

US EPA ARCHIVE DOCUMENT



9-3-92

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 3, 1992

MEMORANDUM

SUBJECT: Transmittal of EFED List C Review for
Methylisothiazolinone (Chemicals #107104, 107103; Case
#3092)

FROM: Fred Betz, Acting Chief *F. Betz*
Science Analysis and Coordination Staff
Environmental Fate and Effects Division (H7507C)

TO: Jay Ellenberger, Chief
Accelerated Reregistration Branch
Special Review and Reregistration Division (H7508C)

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

1. EFGWB review with attached DERs.
2. EEB review with attached DERs.
3. SACS Reregistration Summary Report

If you have any questions concerning this case, please contact
Mary Frankenberry at 305-5694.

cc (with SACS Reregistration Summary Report attached)

Anne Barton
List C File

Hank Jacoby

Doug Urban

List C Cover Memo File

SACS REREGISTRATION SUMMARY REPORT
for Phase IV

FROM: Mary Frankenberry, EFED/SACS *MF* Date: 9/3/92

THRU: Fred Betz, Acting Chief, SACS *Fred Betz*

TO: Linda Deluise, SRRD/ARB

Active Ingredient:

List C

2-Methyl-4-isothiazolin-3-one

5-Chloro-2-methyl-4-isothiazolin-3-one

1. Intro/History

Methylisothiazolinone has a wide variety of aquatic non-food industrial uses that are covered by NPDES permitting regulations, in addition to being used as a wood preservative on lumber products. It is a mixture of two active ingredients.

2. Use Pattern (Sites) and Application Rate.

Indoor non-food; terrestrial non-food; aquatic non-food industrial uses.

3. Registration Information

A. Kind of pesticide.

fungicide; microbicide/microbiostat

B. Target pest.

slime-forming bacteria, fungi, and algae

C. Formulation and Method of application.

soluble concentrate/liquid for dilution in water, brush, impregnation

5. EEB Disciplinary Summary To highlight special issues

All of the basic six studies have been done acceptably with the TEP, which is sufficient for meeting ecotox requirements. In addition, estuarine/marine testing has been completed successfully. The Fish Early Life Stage study (72-4a) is under review, although it is not now required for uses covered by NPDES permits. The Aquatic Invertebrate Life Cycle test (72-4b), also no longer required for the above uses, has been upgraded to "Supplemental."

Accepted

2-18-93

All ecotox data requirements, therefore, have been met.

6. EFGWB Disciplinary Summary To highlight special issues

Because of the special wood preservative use, two special studies are required in addition to the Hydrolysis study (161-1). These are Aqueous availability and Photodegradation on treated wood surfaces. EFED has included references for the two protocols. The Aerobic soil metabolism study (162-1) and the Adsorption/desorption study (163-1), no longer required for the above uses, will be reviewed for their applicability to any potential new uses.

7. Integrating Paragraph to highlight special issues

Only the two special studies mentioned above are required as further testing for this chemical. ~~NO~~ OMB clearance is required, and protocol references are attached.



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MEMORANDUM

DP BARCODE: D180120, D180161, D171650
EFGWB # : 92-1118, 92-1119, 92-0283

SUBJECT: List C Phase IV Response
2-Methyl-4-isothiazolin-3-one (Chemical #107104)
5-Chloro-2-methyl-4-isothiazolin-3-one (Chemical #107103)

FROM: Mah T. Shamim, Ph.D., Chemist *305-5025*
Review Section #2
Environmental Fate and Groundwater Branch
Environmental Fate and Effects Division (H7507C)

TO: Linda Deluise/Tom Myers, Product Manager 52
Accelerated Reregistration Branch
Special Review and Reregistration Division (H7508W)

THRU: Emil Regelman, Supervisory Chemist *305-6084*
Review Section #2
Environmental Fate and Groundwater Branch
Environmental Fate and Effects Division (H7507C)

Henry M. Jacoby, Chief *Henry M. Jacoby*
Environmental Fate and Groundwater Branch
Environmental Fate and Effects Division (H7507C)

Attached is a summary of data requirements and their status for the two active ingredients, 2-methyl-4-isothiazolin-3-one and 5-chloro-2-methyl-4-isothiazolin-3-one, used in a number of products as Fungicides and Microbicides. The LUIS report lists a number of uses; these include the use of these chemicals in Air Washer Water Systems, Commercial/Industrial Water Cooling Systems, Evaporative Condenser Water Systems, Heat Exchanger Water System, Industrial Processing Water, Industrial Scrubbing System, Pulp/Paper Mill Water System, and Secondary Oil Recovery Injection Water. These are all Aquatic Non-Food Industrial uses which are covered by NPDES license restrictions and, therefore, are monitored by the Office of Water. According to the EFGWB Branch Policy, all Aquatic Non-Food Industrial use chemicals which have NPDES license restrictions require only hydrolysis data to satisfy the EFGWB data requirements.

