

US EPA ARCHIVE DOCUMENT

8-28-89

Shaughnessy No: 128101

Date Out of EFGWB: AUG 28 1989

TO: John Lee
Product Manager #31
Registration Division (H-7505C)

FROM: Emil Regelman, Supervisory Chemist
Environmental Chemistry Review Section #2
Environmental Fate and Ground Water Branch EFED (H-7507C)

Emil Regelman (for E.R.)

THRU: Henry M. Jacoby, Acting Chief
Environmental Fate and Ground Water Branch/EFED (H-7507C)

Henry M. Jacoby

Attached, please find the EFGWB review of:

Reg./File #: 707-RIL

Common Name: Not yet assigned

Chemical Name: 4,5-Dichloro-2-octyl-isothiazole

Type product: Marine anti-foulant

Product Name: "C-9211M"

Company Name: Rohm and Haas

Purpose: Review of confirmation of radiopurity. Review of supplemental report to fish accumulation studies. Review of protocols (photolysis in water/sea water; Aerobic/anaerobic aquatic metabolism; Adsorption/desorption; Column leaching (aged).

Date Received: 4/10/89 Action Code: 116

Date Completed: 8/21/89 EAB #(s): 90498

Total Reviewing Time (decimal days): 2.0 days

- Deferrals to: _____ Ecological Effects Branch, EFED
 _____ Science Integration & Policy Staff, EFED
 _____ Non-Dietary Exposure Branch, HED
 _____ Dietary Exposure Branch, HED
 _____ Toxicology Branch I, HED
 _____ Toxicology Branch II, HED

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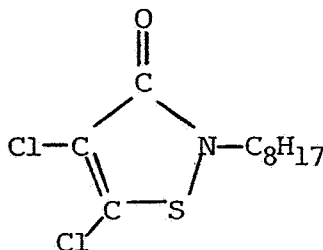
1. CHEMICAL:

Common name: None (identified by the company as RH-5287)
Chemical name: 4,5-dichloro-2-n-octyl-3(2H)-isothiazolone
"4,5-dichloro-2-octyl-isothiazole"

Chemical Abstracts Registry #: 64359-81-5

Trade name(s): Anti-Foulant C-9211M; Kathon-287

Structure:



Formulation: 30-31% active ingredient (RH-5287)
70% inert solvent

Physical/Chemical properties (technical product):

Appearance: tan brown waxy solid
Melting point: 40-41°C
pH: Not applicable
Specific gravity: 1.28 (at 25°C)
Solubility: 14 ppm (in water, 25°C)
Miscible in most organic solvents
Vapor pressure: 4.5×10^{-6} Torr
Octanol/Water
Partition coefficient: logP= 6.4

2. STUDY/ACTION TYPE:

Review of confirmation of radiopurity. Review of supplemental report to fish accumulation studies. Review of protocols (photolysis in water/sea water; Aerobic/anaerobic aquatic metabolism; Adsorption/desorption; column leaching (aged).

3. STUDY IDENTIFICATION:

-Jacobson, A.H. (1989). Confirmation of sample radiopurity during the uptake, depuration, and bioconcentration of ^{14}C -RH-5287 by bluegill sunfish (*Lepomis microchirus*) and Supplemental Report to: uptake, depuration, and bioconcentration of ^{14}C -RH-5287 by bluegill sunfish (*Lepomis microchirus*) [ABC Report No. 32970; (Accession #255912)]. Study completed on March 20, 1989. Performed and submitted by Rohm and Haas Company, Spring House, PA.
EPA MRID #41049601.

- Proposed Protocols for Environmental Fate Studies for Anti-Foulant CM-9211M (EPA File symbol- 707-RTL). Prepared and submitted by Rohm and Haas Company, Philadelphia, PA, March 16, 1989:

1. Aqueous photolysis of $^{13}/^{14}\text{C}$ RH-5287 in natural sunlight
Project Number: 292
2. Sea water photolysis of $^{13}/^{14}\text{C}$ RH-5287 in natural sunlight
Project Number: 293
3. Aerobic aquatic metabolism of $^{13}/^{14}\text{C}$ RH-5287
Project Number: 294
4. Anaerobic aquatic metabolism of $^{13}/^{14}\text{C}$ RH-5287
Project Number: 295
5. Soil adsorption/desorption of ^{14}C RH-5287 by the batch equilibrium method
Project Number: 296
6. Leaching of $^{13}/^{14}\text{C}$ RH-5287 in four soil types following 30 days or one-half life of aerobic aging in sandy loam soil
Project Number: 297

No MRID assigned to the protocols

- Letter of Wendy Bingaman (Rohm and Haas Company) to John Lee (EPA, Product Manager #31), dated 3/17/89 summarizing the minutes of the meeting between Rohm and Haas and EPA held on 3/8/89. Copy attached.
- Letter of Wendy Bingaman (Rohm and Haas Company) to John Lee (EPA, Product Manager #31), dated 3/23/89, and submitted as part of MRID #41049601.

