from 10 A. drainage basin)}$$

EEC of 1 lb a.i. direct application to 1 A. pond 6-foot deep = 61 ppb

$$\text{Therefore, EEC} = 61 \text{ ppb} \times \underline{0.7} \text{ (lb)} = \underline{427} \text{ ppb}$$

II. For incorporated ground application

A. Runoff

$$\underline{\quad} \text{ lb(s)} \div \underline{\quad} \text{ (cm)} \times \underline{0.0} \text{ (depth of incorporation)} \times \underline{\quad} \text{ (\% runoff)} \times \underline{10} \text{ (A)} = \underline{\quad} \text{ lb(s)} \text{ (tot. runoff) (10 A. d.basin)}$$

$$\text{Therefore, EEC} = 61 \text{ ppb} \times \underline{\quad} \text{ (lbs)} = \underline{\quad} \text{ ppb}$$

III. For aerial application (or mist blower)

A. Runoff

$$\underline{\quad} \text{ lb(s)} \times \underline{0.6} \text{ (appl. efficiency)} \times \underline{0.0} \text{ (\% runoff)} \times \underline{10} \text{ (A)} = \underline{\quad} \text{ lb(s)} \text{ (tot. runoff) (10 A. d.basin)}$$

B. Drift

$$\underline{\quad} \text{ lb(s)} \times \underline{0.05} \text{ (5\% drift)} = \underline{\quad} \text{ lb(s)} \text{ (tot. drift)}$$

$$\text{Tot. loading} = \underline{\quad} \text{ lb(s)} \text{ (tot. runoff)} + \underline{\quad} \text{ lb(s)} \text{ (tot. drift)} = \underline{\quad} \text{ lb(s)}$$

$$\text{Therefore, EEC} = 61 \text{ ppb} \times \underline{\quad} \text{ (lbs)} = \underline{\quad} \text{ ppb}$$