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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of **Kathon 886 F Industrial Microbicide**

DP Barcode: **D284575** Reg. No. or File Symbol: **707-130**
Manufacturing-use [**X**] End-use Product [ ]

Active Ingredient Composition:
5-Chloro-2-methyl-4-isothiszolin-3-one.....10.4%
2-Methyl-4-isothiazolin-3-one.....3.7%

TO: Marshall Swindell PM 33

FROM: Alex Traska, Chemist 9/20/02
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C) 9/24/02

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510 C)

BACKGROUND:

This amendment, for the subject manufacturing-use microbicide, was submitted by the registrant, Rohm and Haas Company.

The registrant, in this amended registration, has requested approval to add an additional manufacturing source of the two active ingredients and the finished product. The proposed new manufacturing source of **Kathon 886 F Industrial**

Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

Microbicide is [redacted]

The following documents were submitted and examined in the chemistry review of this submission: registrant's cover letter and transmittal document dated July 11, 2002, application for amended registration dated July 11, 2002, proposed Alternate Formulation CSF (pre and post reaction) dated July 11, 2002, Certification with Respect to Citation of Data dated 7/11/02, Data Matrix for the two active ingredients dated 7/11/02 and product label dated May 31, 2002.

The primary chemistry review of this submission was made by the Oak Ridge National Laboratory. For the secondary review, the Oak Ridge Data Evaluation Report dated September 5, 2002, was examined along with Product Chemistry Data for Series 830 Group A dated May 23, 2002 under MRID # 457210-01.

FINDINGS:

1.The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredients given in the proposed Alternate Formulation agreed with the percentages declared on the label.

2.The certified limits for both the active and inert ingredients are equivalent to the limits approved in a prior reviews and are therefore acceptable.

3. No PC code is required for [redacted] since this material is a process impurity and not a functional inert ingredient.

4. The product name given in the CSF must agree with the product name used on the label. In the CSF and correspondence, the product is referred to as **Kathon 886F Industrial Microbicide** while on the product label (May 31, 2002 and December 14, 2000) the product name is shown only as **Kathon 886F**. The identical product name must be used in the CSF as on the product label.

5. Registrant should correct the total weight of the [redacted] formulation which totals [redacted] The prior CSF dated November 24, 1999, covering the [redacted] manufacturing location, did not show [redacted] and as such totaled 100%. Registrant should comment on the [redacted] difference between the CSF for the product manufactured in the [redacted] (CSF dated 11/24/99) and the product proposed to be manufactured by [redacted] (CSF dated 7/11/02).

6.The CSF for [redacted] (dated July 11, 2002) indicates the concentrations of [redacted] re expressed as ppm [redacted]. This appears to be an error that should be corrected to read [redacted].

7. The data generated by the five-batch analysis, as presented in Series 830 Group-A, support the conclusion that the proposed alternate source possesses the same physical and chemical properties of the product identified in the Basic CSF.

8.The CAS RN for [redacted] Registrant should change the CAS RN, listed incorrectly in Table II (page 5 of 100, Confidential Attachment to MRID 457210-01) for this material.

RECOMMENDATIONS:

This application for amended registration, requesting the use of an alternate source of product manufactured by [redacted] under the **Kathon 886 F Industrial Microbicide** registration, is not accepted.

Registrant should address issues raised in items #4 through #8 under Findings.

09/20/02 AT

DATA EVALUATION RECORD

5-CHLORO-2-METHYL-3(2H)-ISOTHIAZOLONE
(KATHON ® 886F Industrial Microbicide)

STUDY TYPE: **Product Identity and Composition (OPPTS 830.1550)**
Description of Beginning Materials (OPPTS 830.1600)
Description of Production Process (OPPTS 830.1620)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
MRID 45721001

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Action No. 401

Primary Reviewer:
John E. Caton, Ph.D.

Signature:
Date: SEP 0 5 2002

Secondary Reviewers:
Sylvia Milanez, Ph.D., D.A.B.T.

Signature:
Date: SEP 0 5 2002

Robert H. Ross, M.S., Group Leader

Signature:
Date: SEP 0 5 2002

Quality Assurance:
Lee Ann Wilson, M.A.

