UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

March 1, 1991

MEMORANDUM

SUBJECT: Transmittal of EFED List B Review for Octhilinone (Case # 2475; Chemical # 099901)

FROM: Amy Rispin, Chief
Science Analysis and Coordinatin Staff
Environmental Fate and Effects Division

TO: Jay Ellenberger, Chief
Generic Chemical Support Branch
Special Review and Reregistration Division

Attached please find the following documents for the completed EFED review of Octhilinone.

1. EFGWB review and data requirements table
2. EEB review and DERs.
3. SACS Reregistration Summary Report

If you have any questions concerning this case, please contact Betsy Grim at 557-7634.

cc (with SACS Reregistration Summary Report attached)

Anne Barton
Paul Schuda
List B File
List B Cover Memo File
Hank Jacoby
Jim Akerman
Doug Urban

SACS REREGISTRATION SUMMARY REPORT
for Phase IV

FROM: Betsy Grim, SACS, EFED Date: February 28, 1991

THRU: Amy Rispin, Chief SACS Amy Rispin

TO: Frank Rubis, SRRD

Active Ingredient: List B
Octhilinone

1. Background/history

2. Use Pattern (Sites) and Application Rate.

Use groups per LUIS report Jan. 1991 are Terrestrial Food and Feed Crop, Terrestrial Non-Food Crop, Aquatic Non-Food Industrial, Outdoor Residential and Indoor Non-Food.

3. Registration Information

A. Kind of pesticide.
Industrial mildewcide and microbiocide
B. Target.

C. Method of application.

Used as an industrial mildewcide in paints, coatings, wall paper pastes, caulks, sealants, aqueous emulsions, adhesives, polymer compounds, fabric, and leather processing. Octhilinone is also used as a microbiocide in recirculating cooling towers and air washers and as an industrial fungicide for use in metalworking and hydraulic fluids. The LUIS also lists cotton;seed treatment and wood protection treatment.

D. Formulation Issues and Structure:
2-Octyl-3(2H)-isothiazolone; 2-octyl-4-isothiazolin-3-one.

4. EEB Disciplinary Summary To highlight special issues

For Octhilinone, in addition to the basic six studies, EEB is requiring the Acute Estu/Mari Tox Fish (72-3 a), Acute Estu/Mari Tox Mollusk (72-3 b), Acute Estu/Mari Tox Shrimp (72-3c), Early Life-Stage Fish (72-4 a), Life-cycle Aquatic Invertebrate (72-4 b).

2

The chapter specifies those studies which are acceptable, unacceptable, and new requirements.
Octhilinone is slightly toxic to bobwhite quail and mallard ducks. It is highly toxic to bluegill sunfish, to Daphnia magna and sheepshead minnows. Octhilinone is **very** highly toxic to rainbow trout, mysid shrimp and mollusks.

5. EFGWB Disciplinary Summary To highlight special issues
There are currently no Environmental Fate data requirements for the Indoor non-food uses. The fate review had to be revised, when the LUIS report was submitted, to also include Terrestrial food and feed, terrestrial non-food, and outdoor residential uses. In accordance with this use pattern revision, EFGWB is now requiring Hydrolysis (161-1), Photodegradation in water (161-2), Photodegradation in soil, (161-3) Photodegradation in air (161-4), Aerobic soil (162-1), Anaerobic Aquatic (162-3), Aerobic Aquatic 162-4, Leaching-Adsorption/Desorption (163-1), Soil Dissipation (164-1), Aquatic (Sediment) Dissipation (164-2), Confined Rotational Crop (165-1), Irrigated Crops (165-3), and Bioaccumulation in Fish (165-4).
The chapter specifies those studies which are acceptable, unacceptable, and new requirements.

6. Integrating Paragraph to highlight special issues

None at this time.

7. Ecotoxicity studies to be flagged for early review for tier or other decisions

72-4 (a) Early Life-Stage Fish
72-4 (b) Life-Cycle Aquatic Invertebrate

8. Any data waivers, special considerations, or special study needs? (special information needed for data waivers)

None at this time.

SACS REREGISTRATION SUMMARY REPORT
for Phase IV

Betsy Grim

FROM: Betsy Grim, SACS, EFED Date: February 28, 1991

THRU: Amy Rispin, Chief SACS

TO: Frank Rubis, SRRD

Active Ingredient: List B
Octhilinone

1. Background/history

2. Use Pattern (Sites) and Application Rate.

Use groups per LUIS report Jan. 1991 are Terrestrial Food and Feed Crop, Terrestrial Non-Food Crop, Aquatic Non-Food Industrial, Outdoor Residential and Indoor Non-Food.

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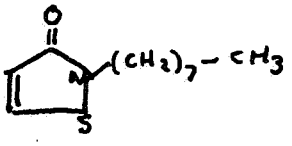
Industrial mildewcide and microbiocide
B. Target.

C. Method of application.

Used as an industrial mildewcide in paints, coatings, wall paper pastes, caulks, sealants, aqueous emulsions, adhesives, polymer compounds, fabric, and leather processing. Octhilinone is also used as a microbiocide in recirculating cooling towers and air washers and as an industrial fungicide for use in metalworking and hydraulic fluids. The LUIS also lists cotton;seed treatment and wood protection treatment.

D. Formulation Issues and Structure:
2-Octyl-3(2H)-isothiazolone; 2-octyl-4-isothiazolin-3-one.



4. EEB Disciplinary Summary To highlight special issues
Octhilinone is slightly toxic to bobwhite quail and mallard ducks. It is highly toxic to bluegill sunfish, to Daphnia magna and sheepshead minnows. Octhilinone is **very** highly toxic to rainbow trout, mysid shrimp and mollusks.

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5. EFGWB Disciplinary Summary To highlight special issues
The fate review had to be revised, when the LUIS report was submitted, to also include Terrestrial food and feed, terrestrial non-food, and outdoor residential uses. There are currently no Environmental Fate data requirements for the Indoor non-food use.

6. Integrating Paragraph to highlight special issues

None at this time.

7. Ecotoxicity studies to be flagged for early review for tier or other decisions

72-4 (a) Early Life-Stage Fish
72-4 (b) Life-Cycle Aquatic Invertebrate

8. Any data waivers, special considerations, or special study needs? (special information needed for data waivers)

None at this time.

ECOLOGICAL EFFECTS BRANCH DATA REQUIREMENTS

LWT 2/26/91

Case No.: 2475 Date: 2/7/91

Chemical: Octhilinone

Chemical No: 099901

Use Patterns: Cotton Seed Treatment, Wood protection treatment to unseasoned forest treatments, Wood protection treatment to Buildings, Textiles, plastics, paints, metal working fluids, leather, laundry (commercial), Emulsions (resins etc), adhesives (industrial)

Reviewers Name: Greg Susanke Telephone No.: 557-1993

GUIDELINES NO./STUDY TYPE	DATA REQUIREMENT FULFILLED (Y-yes; N-no; ~~Reserved~~)	MRIDs/DATES
71-1(a) Acute Avian Oral, Quail/Duck	Y	416080-01 2/6/91
71-1(b) Acute Avian Oral, Quail/Duck (TEP)		
71-2(a) Acute Avian Dietary/Quail	Y	416080-02 2/6/91
71-2(b) Acute Avian Dietary/Duck	Y	416080-03 2/6/91
71-3 Wild Mammal Toxicity		
71-4(a) Avian Reproduction/Quail		
71-4(b) Avian Reproduction/Duck		
71-5(a) Simulated Terrestrial Field		
71-5(b) Actual Terrestrial Field		
72-1(a) Acute Fish/Bluegill	Y	416080-04 2/6/91
72-1(b) Acute Fish/Bluegill (TEP)		
72-1(c) Acute Fish/Rainbow Trout	Y	416080-05 2/6/91
72-1(d) Acute Fish/Rainbow Trout(TEP)		
72-2(a) Acute Aquatic Invertebrate	Y	416080-06 2/6/91
72-2(b) Acute Aquatic Invertebrate(TEP)		

EFGWB No: 90-0801
Case No: 2475
Chemical No: 099901
DP Barcode No: 154526

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: **AMENDMENT TO:** Review of Phase IV Package for Octhilinone

FROM: Dana Spatz, Chemist
Chemistry Review Section #2
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

TO: Amy Rispin, Chief
Science Analysis and Coordination Staff
Environmental Fate and Effects Division (H7507C)

THRU: Henry Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Emil Regelman, Supervisory Chemist
Chemistry Review Section #2
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

MAR 1 1991

The Phase IV review package for List B chemical Octhilinone (case no. 2475) was received by EFGWB on August 21, 1990. The package consisted of the Phase II and Phase III responses from Rohm and Haas including a summary of Chemical Identity data (160-5) and an Aquatic Dissipation "model" study (164-2) that was received by the Agency in May 1990. This model study cannot be evaluated because validated environmental fate data have not been submitted. The data used in the model were generated during the 1970's and were not validated by the Agency and were most likely obtained from studies that are not consistent with current Subdivision N Guidelines.

