

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 22 2002

Rhodia, Inc.
P.O. Box 4439
Glen Allen, VA 23058-4439

AGENT: Eliot Harrison
Lewis and Harrison
122 C Street, N.W. Suite 740
Washington, D.C. 20001

Subject: Tolcide PS200
EPA Registration No. 4564-15
Letters Dated February 25, 2002 and May 10, 2002

The Agency acknowledges your request for an extension of the time-limited approval for the food contact paper and paperboard use pattern which was approved on December 23, 1999. Based upon your letter dated May 10, 2002, you are requesting an extension of the expiration date of June 1, 2002. Due to the recent submittal of a waiver request for the Residue Migration study, a time extension is being granted until October 1, 2002 to allow the Agency sufficient time to review your waiver request. In order for the approval of the food contact paper use pattern to continue, the conditions listed below must be waived, or the data submitted and found acceptable.

A Residue Migration Study must be submitted using the FDA guidance document and the appropriate food simulating solvents. This study should be conducted using "wet end" procedure for making paper and paper board using a validated analytical method.

The waiver for the submittal of the migration study is still under review. The Agency will notify you when the review has been completed. The food contact paper use will automatically expire on October 1, 2002.

The Agency has completed the review of the additional information submitted to upgrade your Two-Generation Reproduction toxicity study in rats (MRID #45320801). The original study was reviewed by the Risk Assessment and Science Support Branch and certain deficiencies were found. The study was classified as unacceptable/upgradable, with the provision that the study could be upgraded if the company submitted data on organ weight data and histopathology data in offspring, as required in the 870.3800 published guidelines. The additional information adequately addressed the cited deficiencies in the original review of the two-generation reproduction toxicity study. The study was upgraded to acceptable.

CONCURRENCES

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Submit and/or cite all data required for the registration/reregistration of your product under FIFRA sec. 3(c)(5) and sec. 4 when the Agency requires all registrants of similar product to submit such data.

The Agency must make a determination under FIFRA section 2(bb)(2) that this use will not result in unreasonable adverse effects. If the Agency is unable to make this determination, then the approval of the food contact paper and paperboard use will expire.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510C)

Enclosure

TOLCIDE® PS200

INDUSTRIAL ANTIMICROBIAL

ACTIVE INGREDIENT:

Tetrakis(hydroxymethyl) phosphonium sulfate..... 20%

INERT INGREDIENTS:..... 80%**TOTAL:**..... 100%

EPA Reg. No. 4564-15

EPA Est. 550-TX-2

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

If in eyes: Flush immediately with large amounts of clean, cool water for at least 15 minutes. Get medical attention immediately.

If swallowed: Promptly drink large quantities of water. Do not induce vomiting. Avoid alcohol. Call a physician immediately.

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

If on skin: Wash with plenty of soap and water. Remove contaminated clothing and wash before reuse. Get medical attention.

Prolonged or frequent skin contact may cause allergic reactions in some individuals.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.**PRECAUTIONARY STATEMENTS****HAZARD TO HUMANS AND DOMESTIC ANIMALS****DANGER:** Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if inhaled. Avoid breathing vapor. Remove contaminated clothing and wash before reuse. Harmful or fatal if swallowed. Avoid contamination of food.**ENVIRONMENTAL HAZARDS**

This product is toxic to fish. 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 local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store this product in a cool, dry area away from direct sunlight and heat to avoid deterioration. In case of a spill, flood the area with large quantities of water.**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, 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:** Triple rinse (or equivalent) all containers and offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or other procedures approved by state and local authorities.**Note:** Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk and/or handling of this material, when such use and/or handling is contrary to label directions.

In case of emergency, call CHEMTREC at 1-800-424-9300

Manufactured for:



Rhodia Inc. • 259 Prospect Plains Road • Cranbury, NJ 08512-7500 • 609-860-4000

Product of the United Kingdom

DIRECTIONS FOR USEACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 22 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

4564-15

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

PAPER MANUFACTURING (for control of bacteria, fungi and algae)

a) For use as a stericide in the manufacture of paper and paperboard products and adhesives that do not contact food.

Dosing: Additions should be made at a point in the system where mixing action is good, e.g. raw stock chest beater or mixing unit. Add intermittently or continuously depending on mill conditions.

Intermittent Dosing: Add 122.5-1750 ppm of TOLCIDE PS200 (24.5-350 ppm THPS) based on total water volume or an equivalent based on dry weight of paper produced.

Continuous Dosing: Add 70-245 ppm of TOLCIDE PS200 (14-49 ppm THPS) based on total water volume or an equivalent based on dry weight of paper produced.

b) For use as a stericide in the manufacture of paper and paperboard products that may contact food.

Dosing: Additions should be made at a point in the system where mixing action is good, e.g. raw stock chest beater or mixing unit. Add intermittently or continuously depending on mill conditions.