Signature:
Date: SEP 0 5 2002

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

August 28, 2002

SUBJECT:PRODUCT CHEMISTRY REVIEW OF:
Kathon ® 886F Industrial Microbicide

DP Barcode: D284575 Reg. No. Or File Symbol: 000707-00130

TGAI/Manufacturing-use Product [x] or End-use Product [ ]

TO: (Team leader/Regulator): _____ Date: _____
PM Team (#):

FROM: (Reviewer), Chemist _____ Date: _____
PM Team (#):
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader _____ Date: _____
PM Team (#):
Product Science Branch
Antimicrobials Division (7510C)

THRU: Michele E Wingfield, Chief _____ Date: _____
PM Team (#):
Product Science Branch
Antimicrobials Division (7510C)

Product Formulation:
Active Ingredient(s): % by wt.
5-Chloro-2-methyl-4-isothiazolin-3-one: 10.4%
2-methyl-4-isothiazolin-3-one: 3.7%

BACKGROUND:

In a letter dated July 11, 2002, the registrant proposes to amend the registration of Kathon® 886F (EPA Reg. No. 000707-00130) to add an additional manufacturing source for the product. This letter indicates that "this alternate source material has a composition and purity that falls within the approved certified limits for the currently registered material. . . .the alternate source material possesses the same physical/chemical properties, toxicological properties, and precautionary statements as the registered material. This amendment will not result in any changes in the ingredient statement on our currently approved label or in the certified limits for the active ingredient. The supplier of this alternate source material in [redacted].

Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

*Product ingredient source information may be entitled to confidential treatment**

FINDINGS:

1. There is slight disagreement between the CSF (dated July 11, 2002) submitted for the new manufacturer [redacted] and the CSF dated November 24, 1999 (for manufacture by [redacted] The CSF submitted for [redacted] lists [redacted] nominal) as a "[redacted]" but the earlier CSF (Nov. 24, 1999; [redacted] and the table of certified limits (MRID 45721001) do not list [redacted] Consequently, the total weight of the [redacted] formulation is [redacted] vs. 100.0% for the earlier CSF (November 24, 1999).

2. The CSF for [redacted] (dated July 11, 2002) indicates the concentrations of [redacted] are expressed as ppm [redacted] This appears to be an error that should read "[redacted]"

3. Five lots of Kathon® 886F from [redacted] were analyzed for the two active ingredients and five of the [redacted] inerts. The composition was within the certified limits for all determined components except acetic acid. Slight modification of the manufacturing process yielded a acceptable [redacted] evels as shown in 10 ten subsequent lots of Kathon® 886F.

4. [redacted] have certified limits listed on the CSF, but no analytical results were reported. A method was described to measure [redacted], however, [redacted] is added at the ppm level so its concentration should always be [redacted] % by weight.

5. The certified limits for the actives and inerts are considerably outside the ranges recommended by OPPTS 830.1750. These limits were approved on the CSF for the previously registered product (manufactured by [redacted]. The analysis of the product manufactured by [redacted] indicates that the limits could be narrower. The registrant needs to explain this discrepancy and consider narrowing the limits for the ingredients.

6. The only physical and chemical characteristics provided were on the CSF, consisting of density, pH, and flammability. The same values were given on the two CSFs, although it is unclear whether these parameters were determined empirically by the new manufacturer. The registrant states: "We have determined through five-batch analysis (Series 830, Group A) that this alternate source material has a composition and purity that falls within the approved certified limits for the currently registered material. Therefore the alternate source material possesses the same physical/chemical properties..."

7. There are seven major steps in the integrated manufacturing process for Kathon® 886F. The new manufacturing source [redacted] instead of [redacted] (Step 4). The new manufacturing source appears to produce a product that is essentially identical to the product prepared by the previously approved manufacturing source.

8. The CAS # for [redacted] It is listed incorrectly in Table II (page 5 of 100, Confidential Attachment to MRID 45721001). A PC code was not found for the inert [redacted]

RECOMMENDATIONS:

1. The registrant needs to provide an explanation for the differences between the CSF for the product manufactured by [redacted] (CSF dated 11/24/99) and the product proposed to be manufactured by [redacted] (CAS dated 7/11/02) regarding the content of [redacted]

2. The registrant should provide an explanation for the wide certified limits for the actives and inerts of the product manufactured by [redacted] which could apparently be narrowed based on the analytical results.

3. Data for physical and chemical properties should be provided for the new manufacturer's product (e.g. density, viscosity, pH) to confirm it is the same as the previous manufacturer's product.

