

707-259

2/12/2001

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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FEB 12 2001

Rohm & Haas
100 Independence Mall West
Philadelphia, PA 19106-2399

Attention: James V. Hagan

Subject: Klarix 4000
EPA Registration Number 707-259
Amendment Dated July 19, 2000

The Agency is conditionally approving your amendment to the registration of the product referenced above under authority of FIFRA Section 3(c)(7)(B). This amendment allows use of the subject product as a mold proofing agent, a preservative in wet lap and sheet pulp, and in pigment dispersions and as a papermill slimicide when incorporated in the manufacture of paper and paperboard intended to contact dry as well as fatty food listed in 21 CFR Part 176.180, or on FDA's "Food Contact Substance Notification Systems."

This amendment will expire automatically on September 1, 2003. In addition, during the 2.5 year period that this amendment is effective, it will be subject to the conditions listed below.

1. This acceptance is based on your commitment letter dated July 19, 2000, in which you state that you intend to fulfill all data requirements to support the addition of food contact uses to the above referenced product label.
2. The following data must be submitted, and found acceptable by September 1, 2003. If you have studies that you believe satisfy these data requirements, you must submit all of them before September 1, 2002.

You can submit these studies as one comprehensive package, or in separate submissions. A risk assessment will not be initiated until all required studies are submitted, and reviewed. If any of the studies you submit do not satisfy these data requirements, you must still satisfy the data requirements by September 1, 2003.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

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Failure to satisfy the data requirements listed below may result in EPA issuing a notice to cancel this amendment under FIFRA section 6(e). This conditional registration will expire automatically on September 1, 2003. Sale or distribution of the subject product bearing labeling for these food contact uses after September 1, 2003 will be illegal.

- A. **Submit a 2-Generation Rat Reproduction Study (870.3800).**
By September 1, 2002, you must submit evidence of laboratory placement and anticipated completion date by the laboratory via a letter from the contracting laboratory itself
- B. **Submit a 90-Day Subchronic Non-Rodent Feeding Study (830.3150).**
This study must be completed and submitted to the Agency for our review by September 1, 2002.
- C. **Submit a Migration Study**
This study must be completed and submitted to the Agency for our review by September 1, 2002.
- D. **Submit a copy of your FDA Petition package and FDA Review Memos.**
You must submit a copy of the Petition package you sent to FDA. If you can obtain FDA review memos, you must also send these.
- E. **Submit copies of any Collateral Labeling Information that Travels With Product**
Any labeling information that travels with the product is considered part of the label and you must submit these on a regular basis for approval. These items are not limited to technical data sheets, case histories, testimonials, user manuals, general/ specific advertising, etc.

A stamped accepted copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)308-6237.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7505C)

KLARIX[®] 4000

Made In USA

Lot Number:

Industrial Microbicide for use in Recirculating Water Cooling Towers, Air Washer Systems, Pulp Mills, Papermill Slime Control, Recirculating Closed Loop Water Cooling Systems, Decorative Fountains, Can Warmer and Brewery Pasteurizers, and Dispersed Pigments.



Product Code: 7-8225

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ACTIVE INGREDIENT:		
4,5-Dichloro-2-n-octyl-3(2H)-isothiazolone	4.25%	
INERT INGREDIENTS:	95.75%	
TOTAL:	100.00%	

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**KEEP OUT OF REACH OF CHILDREN
DANGER
STATEMENT OF PRACTICAL TREATMENT**

DANGER
CORROSIVE
CAUSES IRREVERSIBLE EYE DAMAGE
HARMFUL IF ABSORBED THROUGH THE SKIN
CAUSES SKIN IRRITATION
HARMFUL IF INHALED
MAY CAUSE ALLERGIC SKIN REACTION

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get attention if symptoms persist.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth to mouth. Get medical attention.