The LUIS report, dated January 21, 1991 lists the following use patterns:

Terrestrial Food+Feed Crop
Terrestrial Non-Food Crop
Aquatic Non-Food Industrial
Outdoor Residential
Indoor Non-Food

1

However, based on the Phase IV package, the use patterns for Octhilinone, according to the registrant, are: Aquatic Non-Food (Industrial) and Indoor Non-Food.

According to the registrant, octhilinone is currently used as an industrial mildewcide (paints, coatings, wall paper pastes, caulks, sealants, aqueous emulsions, adhesives, polymer compounds, fabric, and leather processing). Octhilinone is also used as a microbiocide in recirculating cooling towers and air washers and as an industrial fungicide for use in metalworking and hydraulic fluids. The discrepancies between the LUIS report and the registrant's Phase II response are that the LUIS report shows the following use patterns that are not indicated by the registrant: Terrestrial Food+Feed Crop use (cotton; seed treatment), Terrestrial Non-Food Crop use (wood protection treatment), and Outdoor Residential use (wood protection treatment).

The attached table outlines the status of each data requirement. There are currently no Environmental Fate data requirements for the Indoor Non-Food use.

TABLE A
DATA REQUIREMENTS FOR Octhilinone

Data Requirement		Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)?
§158.290 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1	Hydrolysis	PAIRA	1,3,6,11	No		Yes[3]
161-2	Photodegradation In Water	PAIRA	1,3,6	No		Yes[3]
161-3	Photodegradation On Soil	PAIRA	1,3	No		Yes
161-4	Photodegradation In Air	PAIRA	1,3,11	No		No
METABOLISM STUDIES-LAB:						
162-1	Aerobic Soil	PAIRA	1,3,11	No		Yes
162-2	Anaerobic Soil	PAIRA	1,3	No		No[4]
162-3	Anaerobic Aquatic	PAIRA	1,3,6	No		Yes[3]
162-4	Aerobic Aquatic	PAIRA	6	No		Yes[3]
MOBILITY STUDIES:						
163-1	Leaching-Adsorption/Desorption	PAIRA	1,3,6,11	No		Yes[3]
163-2	Volatility (Lab)	TEP	1	No		No[5]
163-3	Volatility (Field)	TEP	1	No		No
DISSIPATION STUDIES-FIELD:						
164-1	Soil	TEP	1,3,11	No		Yes[6]
164-2	Aquatic (Sediment)	TEP	6	No		Yes[6]
164-3	Forestry	TEP				
164-5	Soil, Long-term	TEP	1,3,6,11	No		Reserved[7]

Data Requirement		Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)?
§158.290 Environmental Fate (con't)						
ACCUMULATION STUDIES:						
165-1	Rotational Crops (Confined)	PAIRA	1,3	No		Yes
165-2	Rotational Crops (Field)	TEP	1,3	No		Reserved[8]
165-3	Irrigated Crops	TEP	6	No		Yes[9]
165-4	In Fish	PAIRA	1,3,6	No		Yes
165-5	In Aquatic Non-Target Organisms	TEP	1,3,6	No		Reserved[10]
166-1	Ground Water Small Prospective	TEP	1,3	No		No[11]
166-2	Ground Water Small Retrospective	TEP	1,3	No		No[11]
166-3	Ground Water Large Retrospective	TEP	1,3	No		No[11]
158.440 SPRAY DRIFT:						
201-1	Droplet Size Spectrum	TEP	1,3	No		No[12]
202-1	Drift Field Evaluation	TEP	1,3	No		No[12]

1. Composition: TGAI= Technical grade of the active ingredient; PAIRA= Pure active ingredient, radiolabeled; TEP= Typical end-use product.

2. Use paterns: 1=Terrestrial, Food; 2=Terrestrial, Feed; 3=Terrestrial, Non-Food; 4=Aquatic, Food; 5=Aquatic, Non-Food (Outdoor); 6=Aquatic Non-Food (Industrial); 7=Aquatic Non-Foood (Residential); 8=Greenhouse Food; 9=Greenhouse Non-Food; 10=Forestry; 11=Residential Outdoor; 12=Indoor Food; 13=Indoor Non-Food; 14=Indoor Medical; 15=Indoor Residential.