4. The CSF for [redacted] dated July 11, 2002) should be corrected to indicate that the concentrations of [redacted] are expressed as [redacted] (not as [redacted]

5. A PC code needs to be assigned for [redacted]

PRODUCT CHEMISTRY REVIEW:

1. CONFIDENTIAL STATEMENT OF FORMULA (CSF):

1a. Type of manufacturing process and source active ingredient registration
- Non-integrated formulation system (i.e., all TGAI in product are registered) [ ]
- Integrated production system [x]
- if "ME-TOO," specify EPA Reg. # of existing product: _____

Product ingredient source information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

Product ingredient source information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

TABLE 1. Product Identity, Composition, and Certified Limits for MP manufactured by

[redacted]

Manufacturing process information may be entitled to confidential treatment

1b. Clearance of inerts for non-food or food use:
Cleared for food use under 40 CFR §180.1001: Yes [ ] No [ ] NA [x]

1c. The chemical identity, composition (including that for the TGAI), density, pH, and flammability on the CSF are consistent with guidelines in OPPTS Series 830, Part A and OPPTS 830.7300, 830.7000, and 830.6315 respectively: Yes [x] No [ ]

1d. Nominal Concentrations and Certified Limits for active ingredients are:
Acceptable [x]* Not acceptable [ ]

*Although outside suggested OPPTS 830.1750 guidelines, they are the same as previously accepted limits. The analytical data for the new product indicates the limits could be narrower.

1e. Nominal Concentrations and Certified Limits for inert ingredients are:
Acceptable [x]* Not acceptable [ ] Not applicable [ ]

*Although outside suggested OPPTS 830.1750 guidelines, they are the same as previously accepted limits. The analytical data for the new product indicates the limits could be narrower.

1f. For products produced by an integrated formulation system:
- All impurities of toxicological significance have an Upper Certified Limit?
  Yes [x] No [ ] Not applicable [ ]
- All impurities of $\geq 0.1\%$ in the product have been identified?
  Yes [x] No [ ] Not applicable [ ]

2. PRODUCT LABEL:

2a. The active ingredients statement (chemical IDs and Nominal Concentrations) on the label is consistent with the CSF? Yes [x] No [ ]

2b. The product contains one of the following:

• 10% or more of a petroleum distillate:	Yes [ ]	No [x]
• 1.0% or more of methyl alcohol:	Yes [ ]	No [x]
• Sodium nitrite at any level:	Yes [ ]	No [x]
• a toxic List 1 inert at any level:	Yes [ ]	No [x]
• arsenic in any form:	Yes [ ]	No [x]

2c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [x]

2d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label? Yes [ ] No [ ] Not applicable [x]

2e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses?
Yes [x] No [ ]

2f. Does the product require an expiration date at which time the Nominal Concentration falls below the Lower Certified Limit (based on the one year storage stability data or other information)?
Yes [ ] No [x]

3. OPPTS SERIES §830 GUIDELINES:

TABLE 2. Product Chemistry Series 830, Part A

OPPTS Guideline	Acceptance of Information*	MRID No.
830.1550 Chemical ID[1]	A	45721001 and CSF
830.1600 Description of Materials	A	45721001 and CSF
830.1620 Production Process[2]	A	45721001
830.1650 Formulation Process[3]	NA	
830.1670 Discussion of Impurities[4]	U	45721001
830.1700 Preliminary Analysis[5]	A	45721001
830.1750 Certified Limits[6]	U	CSF and 45721001
830.1800 Analytical Method for AIs	A	45700501

*Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= not required, G=data gap; U=requires upgrading; W=waived: E=EPA estimate.

[1]See Table 1 of Product Chemistry Review for additional information.

[2]For MP or EP products manufactured by an integrated production system.

[3]For products manufactured by a non-integrated system (i.e., using a registered TGAI or MP).

[4]May be waived unless actual/possible impurities are of toxicological concern.

[5]Five batch analysis required for products produced by an integrated production system.

[6]If different from standard Certified Limits recommended in 40 CFR 158.175, discussed under "Findings" of the Product Chemistry Review.

TABLE 3. Product Chemistry Series 830, Part B

Physical/Chemical Properties	Acceptance of data*	Value or qualitative description	MRID No. or other source
830.6302 Color	No data		
830.6303 Physical State	No data		
830.6304 Odor	No data		
830.6314 Oxidation/Reduction	No data		
830.6315 Flammability/Flash Pt		"Not applicable"	CSF
830.6316 Explodability	No data		
830.6317 Storage Stability	No data		
830.6320 Corrosion Character.	No data		
830.7000 pH	A	1.9	CSF
830.7100 Viscosity	No data		
830.7300 Density/sp. gravity	A	10.8 lbs/gallon	CSF

*Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= Not required; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.