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TYPE PRODUCT(S): I, D, H, F, N, R, S Fungicide

DATA ACCESSION NO(S). L. Rossi (21)

PRODUCT MANAGER NO.

PRODUCT NAME(S) RH-3866 Technical, Rally 40W, and Rally 60DF

COMPANY NAME Rohm & Haas Company

SUBMISSION PURPOSE Proposed Registration of Technical and Two End-Use Products for Use on Apples and Grapes

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.
	Myclobutanil	

ECOLOGICAL EFFECTS BRANCH REVIEW

Myclobutanil

100.0 Submission Purpose

The registrant, Rohm & Haas, proposes to register myclobutanil as RH-3866 Technical for manufacturing, and for use on apples and grapes as Rally 40W and Rally 60DF. They provided a fish early life stage toxicity test to support this registration in conjunction with previously submitted data.

100.1 Pesticide Use

Fungicide

100.2 Formulation Information

RH-3866 Technical - 92% Aralkyltriazole
Rally 40W - 40% Myclobutanil
Rally 60DF - 60% Myclobutanil

100.3 Application Methods, Directions, Rates

The maximum application rate is 0.25 lb ai/A (280 g ai/ha) for apples and 0.125 lb ai/A (140 g ai/ha) for grapes. Typically RH-3866 would be applied three to four times per year. Total active ingredient to be applied per season is 2 lb ai/A for apples and 0.6 lb ai/A for grapes.

100.4 Target Organism

Fungus

100.5 Precautionary Labeling

RH-3866 Technical

No specific Environmental Hazard statement was on the technical label.

Rally 40W and Rally 60DF

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.

101.0 Hazard Assessment

101.1 Discussion

According to the label, application should be made with air blast or hydraulic spray equipment.

Apples

Maximum use rate for apples is 0.25 lb ai/A, with maximum seasonal rate of 2 lb ai/A. Apples are grown primarily in Washington, New York, Michigan, Virginia, and California. However, they are also grown in 30 other States. Apple orchards serve as habitat for numerous nontarget species. Rally could be applied up to eight times per season at 7-day intervals. Thus, chronic exposure could occur for several weeks to a variety of organisms.

Grapes

Maximum use rates for grapes is 0.125 lb ai/A, with maximum seasonal rate of 0.6 lb ai/A. Grape production occurs primarily in California. Exposure could occur by wildlife moving into treated vineyards.

Exposure to aquatic organisms could occur through drift or runoff of active ingredient from treated areas to waterways.

101.2 Likelihood of Adverse Effects to Nontarget Organisms

Toxicity Information

Myclobutanil is slightly toxic to practically nontoxic to birds with an LD_{50} of 510 mg/kg (bobwhite) and LC_{50}s of > 5000 ppm for both bobwhite and mallards.

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

Myclobutanil is moderately toxic to fish with LC_{50}s of 4.2 and 2.4 ppm for rainbow trout and bluegill, respectively. The daphnid LC_{50} is 11 ppm, representing slight toxicity.

The avian reproduction tests showed no adverse effects at 60 ppm (highest level tested) to bobwhite and mallards.

The fish early life stage test was validated as supplemental pending receipt of additional information. The results of this study suggest that fish development and survival MATC > 0.98 < 2.2 ppm. When the additional data are provided the study will be reevaluated.

Terrestrial

Apple - 0.25 lb ai/A

Residues on Terrestrial Food Items (ppm)

	Short Grass	Long Grass	Leafy Plants	Forage Insects	Seed Pods	Fruit
Maximum	60	25	31	15	3	2
Typical	31	23	9	8	1	< 1

Grape - 0.125 lb ai/A

Residues on Terrestrial Food Items (ppm)

	Short Grass	Long Grass	Leafy Plants	Forage Insects	Seed Pods	Fruit
Maximum	30	13	16	8	2	1
Typical	16	12	5	4	< 1	< 1

The maximum estimated residue for apples does not exceed the avian reproduction NOEL (60 ppm). This maximum residue barely exceeds the systemic NOEL (50 ppm) for mammals but not the reproductive NOEL (200 ppm). The estimated typical residues do not exceed the two-generation NOEL. Therefore, these uses would be expected to have minimal acute and chronic effects on birds, mammals, or other terrestrial vertebrates.

Aquatic

If myclobutanil is applied at 0.25 lb ai/A to a 10 acres of apple orchard which drains into a 1-acre pond 6 feet deep, the following concentrations are expected.

% Runoff	Concentration
1%	1.5 ppb
5%	7.6 ppb

(0.25 x 10 x 0.01 x 61 = 1.525)

Direct application to 6" of water would result in 183.5 ppb. This is substantially less than the fish and aquatic invertebrate LC_{50}s (2.4 ppm, fish; 11 ppm, Daphnia magna) and the NOEL of the fish early life stage test (980 ppb). Minimal adverse acute or chronic effects are expected to aquatic organisms due to the proposed use of myclobutanil on apples and grapes.

101.3 Endangered Species Considerations

The endangered species triggers are:

Group	LC_{50}/LD_{50}	Trigger
Birds	5000 ppm/10	= 500 ppm
Mammals	*1454 ppm/10	= 145 ppm
Fish	2.4 ppm/20	= 120 ppb
Aquatic Invertebrates	11 ppm/20	= 550 ppb

*Based on LD_{50} of 1600 mg/kg/1.1 (extrapolated to a 1-day LC_{50} for the least shrew which eats 1.1 times its weight per day. The LC_{50}s for other mammals would be higher since they eat less per body weight than this insectivore).

The estimated residues on terrestrial food items do not exceed 1/10th the lowest avian or mammal LC_{50}s. The estimated concentrations in water adjacent to treated areas are less than 1/20th the fish and aquatic invertebrate LC_{50}. Therefore, it is not expected that these proposed uses would affect endangered species.

101.4 Adequacy of Toxicity Data

The available data were sufficient to assess hazards to nontarget organisms. The study submitted with this submission, a fish early life stage test with fathead minnows, was evaluated and characterized as supplemental. It may be upgraded if additional information is provided. See section 8, Recommendations, of the attached Data Evaluation Report.

101.5 Adequacy of Labeling

The technical label must have the following environmental hazard statement:

> Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

The label statement for Rally 40W and Rally 60DF is adequate.

102.0 Classification

This pesticide does not exceed restricted use criteria.

103.0 Conclusion

grapes ? N Cook 6.14.90

EEB has reviewed the proposed registration of myclobutanil as RH-3866 Technical for manufacturing and for use on apples and ~~pears~~. Based on available data and use information, EEB concludes these uses would provide for minimal adverse effects to nontarget organisms. This registration is not expected to affect endangered species.

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DATA EVALUATION REPORT

1. Chemical: Rally, RH-3866
Shaughnessy No. 128857

2. Test Material: Technical RH-3866, Log 1# 84-0009, Test #83159
Pail #5, 91.9% purity (Myclobutanil)

3. Study Type: Early Life Stage Toxicity Test with Fathead Minnow (Pimephales promelas)

4. Study ID: McAllister, William A.; McLain, Terri; Seidel, Alan; Franklin, Brenda B. Early Life Stage Toxicity of RH-3866 to Fathead Minnow (Pimephales promelas) in a Flow-Through System. Report No. 34538. October 15, 1986. Test performed by Analytical Bio-Chemistry Laboratories, Inc. and submitted by Rohm & Haas Company. Accession No. 266119

5. Reviewed By: Daniel Rieder
Wildlife Biologist
EEB/HED
Signature: Daniel Rieder
Date: 7-31-87

6. Approved By: Norman J. Cook
Section Head, Section II
EEB/HED
Signature: Norman J. Cook
Date: 7 31-87

7. Conclusion:

This study appears to have been conducted in a scientific manner; however, substantial data and procedural description were not provided. Because of these deficiencies in reporting, this study does not fulfill the requirements for a fish early life stage chronic toxicity test. When the additional information has been provided as identified in section 8, the test may be upgraded to fulfill Guideline requirements.

8. Recommendations:

The following information is required to complete the evaluation of this test.

a. Indicate specifically how eggs were obtained, i.e., from stripping female or from substrate.

b. Indicate if fertilization was accomplished before or after eggs (embryos) were placed in test solutions. If fertilization occurred before placing embryos into test solutions indicate age of embryos.

c. Indicate procedures on posthatch selection and thinning of larval fish. Indicate "time to hatch" in each concentration.

d. Indicate if feeding of juvenile fish was discontinued 24 hours before fish were weighed at end of test.

e. Indicate time to swim up at each test level.

f. Indicate specifically if the "percent of hatch" is percent of initial eggs (embryos) or percent of surviving embryos at time of hatch. If it is the latter, indicate number or percent of embryos surviving.

g. Provide raw data or provide transcripts of raw data indicating measurements and counts of the following endpoints:

- number of embryos hatched (not percent);
- time to hatch (by concentration);
- mortality (and time detected) for embryos, larval fish, and juveniles;
- time to swim up (by concentration); and
- measurements of length and weight.

9. Background:

This test was conducted to support registration.

10. Discussion of Individual Tests: N/A.

11. Materials and Methods:

Fathead minnow embryos were exposed (15 per replicate, 4 replicates, 60 embryos per concentration) to Rally (RH-3866 Technical 91.9% ai) in 5 concentrations at 0.5, 1, 2, 4, and 8 ppm. Untreated controls and solvent controls (acetone) were used. Temperature was 25 ± 1 °C. Exposure continued until 30 days after hatching was 95% complete. Test concentrations were measured weekly. See Attachment 1, copy of study for more detailed information.

Statistics used include analysis of variance and Tukey's HSD multiple comparison test.

12. Reported Results:

Based on standard length measurements of juvenile fish at end of 35-day exposure (embryo, larval fish, and juvenile) the MATC is > 0.98 < 2.2 ppm. However, growth as determined by wet weight was significantly affected at 4 ppm. One hundred percent mortality occurred at 8.5 ppm. Measured concentrations were 0.45, 0.98, 2.2, 4, and 8.5 ppm.

13. Study Author's Conclusions:

Highest no-observed-effect level = 0.98 ppm;
Lowest observed effect level = 2.2 ppm (standard length).

14. Reviewer's Discussion and Interpretation:

Generally, the study was conducted in an acceptable manner. The Standard Evaluation Procedure for Fish Early Life Stage indicates a minimum of 20 embryos should be used per replicate, or 80 per concentration. This study only used 15 per replicate or 60 per concentration. This does not reduce the value of the test because the dose response clearly shows a highest no-observed-effect level and a lowest observed effect level. Furthermore, the concentrations at which effects occurred were relatively high. The problem with the test was due to insufficient reporting of results and specific methodology as indicated in section 8.

No independent statistical analysis could be performed without raw response data.

The results suggest that RH-3866 or Rally will not affect fish embryo hatching success at up to 8.5 ppm. It does not reduce growth of larvae and juvenile fish at 8.98 ppm and does not reduce survival at 4 ppm.

The test is scientifically sound but does not fulfill requirements.

Category: Supplemental.

Additional data required are listed in section 8.

15. One-Liner: Not completed.

16. CBI Appendix:

The attached report is considered to be CBI.

Attachment

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