Intermittent Dosing: Add 122.5-420 ppm of TOLCIDE PS200 (24.5-84 ppm THPS) based on total water volume or an equivalent based on dry weight of paper produced. The maximum use concentration of THPS in the slurry cannot exceed 84 ppm.

Continuous Dosing: Add 70-245 ppm of TOLCIDE PS200 (14-49 ppm THPS) based on total water volume or an equivalent based on dry weight of paper produced. The maximum use concentration of THPS in the slurry cannot exceed 84 ppm.

c) For use as a preservative for Alkyl Ketene Dimer (AKD) Emulsions.

This product can be used to prevent bacterial and fungal contamination of AKD emulsions that are applied to food-contact paper and paperboard at the dry end of the paper machine.

Dosing: Apply from 875-2485 ppm of Tolicide PS200 (175-497 ppm THPS) to the AKD emulsion to be preserved.

INDUSTRIAL AND/OR COMMERCIAL RECIRCULATING COOLING WATER SYSTEMS (for control of bacteria, fungi and algae)

Initial Slug Dose: Add 350-1312.5 ppm of TOLCIDE PS200 (70-262.5 ppm THPS) based on total water volume. Repeat until control is obtained. Thereafter, add either Intermittently 131.25-525 ppm of TOLCIDE PS200 (26-105 ppm THPS) or Continuously 70-245 ppm of TOLCIDE PS200 (14-49 ppm THPS) per day. Dirty systems must be cleaned prior to treatment.

HEAT TRANSFER SYSTEMS (Evaporative Condensers, Dairy Sweetwater Systems, Hydrostatic Sterilizers and Retorts, Brewery and Other Pasteurizers, and Warmers)

Add TOLCIDE PS200 at the same application rates, and in the same manner as described above. It should be added to the system at a point of uniform mixing such as a basin area, sump area, or other reservoir or collecting area from which the treated water will be circulated uniformly throughout the system.

AIR WASHER SYSTEMS

For control of bacteria and fungi. Pre-clean the system with detergent and allow air washer to run with fan on for two hours. Flush and check nozzles, manually cleaning as necessary. Add 131.25-350 ppm of TOLCIDE PS200 at a point where uniform mixing and even distribution will occur. Repeat as needed to maintain control.

SOLUTIONS / EMULSIONS

Not for use in manufacture of paper and paperboard products and adhesives that may come in contact with food. For the preservation of solutions, emulsions, adhesives and other aqueous liquid products, the addition of 0.0875% to 0.875% of TOLCIDE PS200 (0.0175-0.175% THPS) is effective. Add at a point in the processing system where there will be sufficient time and agitation for good mixing and dispersion. The exact amount of TOLCIDE PS200 to be added for the preservation of given formulations will depend on the components as well as local storage time and requirements.

OIL FIELD OPERATIONS

TOLCIDE PS200 is effective in controlling sulfate reducing bacteria, general aerobic bacteria, including microorganisms that contribute to biofilm formation in oil field recovery, processing and distribution applications and supporting systems; such as injection water, water holding tanks, disposal well water, recirculating water handling systems, and pipelines. TOLCIDE PS200 has been shown to dissolve iron sulfide and sequester iron when used under these conditions, leading to improved filter life and well injectivity, and reduction of hydrocarbon sheen. TOLCIDE PS200 is also effective for use in controlling microbial growth in fluids used for drilling and stimulation of oil wells.

Water Floods

Tolcide PS200 should be added to a water flood system at a point where uniform mixing will occur.

Initial Treatment: For a noticeably fouled system, add 350-1312.5 ppm TOLCIDE PS200 (70-262.5 ppm THPS). When added to a flowing system, slug dose for 2-6 hours based on flow rates. Repeat as necessary until control is achieved.

Subsequent Treatment: Once control has been achieved, add 52.5-387.5 ppm TOLCIDE PS200 (10.5-73.5 ppm THPS) weekly or as needed to maintain control. When added to a flowing system, slug dose for 2-6 hours based on flow rates.

Continuous Treatment: TOLCIDE PS200 can be dosed continuously at a level of 52.5-250 ppm (10.5-50 ppm THPS).

Oil and Gas Pipelines

TOLCIDE PS200 should be added at a point in the pipeline where uniform mixing will occur.

Slug Dosing: Follow instructions for water flood treatment.

Continuous Dosing: TOLCIDE PS200 can be dosed continuously at a level of 52.5-376 ppm (10.5-75 ppm THPS).

Drilling Muds, Packer Fluids, Completion and Workover Fluids

TOLCIDE PS200 should be added to these fluids at a point where uniform mixing will occur. Add 122.5-5250 ppm of TOLCIDE PS200 (24.5-1050 ppm THPS) to a freshly prepared fluid depending on severity of contamination.

TOLCIDE® is a registered trademark of Rhodia Consumer Specialties Limited.

NET CONTENTS: As Marked on Container

ACCEPTED 340-0501
with COMMENTS
in EPA Letter Dated:

MAY 22 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

4-5-6-4-1-15