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

This product is a dermal sensitizer. Do not get in eyes, on skin, or on clothing. Wear goggles and face shield, protective clothing and rubber gloves. Avoid breathing vapor or spray mist. Keep container closed. Use with adequate ventilation. Do not take internally. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA. Do not contaminate water by cleaning of equipment or disposal of waste. Apply this pesticide only as specified on this label.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

CONDITIONS OF SALE AND WARRANTY

Rohm and Haas warrants that this product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with label directions under normal conditions of use. ROHM AND HAAS MAKES NO OTHER EXPRESS OR IMPLIED WARRANTIES EITHER OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE. Handling, storage, and use of the product by Buyer or User are beyond the control of Rohm and Haas and Seller. Risks such as ineffectiveness or other unintended consequences resulting from, but not limited to, failure to follow label directions will be assumed by the Buyer or User. IN NO CASE WILL ROHM AND HAAS OR SELLER BE HELD LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE HANDLING, STORAGE OR USE OF THIS PRODUCT.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Refer to the table at the end of this section for dosing details for the following applications.

INDUSTRIAL RECIRCULATING WATER COOLING TOWERS

For the control of bacteria, algae and fungi add Klarix 4000 microbicide to the tower basin, distribution box, or some other point to insure uniform mixing. Treatment may be made by slug dosing or continuous dosing to achieve the desired level of biocide.

CAN WARMERS AND BREWERY PASTEURIZERS

For the control of bacteria, algae and fungi in brewery pasteurizer and can warmer systems, add Klarix 4000 microbicide at a point in the system to insure uniform mixing.

DECORATIVE FOUNTAINS

For the control of algae, fungi and bacteria, add Klarix 4000 microbicide to the basin, recirculation line or some other point in the system to insure uniform mixing. Treatment may be by slug dosing or continuous dosing to achieve the desired level of biocide.

For noticeably fouled systems, repeat until control is achieved. Badly fouled systems should be cleaned before treatment is begun.

lb. of product per 1000 gal fluid	fl oz of product per 1000 gal fluid	ppm of product	ppm active ingredient
0.39 lb.	5.9 fl oz.	47 ppm	2 ppm
1.20 lb.	18 fl oz	141 ppm	6 ppm

When microbial control is evident, dose weekly or as needed to maintain control.

lb. of product per 1000 gal fluid	fl oz of product per 1000 gal fluid	ppm of product	ppm active ingredient
0.05 lb.	0.74 fl oz	5.9 ppm	0.25 ppm
0.39 lb	5.90 fl oz	47.0 ppm	2.0 ppm

AIR WASHER SYSTEMS

Add Klarix 4000 microbicide to the air washer sump or chill water sump to insure uniform mixing for control of fungi, bacteria and algae.

For noticeably fouled systems, apply 47 - 141 ppm Klarix 4000 microbicide (2 - 6 ppm active ingredient) (0.39 - 1.2 pound or 5.9 - 18 fluid ounce) per 1000 gallon of water. Repeat until control is achieved. Badly fouled systems should be cleaned before treatment is begun.

When microbial control is evident, add 12 - 47 ppm Klarix 4000 microbicide (0.50 - 2 ppm active ingredient) (0.10 - 0.39 pound or 1.58 - 5.9 fluid ounce) per 1000 gallon of water. Dose weekly or as needed to maintain control.

NOTE: For use only in industrial air washing systems that maintain effective mist-eliminating components.

INDUSTRIAL RECIRCULATING CLOSED LOOP WATER COOLING SYSTEMS

For the control of bacteria, algae and fungi add Klarix 4000 microbicide to the reservoir, recirculating line, or some other point in the system to insure uniform mixing

For noticeably fouled systems, apply 47 - 141 ppm Klarix 4000 microbicide (2 - 6 ppm active ingredient) (0.39 - 1.2 pound or 5.9 - 18 fluid ounce) per 1000 gallon of water. Repeat until control is achieved. Badly fouled systems should be cleaned before treatment is begun.