3. Registrant has committed to supply a new study.

4. Anaerobic Aquatic Metabolism study will support this data requirement.

5. Not required for seed treatment.

6. A modeling study (41482511) has been submitted. However, the model cannot be evaluated because validated environmental fate data have not been submitted. The aquatic field study is required.

7. Reserved pending the results of the laboratory metabolism and short-term field dissipation data.

8. Reserved pending results of 165-1.

9. Registrant may request a waiver if it can be demonstrated that the active ingredient and any significant degradates will not contaminate water that may be used for irrigation purposes.

10. Reserved pending results of 165-4.

11. Not required at this time.

12. Not required for current uses/application techniques.

DP BARCODE: D159539 Data Review REREG CASE # 2475

CASE: 815711 DATA PACKAGE RECORD DATE: 12/17/90
SUBMISSION: S380416 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 603 PHASE 3 INITIAL SUB
CHEMICAL: 099901 Octhilinone
ID#: 099901-000707
COMPANY: 000707 ROHM & HAAS COMPANY
PRODUCT MANAGER: 50 JAY ELLENBERGER 703-308-8085 ROOM: CST 4J1
PM TEAM REVIEWER: FRANKLIN RUBIS 703-308-8184 ROOM: CST 4J6
RECEIVED DATE: 05/25/90 DUE OUT DATE: / /

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 159539 EXPEDITE: N DATE SENT: 12/17/90 DATE RET.: / /
DP TYPE: 101 Phase IV Review
ADMIN DUE DATE: 01/07/91 CSF: N LABEL: N

ASSIGNED TO	DATE IN	ASSIGNED TO	DATE IN
DIV : EFED	12/26/90	REVR :	/ /
BRAN: EEB	/ /	CONTR:	/ /
SECT:	/ /		

* * * DATA PACKAGE REVIEW INSTRUCTIONS * * *

Please review data. MRID 417007.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
154515	RSB	08/17/90	09/07/90	Y	N	N
154518	NDEB	08/17/90	09/07/90	Y	N	N
154521	TB/IRS	08/17/90	09/07/90	Y	N	N
154525	EEB	08/17/90	09/07/90	Y	N	N
154526	EFGB/CRS2	08/17/90	09/07/90	Y	N	N

11.

INDEPENDENCE MALL WEST PHILADELPHIA, PA. 19105, U.S.A. TELEPHONE (215) 592-3000
CABLE ADDRESS: ROHMHAAS TELEX 845-247 TWX 710-670-5335 TELECOPIER (215) 592-3377

ROHM AND HAAS COMPANY

TRANSMITTAL DOCUMENT

November 16, 1990

Ms. Susan Lewis (PM 21)
Fungicide-Herbicide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

417007-00

Dear Ms. Lewis:

Subject: Submission of an Acute Toxicity Study on Eastern Oysters under FIFRA Section 6(a)(2)

Submitter: Rohm and Haas Company
Company Number: 707
Active Ingredient: 2-n-Octyl-4-isothiazolin-3-one
Chemical Name: Octhilinone
Chemical Code: 99901, List B
EPA Reg. No: 707-143 - Kathon 893T Industrial Microbicide

Rohm and Haas Company is hereby submitting under Section 6(a)(2) of FIFRA three copies of an acute toxicity study conducted on Eastern Oysters on the Rohm and Haas Company product Kathon 893T Microbicide.

Guideline Ref. Num.	Study Title
72-3	Dionne, E. (1990): (Octhilinone) - Acute Toxicity to Eastern Oysters (Crassostrea virginica) under Flow-Through Conditions. Rohm and Haas Company Report No. 90RC-0033, Unpublished study prepared by Springborn Laboratories, Inc. and submitted by Rohm and Haas Company, Philadelphia, PA. 62 pages (Volume 1 of 1)

Please feel free to contact me with any questions.

Sincerely,

Wendy W. Bingaman

Wendy W. Bingaman
Regulatory Manager
Biocides
North American Region
(215) 592-3425

WWB:cde
3u/427u

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

DEC 05 1990

ROHM & HAAS COMPANY
P.O. BOX 1348
PHILADELPHIA, PA 19105

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 11/23/90. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal has not been analyzed for compliance with PR Notice 86-5, due to the fact that it was submitted under the requirements of FIFRA Section 6(a)2. A copy of your transmittal letter is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted.

