US EPA ARCHIVE DOCUMENT

Shaughnessy No.: 128857

Date out of EAB: DEC 21 1987

To: Lois Rossi
Product Manager 21
Registration Division (TS 767C)

From: Emil Regelman, Supervisory Chemist
Review Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS 769C)

Thru: Paul F. Schuda, Chief
Exposure Assessment Branch/HED (TS 769C)

Attached, please find the EAB review of...

Reg./File # 707-ERE, -ERN, -ERR

Chemical Name: Myclobutanil

Type Product: fungicide

Product Name: Rally

Company Name: Rohm and Haas

Purpose: request for acceptance of study previously deemed unacceptable

Date Received: 9/3/87

Action Code: 111

Date Completed:

EAB # (s): 70935, -36, -37

Monitoring Study Requested:

Total Reviewing Time: 0.5 day

Monitoring Study Volunteered:

Deferrals to: _____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

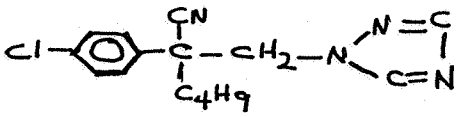
1. CHEMICAL:

chemical name: alpha-butyl-alpha- (4-chlorophenyl-1H-1,2,4-triazole-1-propanitrile

common name: Myclobutanil

trade name: Rally

structure:



CAS #:

Shaughnessy #: 128857

2. TEST MATERIAL: see EBC review 5/20/87

3. STUDY/ACTION TYPE:

The applicant is requesting reconsideration of a previously rejected study on soil photodegradation.

4. STUDY IDENTIFICATION:

Nelson, S.S. Laboratory Soil Photolysis Study of RH-3866. Rohm and Haas Company, Philadelphia, PA. Technical Report No. 310-85-08 dated April 26, 1985, received 11/5/86. Acc. # 7F3475, 7H5524

5. REVIEWED BY:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 3
Organization: EAB/HED/OPP

E. Brinson Conerly
12/21/87

6. APPROVED BY:

Typed Name: Emil Regelman
Title: Supervisory Chemist, Review Section 3
Organization: EAB/HED/OPP

DEC 21 1987

7. CONCLUSIONS:

The study is still not acceptable. The data requirement is still unfulfilled. Per our previous review the study is unacceptable because the light source lacked visible wave length -- i.e. it did not closely simulate natural sunlight.

Further, the absorption spectrum of the compound is not absolute proof of its lack of photolability. It is not possible to predict the behavior of a compound when it is soil-bound from its behavior in solution,

particularly in a non-aqueous system. We quote from the Standard Evaluation Procedure on Soil Photolysis, page 14, "Recent studies by Gohré and Miller [J.Agr.Food Chem, 31, 11654-1168] have shown that sunlight absorption by soils leads to production of singlet oxygen, a reactive, excited form of dioxygen. Singlet oxygen reacts rapidly with certain pesticides and also is known to react with natural substances to form other reactive oxidants such as peroxides. The likely precursors of singlet oxygen, soil components in their excited triplet states, are likely to be chemically reactive. This finding strongly indicates that **sunlight induced transformations of pesticides that do not even absorb sunlight may be significant on soil surfaces ...**"

8. RECOMMENDATIONS:

The applicant should submit a properly done study with all due speed.

9. BACKGROUND:

The applicant company argues that the spectrum of the compound **run in ethanol** shows no light absorption in the visible, and that therefore no light-mediated degradation will take place. Further, they argue that that our Standard Evaluation Procedures allow for the use of simulated sunlight, and that therefore the study should be acceptable.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: see EBC 5/22/87

11. COMPLETION OF ONE-LINER: n.a.

12. CBI APPENDIX: n.a.

Shaughnessy No.: 128857
Date out of EAB: MAY 22 1987

To: Lois Rossi
Product Manager 21
Registration Division (TS 767C)

From: Emil Regelman, Supervisory Chemist
Review Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS 769C)

Attached, please find the EAB review of...

Reg./File # 701-ERE, - ERN, -ERR

Chemical Name: Myclobutanil

Type Product: fungicide

Product Name: Rally

Company Name: Rohm and Haas

Purpose: submission of environmental fate data in support of registration

Action Code: 110

EAB # (s): 70448, 70449, 70450

Date Received: 3/25/87

TAIS Code:

Date Completed: MAY 22 1987

Total Reviewing Time: 0.5 Day

Monitoring Study Requested:

Monitoring Study Volunteered:

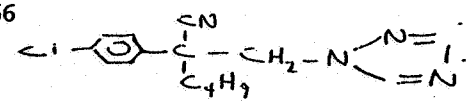
Deferrals to: _____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

1. CHEMICAL:

chemical name: alpha-butyl-alpha-(4-chlorophenyl-1H-1,2,4-triazole-1-propanenitrile
common name: myclobutanil
trade name: Rally™, RH-3866
structure:



CAS #
Shaughnessy #: 128857

2. TEST MATERIAL: described in specific study

3. STUDY/ACTION TYPE: data submission in support of registration

4. STUDY IDENTIFICATION:

Nelson, S.S. Laboratory Soil Photolysis Study of RH-3866. Rohm and Haas Company, Philadelphia, PA. Technical Report No. 310-85-08 dated April 26, 1985, received 11/5/86. Acc. # 7F3475, 7H5524

5. REVIEWED BY:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 3
Organization: EAB/HED/OPP

E. Brinson Conerly 5/20/87

6. APPROVED BY:

Typed Name: Emil Regelman
Title: Supervisory Chemist, Review Section 3
Organization: EAB/HED/OPP

E Regelman MAY 22 1987

7. CONCLUSIONS:

This study is not acceptable to fulfill the requirements for photolysis on soil, because the light source used had essentially no visible wavelengths, and therefore did not simulate sunlight. The applicant has demonstrated stability of the compound at 34° C in the dark and under "black-light" irradiation, but this study does not translate into usual environmental conditions. Commercial sources of sun-simulating light are available.