When microbial control is evident, add 24 - 47 ppm Klarix 4000 microbicide (1 - 2 ppm active ingredient) (0.20 - 0.39 pound or 2.95 - 5.9 fluid ounce) per 1000 gallon of water. Dose weekly or as needed to maintain control.

The active ingredient in Klarix 4000 has FDA Clearances under 21 CFR 176.170 (a)(b), 21 CFR 176.180(b)(1) and 21 CFR 176.300 (c) for the following uses: wet lap and sheet pulp, pigment dispersions, mold proofing, components of paper and paperboard in contact with aqueous, fatty and dry foods, and papermill slimicide.

DISPERSED PIGMENTS PRESERVATION

Klarix 4000 microbicide is recommended for the control of bacteria and fungi in the manufacture and storage of dispersed pigments such as kaolin and montmorillite clays, titanium dioxide, calcium carbonate, calcium sulfate, barium sulfate, and magnesium silicate used in paint and paper production. Add 0.24 - 1.2 pound (3.6 - 18 fluid ounce) of Klarix 4000 microbicide per 1000 pound of fluid to provide 235 - 1176 ppm product (10-50 ppm active ingredient).

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Avg. Gross: LB KG
Net: LB KG
Avg. Tare: LB KG
Label Number
KLARIX EPA LABEL
07/19/00

STORAGE AND DISPOSAL PROHIBITIONS

This product is corrosive to mild steel. Do not store or transport in unlined metal containers. Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Keep product from freezing.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

METAL CONTAINERS

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

PLASTIC CONTAINERS

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

GENERAL: CONSULT FEDERAL, STATE OR LOCAL DISPOSAL AUTHORITIES FOR APPROVED ALTERNATIVE PROCEDURES.

Date of Manufacture: location for date
EPA Reg. No. 707-259
EPA Est. No. 707-TX-1

ACCEPTED
with COMMENTS
to EPA Label Dataset
FEB 12 2001
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
registered under FIFRA Reg. No.
707-259

PAPERMILLS

To control fungal, bacterial and algal growth on paper and paperboard machines, add Klarix 4000 microbicide at 0.1 - 0.8 pound (1.5 - 12 fluid ounce) per ton of dry paper or paperboard produced at a location to insure uniform mixing (including beaters, wire pit, saveall tanks, headbox or machine chest). Treatment may be by slug or continuous dosing to achieve 12 - 94 ppm Klarix 4000 microbicide. (0.5 - 4 ppm active ingredient) in the wet end portion of the system. Dosing frequency will depend on mill conditions and the level of microbial fouling.

For preparation of mold-resistant food contact paper or paperboard, Klarix 4000 microbicide may be dosed to achieve 588 - 2,353 ppm product (25 - 100 ppm active ingredient) on the final paper (dry basis). For uncoated paper or board, Klarix 4000 microbicide may be added to the surface sizing solution, water or other solvents and applied to the surface of the paper by means of applicator roll. It may also be added directly to the pulp slurry at the machine chest or headbox. For coated paper or paperboard, Klarix 4000 microbicide is incorporated into the coating mix prior to application of the coating to the paper.

For the preservation of agricultural mulch paper, Klarix 4000 microbicide should be added at 1.2 - 4.8 pound (18 - 72 fluid ounce) per ton of dry paper. It is applied to the surface of the mulch paper by spray or applicator roll before the paper is coated.

PULP MILLS

To prevent fungal degradation of wood chips during storage, add Klarix 4000 microbicide at 0.6 - 5.5 pound (9 - 53 fluid ounce) per ton of oven-dry wood. It may be applied by water shower or drip feeder during transport of the chips on a conveyor belt to the storage pile.

For preservation of wet-lap or sheet pulp, Klarix 4000 microbicide should be added at 1.2 - 4.8 pound (18 - 72 fluid ounce) per ton of oven-dry fiber. It may be applied directly to the surface of the dewatered sheet by spray, water shower or application rollers or it may be dosed in the pulp slurry prior to dewatering of the sheet.

Klarix™ 4000 microbicide weighs 8.5 pound per gallon.