The LUIS report also lists the use of these chemicals for control of surface mold and mildew on wood and wood products such as landscape timbers, fences, posts, pilings, cross ties, decks and similar exterior structures. Although, the LUIS report lists the



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use pattern as Terrestrial Non-Food Crop use, the wood treatment chemicals are considered special use chemicals and require a different set of data to satisfy the EFGWB data requirements. The following data is, therefore, needed for the registration of these chemicals as wood treatment chemicals:

Hydrolysis
Aqueous Availability
Photodegradation on Wood Surfaces.

The Registrant, Rohm and Haas Company, has requested waivers for the following data requirements:

161-4 Photodegradation in Air
162-1 Aerobic Soil Metabolism
164-1 Terrestrial Field Dissipation

These waivers do not apply to the current data requirements because due to further clarification of the use pattern, the above mentioned data is no longer needed to satisfy the EFGWB data requirements.

The Registrant has also submitted the following two studies for review:

162-1 Aerobic Soil Metabolism (MRID #42086901)
163-1 Adsorption and Desorption (MRID #42086902)

The studies were screened against the acceptance criteria and were found to be reviewable. Although these studies are no longer needed to satisfy the EFGWB data requirements, they will be put in review and the information added to the database to satisfy any future data requirements that might become applicable due to addition of other uses.

Data Requirements for 2-Methyl-4-isothiazoline-3-one & 5-Chloro-2-methyl-4-isothiazoline-3-one

Data Requirement	Use Pattern	Does EPA have data to satisfy this requirement?	Bibliographic citation	Additional data required by EPA
<u>158.290 Environmental Fate</u>				
161-1 Hydrolysis	FC	No		Yes
<u>SPECIAL STUDIES-LAB:</u>				
Aqueous Availability	C	No		Yes ²
Photodegradation on treated wood surfaces	C	No		Yes ³

FOOTNOTES:

- 1 The use pattern is coded as follows: Aquatic Non-Food Industrial = F; Terrestrial Non-Food Crop = C
- 2 For applied end use products, tests are to be made after product is applied by normal processing techniques and allowed to cure in usual manner. Products to be tested will be the treated wood or wood products as available in the marketplace and typical metal surfaces. Attached, please find a protocol for the aqueous availability test for treated wood products.
- 3 A generally acceptable protocol for this type of study can be found in Environmental Science and Technology Vol. 14(2):196-200

AQUEOUS AVAILABILITY TEST FOR THE WOOD TREATMENT CHEMICALS

There are no official guidelines for the determination of availability of pesticides from treated wood products. However, EFGWB recommends that the study be conducted as follows:

1. The maximum label application rate should be used.
2. The treated material should be then allowed to dry or cure according to label instructions.
3. Each of the treated products to be tested should be immersed in the following solutions:
 - a. Unbuffered distilled water
 - b. Distilled water buffered at pH 5.
 - c. Distilled water buffered at pH 7.
 - d. Distilled water buffered at pH 9.
 - e. Unbuffered sea water.
4. Solutions in which treated products are immersed should be monitored for up to 30 days.
5. Test protocols can be submitted for review by EFGWB.
6. EFGWB will entertain questions concerning the proper conduction of the above suggested study.



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PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Subject: List C Phase IV Review for Methylisothiazolinone
(Case No. 3092, Chemical No's: 107103 & 107104)

From: Douglas J. Urban, Acting Branch Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C) 8/21/92

To: Linda Deluise, Product Manager 52
Tom Myers, Team Reviewer
Special Review and Reregistration Division (H7508W)

Methylisothiazolinone is an industrial microbiocide with indoor non-food, and aquatic non-food uses. It also has terrestrial non-food uses (wood pressure/protection treatment to forest products). Toxicity testing was performed with the typical end-use product Kathon 886F Micorobiocide (EPA Reg. No. 707-130) which has two active ingredients (5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one). There is no technical grade per se. The active ingredients are formed as a result of the manufacturing process (refer to the Data Requirement table for a complete discussion).