INDEPENDENCE MALL WEST PHILADELPHIA, PA. 19105. U.S.A. TELEPHONE (215) 592-3000
CABLE ADDRESS: ROHMHAAS TELEX 845-247 TWX 710-670-5335 TELECOPIER (215) 592-3377

ROHM AND HAAS COMPANY

TRANSMITTAL DOCUMENT

November 16, 1990

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Active Ingredient: 2-n-Octyl-4-isothiazolin-3-one
Chemical Name: Octhilinone
Chemical Code: 99901, List B
EPA Reg. No: 707-143 - Kathon 893T Industrial Microbicide

Rohm and Haas Company is hereby submitting under Section 6(a)(2) of FIFRA three copies of an acute toxicity study conducted on Eastern Oysters on the Rohm and Haas Company product Kathon 893T Microbicide.

Guideline Ref. Num.		Study Title
72-3	41700701	Dionne, E. (1990): (Octhilinone) - Acute Toxicity to Eastern Oysters (Crassostrea virginica) under Flow-Through Conditions. Rohm and Haas Company Report No. 90RC-0033, Unpublished study prepared by Springborn Laboratories, Inc. and submitted by Rohm and Haas Company, Philadelphia, PA. 62 pages (Volume 1 of 1)

Please feel free to contact me with any questions.

Sincerely,

Wendy W. Bingaman

Wendy W. Bingaman
Regulatory Manager
Biocides
North American Region
(215) 592-3425

WWB:cde
3u/427u

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INDEPENDENCE MALL WEST PHILADELPHIA, PA. 19105, U.S.A. TELEPHONE (215) 592-3000
CABLE ADDRESS: ROHMHAAS TELEX 845-247 TWX 710-670-5335 TELECOPIER (215) 592-3377

ROHM AND HAAS COMPANY

ADMINISTRATIVE INFORMATION ONLY

November 16, 1990

Ms. Susan Lewis (PM 21)
Fungicide-Herbicide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Subject: Submission of an Acute Toxicity Study Conducted on Eastern Oysters under FIFRA Section 6(a)(2)

Submitter: Rohm and Haas Company
Company Number: 707
Active Ingredient: 2-n-Octyl-4-isothiazolin-3-one
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Chemical Code: 99901, List B
EPA Reg. No: 707-143 - Kathon 893T Industrial Microbicide

Rohm and Haas Company is hereby submitting under Section 6(a)(2) of FIFRA three copies of an acute toxicity study to Eastern Oysters conducted on the Rohm and Haas Company product Kathon 893T Industrial Microbicide. Rohm and Haas had committed to perform this study as part of a comprehensive ecotoxicity battery under Phase II of reregistration. These studies are required to support an aquatic non-food industrial end-use pattern (industrial recirculating cooling towers and air washers).

Results of the study are as follows:

96-Hour EC50 (95% confidence interval) = 13 (6.4-25) ug a.i./L
96-Hour NOEC = <3.0 ug a.i./L

The study is being submitted to the Agency under FIFRA Section 6(a)(2) for the following reasons:

1) The test substance (octhilinone) had a toxic effect at a lower dosage than in any acute aquatic toxicity study previously reported to EPA.

2) The test substance (octhilinone) had a toxic effect in a different species (eastern oyster) than those previously reported to EPA.

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Enclosed find three copies of the subject study.

Guideline Ref. Num.	Study Title
72-3	Dionne, E. (1990): (Octhilinone) - Acute Toxicity to Eastern Oysters (Crassostrea virginica) under Flow-Through Conditions. Rohm and Haas Company Report No. 90RC-0033, Unpublished study prepared by Springborn Laboratories, Inc. and submitted by Rohm and Haas Company, Philadelphia, PA. 62 pages (Volume 1 of 1)

The affected end-use product registration (Kathon LM Industrial Microbicide - EPA Reg. No. 707-121) currently contains the label statement "This product is toxic to fish and aquatic invertebrates." Please feel free to contact me with any further questions.

Sincerely,

Wendy W. Bingaman

Wendy W. Bingaman
Regulatory Manager
Biocides
North American Region
(215) 592-3425

WWB:cde
Enclosure
3u/427u

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