4. REVIEWED BY:

Silvia C. Termes
Chemist, Review Section #2
OPP/EFED/EFGBW

Signature: 

Date: August 21, 1989

5. APPROVED BY:

Emil Regelman
Supervisory Chemist
Review Section #2
OPP/EFED/EFGBW

Signature:  (for E.R.)

Date: AUG 28 1989

6. CONCLUSIONS:

a. Confirmation of sample radiopurity and supplemental data for the bioaccumulation in fish study

EFGWB accepts the registrant's explanation that the radiopurity of test material was of sufficient radiopurity at the beginning of the experiment. Even though the radiopurity of the test material was not determined at the beginning of the experiment, the registrant has presented data showing that determination of radiopurity carried on at later time (four years after synthesis) still remained close to 90% (from 98.5% determined at the time of synthesis). Rohm and Haas has also presented additional data showing the stability of ^{14}C RH-5287 in organic solvents.

The supplemental information to be submitted by the registrant concerned data on water quality, temperature, dissolved oxygen content, and pH of the bathing media during the uptake and depuration phases at the time of sampling. Although the registrant states that this information is shown in Table 11 (page 26) of the submitted report, the report contains only 23 pages. Therefore the data is still missing and should be sent to the Agency as soon as possible.

Rohm and Haas is currently performing experiments aimed to identify residue/metabolites in fish part, as informed by Wendy Bingaman (Rohm and Haas) during a telephone conversation with S. Termes (EFGWB) on 2/6/89.

b. Protocols:

1. Photodegradation in water under natural sunlight (Project 292):

The submitted protocol is acceptable. The registrant, however, should also make sure that if a cosolvent is used, the cosolvent is not a photosensitizer. The electronic absorption spectrum of the test substance in the same solvent (buffer) system used in the experiment in the wavelength region of natural sunlight should be included in the report; molar absorptivities for each band (chromophore) in the spectrum must be included too.

2. Photodegradation in sea water under natural sunlight (Project 293):

The submitted protocol is basically acceptable, but it is not clear from it if synthetic or natural sea water will be used. In either case, the results of characterization of the water (as planned by the registrant) should be reported. If natural sea water is used, its origin should be specified; if synthetic sea water is used, it should be explained how it was prepared. The electronic absorption spectrum in the chosen sea water system should also be included in the report (see comments for Project 292).

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3. Aerobic aquatic metabolism (Project 294):

The submitted protocol is acceptable. EFGWB recommends that the nature of the anions and cations present in the sea water be clearly established. It is also recommended that, if possible, a mineralogical characterization of the sediment be performed and the results included in the report. Origin of sea water and sediment should be clearly indicated in the report.

4. Anaerobic aquatic metabolism (Project 295):

The submitted protocol is acceptable. The same recommendations noted for the aerobic aquatic metabolism study are valid for the anaerobic aquatic metabolism study.

5. Adsorption/desorption (batch equilibrium) (Project 296):

The submitted protocol is acceptable. Results of preliminary experiments (aimed to determine a suitable equilibration time) should also be included in the report. Freundlich sorption coefficients (" K_d s") should be calculated for both the adsorption phase and the desorption phase; the same applies for " K_{oc} s".

6. Column leaching (aged) (Project 297):

Although the protocol is basically acceptable, EFGWB recommends that a similar experiment be also conducted with the sediment used in the aquatic metabolism studies. In this case, the sample should be incubated for one half-life or thirty days (whatever comes first); this information can be obtained from the aerobic aquatic metabolism study. Identity of radioactive material in eluates and in soil/sediment segments should be established, when possible.

All the proposed studies will be performed by Pharmacology and Toxicology Research Laboratory, Lexington, KY. Copies of each of the protocols will be kept in EFGWB files. If there is any deviation from the protocols during the course of the study, this should be clearly indicated in the final report.

c. Letter of Wendy Bingaman (Rohm and Haas) containing the minutes of the meeting held between Rohm and Haas and the Agency to discuss the aquatic field dissipation data requirements:

Copy of this letter is attached to the review. After extensive discussion, it was agreed that Rohm and Haas will develop a protocol to perform an aquatic field dissipation study and that this protocol will be submitted to EFGWB for review and approval. The registrant will also rerun and resubmit the EXAMS model for C-9211M once environmental fate and

toxicology studies are complete (the modeling study will be considered supplemental). Rohm and Haas will also conduct dynamic leach rate studies in order to select the appropriate paint formulation for the aquatic field dissipation study (the dynamic leach rate values will also be used in the EXAMS model).

Rohm and Haas (A.H. Jacobson) has informed EFGWB (S.C. Termes) that dynamic leach rate tests have been conducted and that a protocol for the aquatic field dissipation study is being prepared. Dr. Jacobson has informed that it has been very difficult to find suitable study sites. (Telephone conversations July and August 1989). EFGWB has recommended to Dr. Jacobson that E_h of the water system be closely monitored and that a mineralogical characterization of the sediment be considered as part of the study.

7. RECOMMENDATIONS:

The registrant should be informed of the following:

- a. That the missing "Table 11 (page 26)" be submitted.
That the explanation given for the determination of the radiopurity is acceptable.
- b. That all the protocols are basically acceptable, but that the registrant be informed of EFGWB recommendations for each study, as explained in the CONCLUSIONS section.
- c. That EFGWB is following with interest the development of the aquatic field dissipation studies and is willing to cooperate with the registrant by giving guidance, when requested.

8. BACKGROUND:

a. Introduction

The only study that has fulfilled data requirements is the Hydrolysis study (Manning's review, 8/11/83). Photogradation in water, anaerobic and aerobic aquatic metabolism, leaching and adsorption/desorption studies, pesticide bioaccumulation in fish were submitted and reviewed (Termes, 12/3/87). These studies did not fulfill data requirements. After the response of this review and submission of additional data, the studies were still considered unacceptable (Termes, 11/21/88). In a meeting held on 7/11/89 it was agreed that these studies will be repeated. Protocols for these studies were submitted by the registrant and are reviewed here.

Also, the registrant has submitted a modeling study with the purpose of fulfilling data requirements for aquatic field dissipation studies. However, in a meeting held between Rohm and Haas and EFGWB on 3/8/89, it was agreed that the modeling study (or any modeling study generated at a later day) will be considered as providing only supplemental information and that, therefore, an actual aquatic field dissipation study had to be conducted.

b. Directions for use

C-9211M (active ingredient RH-5287) is an algicide/barnicide developed for use in antifouling marine coatings (aquatic nonfood use). It is intended for distribution to the largest industrial formulators/painters involved in the painting of large military and commercial ships; it should not be available to private boat owners or small commercial establishments. The active ingredient RH-5287 (4,5-dichloro-2-octylisothiazole) is formulated (30-31%) active ingredient in an organic solvent, which will be then formulated into paint by the purchaser.

9. DISCUSSION OF INDIVIDUAL STUDIES:

No studies were submitted.

10. COMPLETION OF ONE-LINER: No one-liner has been completed.

11. CBI APPENDIX:

The material reviewed here is considered CBI by the registrant and must be treated as such.



March 17, 1989

Mr. John Lee
Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Dear Mr. Lee:

Subject: Anti-Foulant C-9211M
EPA File Symbol 707-RTL

Minutes of Meeting on March 8, 1989 to Discuss
Aquatic Field Dissipation Study Data Requirement

This letter is a summary of our understanding of the discussions and conclusions that were reached between Rohm and Haas Company and the Agency at our March 8, 1989 meeting. The following individuals were in attendance:

EPA

John H. Lee, PM-31 Registration Division
Valdez Goncarous, Registration Division
Robert Hitch, Monitoring Section EFGWB
Dana Spatz, EFGWB
Sylvia Termes, Chemist EFGWB

Rohm and Haas

Wendy W. Bingaman, Regulatory Specialist
Norman A. Leister, RH-5287 Technical Manager
David R. Streefman, Section Manager, Residue, Metabolism
and Environmental Science
Andrew H. Jacobson, Senior Scientist, Residue, Metabolism and
Environmental Science
John A. Weeks, Labat-Anderson

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Dr. David Streelman gave a brief summary of the rationale for proposing a modeling study to fulfill the requirement for an aqueous dissipation study. John Weeks followed by presenting an overview of the objectives, inputs, sample environments and conclusions of the EXAMS model. A lengthy discussion followed on the feasibility of conducting an actual field dissipation study. The following conclusions were reached:

- The EFGWB will not accept a modeling study to fulfill the requirements of an aqueous field dissipation study. An actual field study will be required. Those members of EFGWB present at the meeting could not give any specific guidance as to how the study should be conducted.
- Bob Hitch indicated that Bob Ambrose (Athens, GA) and Richard Lee (EEB) might have a better feel regarding the validity of the EXAMS model in estuary environments. Bob indicated that individuals within EEB would most likely be interested in reviewing the model on C-9211M as this type of modeling is done on a more routine basis in EEB.
- Dana Spatz reiterated that the ASTM dynamic leach protocol is only intended to supply a relative ranking of tributyltin release from different paint formulations. It is not intended to simulate the dynamic release rate of an anti-foulant in the environment. Therefore, it does not appear necessary for Rohm and Haas to run or submit dynamic leach data for Anti-foulant C-9211M in order to fulfill a registration requirement.
- Sylvia Termes indicated that from her perspective, dynamic leach data developed on paints containing C-9211M would be valuable in order to justify an appropriate paint for use in the aqueous field dissipation study. The Agency would be interested in seeing the field study performed with a paint formulation characterized as having a "worst case" release rate.
- John Lee cautioned Rohm and Haas on two additional points of consideration. First, John indicated that the Agency will be very interested in aquatic toxicity data on non-target species. Secondly, because C-9211M will be used in combination with tin or copper, the Agency may have concerns about the synergistic effects of a combination product. John indicated that the branch chief in EEB would most likely have to decide whether there would be additional aquatic toxicity concerns. Rohm and Haas may want to alert the paint companies on this issue.
- Rohm and Haas questioned the Agency as to whether they would consider granting a conditional registration for C-9211M pending completion and approval of all the required studies except the aqueous dissipation study. No commitment was made at this meeting, but Rohm and Haas would like to continue to pursue this approach with the Agency.

As a result of the above discussion, the following actions were agreed upon:

ROHM AND HAAS

- 1) Rohm and Haas will develop a protocol to perform an aqueous field dissipation study which will fulfill guideline requirement 164-2. Rohm and Haas will submit the protocol for review and approval by the EFGWB before proceeding.
- 2) Rohm and Haas will rerun and resubmit the EXAMS model for Anti-foulant C-9211M once ongoing environmental fate and aquatic toxicology studies are complete. Rohm and Haas understands that the model will be considered as supplemental information by both EFGWB and EEB.
- 3) Dynamic leach rate studies will be performed in order to select an appropriate paint formulation for the aqueous field dissipation study. Dynamic leach rate values will also be utilized for the EXAMS model. Rohm and Haas will use a modified ASTM organotin protocol to develop dynamic leach data due to the fact that it is the best available laboratory method to generate dynamic leach data.

EPA

- 1) Bob Hitch will forward to Wendy Bingaman the name of the individual in EEB who is working on guidelines for conducting mesocosm studies. A copy of the guidelines will be sent to Rohm and Haas if available.
- 2) Bob Hitch will check with Bob Ambrose at Athens, GA about the use of the EXAMS model in estuary environments. Bob advised that at some point individuals from EEB should also be informed about the use of the EXAMS model for Marine Anti-foulant C-9211M.
- 3) Bob Hitch will also forward a copy of the study which the Navy conducted in San Diego harbor on tributyltin dynamic leach rate measurements.

Rohm and Haas appreciated the opportunity to meet with members of the EFGWB regarding our Anti-foulant C-9211M registration. I believe we received answers to our most critical questions. Please feel free to contact me if the Agency is not in agreement with any of the above conclusions or actions. Thanks one again for meeting with us on such short notice.

Sincerely,

Wendy W. Bingaman

Wendy W. Bingaman
Regulatory Specialist
Industrial Chemicals North America
(215) 592-3425

KATHON 287 T

Page _____ is not included in this copy.

Pages 11 through 12 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