Toxicological studies submitted with the current data package have been reviewed and have been found to satisfy guideline data requirements. They are:

71-1(a) Avian Acute Oral-Quail	MRID 41719501
71-1(b) Avian Acute Dietary-Quail	MRID 41719502
71-2(b) Avian Acute Dietary-Duck	MRID 41719503

The following study is in review:

72-4(a) Fish Early Life Stage	MRID 42012201
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Summaries of previous estuarine studies were submitted. They have been re-reviewed and have been found to satisfy guideline data requirements. They are:

72-3(d) Est. Fish Acute Toxicity-Sheepshead Minnow	MRID 00042556
72-3(e) Est. Mollusc Acute Toxicity-Eastern Oyster	MRID 00042558
72-3(f) Est. Crustacean Acute Toxicity-Pink Shrimp	MRID 00042559

Included in this data package is a response by the registrant concerning the reclassification of several EEB studies. The response has been considered and EEB concurs with the registrants rationale. The following studies have been upgraded to core status, thereby satisfying these data requirements:

72-1(8) Fish Acute Toxicity-Bluegill Sunfish	MRID 41718801
72-1(d) Fish Acute Toxicity-Rainbow Trout	MRID 41718802
72-1(d) Fish Acute Toxicity-Rainbow Trout	MRID 41963503
72-2(b) Invertebrate Acute Toxicity-Daphnia magna	MRID 41718803

The following study has been upgraded to supplemental, the study does not need to be repeated:

72-4(b) Invertebrate Life Cycle-Daphnia magna	MRID 41963502
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Ecological Effects Data requirements have been fulfilled. There are no outstanding requirements.

Date: 8/18/92
Case No: 3092
Case Name: Methylisothiazolinone
Chemical No: 107103 5-chloro-2-methyl-4-isothiazolin-3-one
107104 2-methyl-4-isothiazolin-3-one

PHASE IV

DATA REQUIREMENTS FOR

ECOLOGICAL EFFECTS BRANCH

Data Requirements	Composition ¹	Use Group ²	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)?
6 Basic Studies in Bold					
71-1(a) Acute Avian Oral, Quail/Duck					
71-1(b) Acute Avian Oral, Quail/Duck	TEP ³	C,F,M	YES	MRID 417195-01	NO
71-2(a) Acute Avian Diet, Quail	TEP ³	C,F,M	YES	MRID 417195-02	NO
71-2(b) Acute Avian Diet, Duck	TEP ³	C,F	YES	MRID 417195-03	NO
71-3 Wild Mammal Toxicity					
71-4(a) Avian Reproduction Quail					
71-4(b) Avian Reproduction Duck					
71-5(a) Simulated Terrestrial Field Study					
71-5(b) Actual Terrestrial Field Study					
72-1(a) Acute Fish Toxicity Bluegill	TEP ³				
72-1(b) Acute Fish Toxicity Bluegill		C,F	YES	MRID 417188-01 U	NO
72-1(c) Acute Fish Toxicity Rainbow Trout	TEP ³				
72-1(d) Acute Fish Toxicity Rainbow Trout		C,F,M	YES	MRID 417188-02 U MRID 419635-03 U	NO
72-2(a) Acute Aquatic Invertebrate Toxicity					
72-2(b) Acute Aquatic Invertebrate Toxicity	TEP ³	C,F,M	YES	MRID 417188-03 U MRID 423587-01	NO
72-3(a) Acute Estu/Mari Tox Fish					
72-3(b) Acute Estu/Mari Tox Mollusk					
72-3(c) Acute Estu/Mari Tox Shrimp					

Date: 8/18/92

Case No: 3092

Case Name: Methylisothiazolinone

Chemical No: 107103 5-chloro-2-methyl-4-isothiazolin-3-one
107104 2-methyl-4-isothiazolin-3-one

