

707-259

6-12-2003

1/3



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 12 2003

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Valerie T. Phillip
Regulatory Specialist for,
Rohm and Haas Company
100 Independence Mall West
Philadelphia, PA 19106-2399

Subject: Klarix 4000
EPA Registration Number 707-259
Your Submission Dated April 2nd, 2003
EPA Received Date April 4th, 2003

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 the product labeling to be revised to comply with PR Notice 2001-1.

This amendment will expire automatically on September 1st, 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 our commitment letter dated July 19th, 2000, in which you state that you intent 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 1st, 2003. If You have studies that you believe satisfy these data requirements, you must submit all of them before September 1st, 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 1st, 2003.

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 1st, 2003. Sale or distribution of the subject product bearing labeling for these food contact uses after September 1st, 2003, will be illegal.

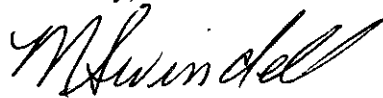
- A. Submit a 2-Generation Rate Reproduction study (870.3800).
By September 1st, 2002, you must submit evidence of laboratory placement and anticipated completion date by the laboratory via a letter from the contracting laboratory itself.

- B. Submit a 90-Day Subchronic Non-Rodent Feeding Study (830.31500).
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 1st, 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 copy of the labeling 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(7510C)

KLARIX[®] 4000

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.

Made In USA

Lot Number



Product Code: 7-8225

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

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 min.
- Call a poison control center or doctor for advice.

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 min.
- Remove contact lenses, if present, after first 5 min. then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth.
- Call a poison control center or doctor for advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for advice.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Have person sip a glass of water if able to swallow. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsions may be necessary.

SEE SIDE PANELS FOR ADDITIONAL PRECAUTIONARY STATEMENTS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

CORROSIVE

CAUSES IRREVERSIBLE EYE DAMAGE

HARMFUL IF ABSORBED THROUGH THE SKIN

CAUSES SKIN IRRITATION

HARMFUL IF INHALED

MAY CAUSE ALLERGIC SKIN REACTION

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.

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 rinseate 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.

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 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.

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

DIRECTI
It is a viola
labeling.

Refer to th
applicatio
INDUSTRI
For the con
basin, dist
be made by
CAN WA
For the con
systems, ac
mixing.
DECORA
For the con
recirculatio
Treatment
biocide.

For notices
should be
lb. of prod
per 1000
0.39 lb.
1.20 lb.

When mic
lb. of prod
per 1000
0.05 lb.
0.39 lb.

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.

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 montmorillonite 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).

This product is not cleared by FDA or EPA for use in the manufacture of paper and paper board products, including dispersed pigments, pulp slurries, paper coatings, paper and paper board, that may come in contact with food.

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.

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 non-wood contact paper or paperboard, Klarix 4000 microbicide may be added to achieve 588 - 2,352 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.

This product is not cleared by FDA or EPA for use in the manufacture of paper and paper board products, including dispersed pigments, pulp slurries, paper coatings, paper and paper board, that may come in contact with food.

PULP MILLS

To prevent fungal degradation of wood chips during storage, add Klarix 4000 microbicide at 0.6 - 3.5 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.

This product is not cleared by FDA or EPA for use in the manufacture of paper and paper board products, including dispersed pigments, pulp slurries, paper coatings, paper and paper board, that may come in contact with food.

Klarix™ 4000 microbicide weighs 8.5 pound per gallon.

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.

This product is not cleared by FDA or EPA for use in the manufacture of paper and paper board products, including dispersed pigments, pulp slurries, paper coatings, paper and paper board, that may come in contact with food.

Klarix™ 4000 microbicide weighs 8.5 pound per gallon.