We reiterate our previous review of December 1986 (EBC -- copy attached) which acknowledges the existence of the referenced studies and gives their status:

hydrolysis -- satisfied
photodegradation in water -- a study is on file, but was not acceptable since it was done with pond water instead of deionized or distilled water containing an appropriate buffer
photodegradation in soil -- reviewed in this document
aerobic and anaerobic soil metabolism -- a study is on file which requires information on degradates to be acceptable
leaching -- not fully satisfied, requires data on "aged" compound
adsorption/desorption -- satisfied
field dissipation -- not satisfied -- information needed from study on file regarding identification of degradates and specificity of analytical method
fish bioaccumulation -- requires additional information on k_{ow}s of

principal degradates.

To our knowledge, the requested additional information and studies have not been submitted.

8. RECOMMENDATIONS:

The applicant should furnish a similar study, done either in sunlight or using a light source which closely simulates sunlight.

9. BACKGROUND:

The applicant has submitted three volumes of material: the A, B, E, F, and G sections of the tolerance petition in one volume, the above described photolysis study in the second volume, and summary and discussion of RH-3866 environmental fate. Previous reviews have been written regarding other submissions which the applicant mentions as being on file.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

A. STUDY IDENTIFICATION

Nelson, S.S. Laboratory Soil Photolysis Study of RH-3866. Rohm and Haas Company, Philadelphia, PA. Technical Report No. 310-85-08 dated April 26, 1985, received 11/5/86. Acc. # 7F3475, 7H5524

B. MATERIALS AND METHODS

test chemical - Solubility in water is 142 ppm.
^{14}C RH-3866 was labelled as follows:
in the 3,5 position of the triazole ring -- 10.98 mCi/gm, 100% radiopure
working solution -- 0.71 ml solution to 10.0 ml with methanol
uniformly in the phenyl ring -- 10.28 mCi/gm, 98.0% radiopure
working solution -- 0.94 ml solution to 10.0 ml with methanol.
^{14}C 2,4-D was uniformly labelled in the aromatic ring, 26.42 mCi/gm, 91.7% radiopure
working solution -- 0.93 mg in 10.0 ml methanol
analytical methods
LSC -- direct counting of liquid samples, or combustion followed by counting
autoradiography
TLC
ethyl acetate/2-propanol/H_2O 70:20:10
chloroform/methanol 90:10
photolysis apparatus -- alternating fluorescent blacklights and fluorescent sunlamps, said by the author to emit a range of 290 - 760 nm.
test soil -- Lawrenceville silt-loam soil (see attached table of properties) air-dried, sieved to <2.00 nm. 15 gm aliquots were used for the tests.
test samples -- Aliquots spiked with 1.5 ml of working solutions of RH-3866 or 0.75 ml working solution 2,4-D. Incubation flasks were continuously purged with filtered air (water and CO_2 removed). Volatile organic compounds in the effluent were trapped on Chromosorb, and CO_2 was trapped in 30% ethanolamine/methyl cellosolve.
sampling protocol -- Soil was sampled at day 3, 7, 16, and 30. Trapping solutions And Chromosorb were changed at the same intervals.

soil extraction -- The entire 15 gm aliquot was extracted with 25 ml acetonitrile/1 M acetic acid 70:30 with mixing for 2 minutes. The mixture was centrifuged, the supernatant decanted, and the soil pellet reextracted as described. The combined supernatants were diluted with 50 ml H_2O and extracted with 3 x 50 ml chloroform. The combined chloroform extracts were concentrated under reduced pressure and analyzed by TLC (for the RH-3866 samples were done in both systems, for 2,4-D only in the first system above).

temperature of incubation -- said to be 34 ^{o}C

C. REPORTED RESULTS

There was little or no degradation either in the irradiated samples or dark controls, while reference 2,4-D did degrade when irradiated. The projected half-lives for the differently labelled compound agreed well.

D. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES

1) Photodegradation performed under "black light" and at 34 ^{o}C showed little or no degradation.
2) The projected half life of 142 days for photolysis is much greater than the soil metabolic half-life of 66 days. Therefore, photolysis will not be a major degradative pathway.
3) Day 0 controls were consistently higher than in later samples, possibly due to solvent evaporation of working solution during the storage period.
4) The rationale for using more extreme conditions than Guidelines prescribe was to "force" photoproducts to occur.
5) The compound does not absorb in the visible range, and additional light in in the visible range would not affect the outcome.

E. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS

1) The study is clearly non-Guidelines, but does demonstrate stability under the experimental conditions.
2) By our treatment of the submitted data, only the phenyl-labelled Day 0 sample is an "outlier" in relation to the later samples. Reporting the results as percent of recovered does not appear to alter the interpretation of the data, although the general practice is should be to report % of applied.
3) Although the applicant makes a case for the limited spectrum of the irradiating light, we cannot accept this study as fully satisfying this data requirement. If type and degree of photolability were completely predictable on the basis of theoretical considerations such as molecular structure and spectral characteristics, another study would indeed seem to be unnecessary. However, the only way to determine the actual behavior is to simulate "real-life" conditions as nearly as feasible.

11. COMPLETION OF ONE-LINER: n.a.

12. CBI APPENDIX: included

Table 2

Physical Properties of Lawrenceville Silt Loam

Sand	13.0%
Silt	61.0%
Clay	26.0%
Organic Matter	1.2%
Field Moisture Capacity at 1/3 bar	27.4%
pH	5.3%
Cation Exchange Capacity (meq/100 g)	5.3%

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