PHASE IV

DATA REQUIREMENTS FOR
ECOLOGICAL EFFECTS BRANCH

Data Requirements	Composition ¹	Use Group ²	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation
72-3(d) Acute Estu/Mari Tox Fish	TEP ³	C,F	YES	MRID 00042556
72-3(e) Acute Estu/Mari Tox Mollusk	TEP ³	C,F	YES	MRID 00042558
72-3(f) Acute Estu/Mari Tox Shrimp	TEP ³	C,F	YES	MRID 00042559
72-4(a) Early Life-Stage Fish	TEP ³	C,F	YES ⁴	MRID 42012201
72-4(b) Life-Cycle Aquatic Invertebrate	TEP ³	C,F	YES ⁴	MRID 41963502
72-5 Life-Cycle Fish				
72-6 Aquatic Org. Accumulation				
72-7(a) Simulated Aquatic Field Study				
72-7(b) Actual Aquatic Field Study				
122-1(a) Seed Germ./Seedling Emerg.				
122-1(b) Vegetative Vigor				
122-2 Aquatic Plant Growth				
123-1(a) Seed Germ./Seedling Emerg.				
123-1(b) Vegetative Vigor				
123-2 Aquatic Plant Growth				
124-1 Terrestrial Field Study				
124-2 Aquatic Field Study				
141-1 Honey Bee Acute Contact				
141-2 Honey Bee Residue on Foliage				
141-5 Field Test for Pollinators				

* In Bibliographic Citation column indicates study may be upgradeable

Date: 8/18/92
Case No: 3092
Case Name: Methylisothiazolinone
Chemical No: 107103 5-chloro-2-methyl-4-isothiazolin-3-one
107104 2-methyl-4-isothiazolin-3-one

PHASE IV

DATA REQUIREMENTS FOR

ECOLOGICAL EFFECTS BRANCH

Data Requirements	Composition ¹	Use Group ²	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)?
72-3(d) Acute Estu/Mari Tox Fish	TEP ³	C,F	YES	MRID 00042556	NO
72-3(e) Acute Estu/Mari Tox Mollusk	TEP ³	C,F	YES	MRID 00042558	NO
72-3(f) Acute Estu/Mari Tox Shrimp	TEP ³	C,F	YES	MRID 00042559	NO
72-4(a) Early Life-Stage Fish	TEP ³	C,F	YES ⁴	MRID 42012201	NO
72-4(b) Life-Cycle Aquatic Invertebrate	TEP ³	C,F	YES ⁴	MRID 41963502	NO
72-5 Life-Cycle Fish					
72-6 Aquatic Org. Accumulation					
72-7(a) Simulated Aquatic Field Study					
72-7(b) Actual Aquatic Field Study					
122-1(a) Seed Germ./Seedling Emerg.					
122-1(b) Vegetative Vigor					
122-2 Aquatic Plant Growth					
123-1(a) Seed Germ./Seedling Emerg.					
123-1(b) Vegetative Vigor					
123-2 Aquatic Plant Growth					
124-1 Terrestrial Field Study					
124-2 Aquatic Field Study					
141-1 Honey Bee Acute Contact					
141-2 Honey Bee Residue on Foliage					
141-5 Field Test for Pollinators					

⁴ In Bibliographic Citation column indicates study may be upgradeable

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

2. Use Group: A = Terrestrial/Food; B = Terrestrial/Feed; C = Terrestrial Non-Food; D = Aquatic Food; E = Aquatic Non-Food (Outdoor); F = Aquatic Non-Food (Industrial); G = Aquatic Non-Food (Residential); H = Greenhouse Food; I = Greenhouse Non-Food; J = Forestry; K = Residential Outdoor; L = Indoor Food; M = Indoor Non-Food; N = Indoor Medical; O = Indoor Residential; Z = Use Group for Site 0000

3. No TGA I exists. The active ingredients consist of a reaction mixture of about 75 weight percent 5-chloro-2-methyl-4-isothiazolin-3-one and 25% 2-methyl-4-isothiazolin-3-one. Kathon 886 F microbicide is the formulation grade registration (EPA Reg. No. 707-130) which defines this combination of active ingredients as produced by an integrated production process.

Kathon 886 F microbicide is an aqueous solution consisting of approximately 13.1% by weight a.i.

[REDACTED] This composition reflects the highest active ingredient level which is stable. Based on historical production experience the following certified limits have been established:
5-chloro-2-methyl-4-isothiazolin-3-one ... 8.6 - 12.1%
2-methyl-4-isothiazolin-3-one 2.6 - 4.6%

Based on the previous information, toxicity testing with the TEP is sufficient to fulfill guideline data requirements.

4. 72-4(a) Fish Early Life Stage and 72-4(b) Aquatic Invertebrate Life Cycle studies are no longer required for industrial microbiocide use patterns. Although the fish early life stage study is in review and the classification of the aquatic invertebrate life cycle study is considered supplemental they are presented in the table to show that EEB has information regarding chronic toxicity values for aquatic organisms, and that the studies do not need to be repeated regardless of their classification.

INERT INGREDIENT INFORMATION IS NOT INCLUDED
MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED