

83402-2

3/5/2009

10/8

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 83402-2

Date of Issuance: MAR - 5 2009

Term of Issuance:

Conditional

Name of Pesticide Product:

ZeStat Preservative

NOTICE OF PESTICIDE:

[x] Registration
[] Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Vertellus Health and Specialty Products, LLC
215 N. Centennial Street
Zeeland, MI 49464

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(c) provided that:

- 1. The following five studies listed below are received by the Agency, reviewed and found to be acceptable in order to fulfill the conditions of this Registration:
a. OPPTS Guideline 870.5100 Bacterial Gene Mutation Assay
b. OPPTS Guideline 835.3110 Ready bio-degradability
c. OPPTS Guideline 835.1110 Activated sludge sorption isotherm
d. OPPTS Guideline 850.6800 Activated sludge, respiration inhibition test
e. OPPTS Guideline 850.5400 Algal toxicity

Signature of Approving Official:

[Handwritten Signature]

Date:

MAR - 5 2009

Table with columns for SYMBOL, SURNAME, DATE, and CONCURRENCES. Includes handwritten entries for 'Product Manager Team-31', 'Regulatory Management Branch I', 'Antimicrobials Division (7510P)', '7510P', 'J. Fuchs', and '3/5/09'.

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2. This data must be conducted in accordance with established protocols and submitted to the Agency for review by March 6, 2010.

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

4. If these conditions including the labeling changes which follow are not complied with, this Registration will be subject to cancellation in accordance with FIFRA section 6 (e).

5. Your release for shipment of this product constitutes acceptance of these conditions.

6. Make the labeling changes listed below before you release the product for shipment:

a. Revise the EPA Registration Number to read, "EPA Reg. No. 83402-2".

b. Add a "Physical or Chemical Hazards" heading to the front panel of the label placing the following information in this section: "ZeStat Preservative is a cationic material. Do not mix with soap or other anionic materials."

c. Revise the following statement on the front panel of the label: "An antimicrobial additive for the control of bacteria and fungi (*mold and mildew*) which cause odor, staining and discoloration in industrial applications as specified on this label."

d. Add the following language to the "Precautionary Statements": "...Harmful if swallowed. *Do not get in eyes, on skin or on clothing.* Do not breathe..." and "...protective clothing and a dust/mist filtering respirator (*MSHA/NIOSH approval number prefix TC-21C*), or a *NIOSH approved* respirator with and N-, R-, P or HE filter..."

e. Delete the proposed "Pesticide Disposal" statement and replace with the following language as per the Label Review Manual, chapter 13: "*Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If 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.*"

f. Revise the "Pesticide Storage" section by deleting the following information which is no appropriate for this product: "Do not store in areas accessible to children." A manufacturing use product such as this should never be found in an area accessible to children.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

g. Revise the Warranty Statement to be in agreement with Agency policy. Delete the statement: "Handling, storage and use of this product by buyer or user are beyond the control of Vertellus and seller." Replace with the following statements: "Buyer assumes all risks of use, storage or handling of this material not in strict accordance with direction given herewith. Seller's guarantee shall be limited to the terms of the label, and subject thereto the buyer assumes risk to persons or property arising out of use or handling and accepts the product on these conditions."

h. Revise the first section in the "Directions for Use" to read: "ZeStat Preservative in an antimicrobial powder for industrial use." Also revise the same section to state: "ZeStat Preservative suppresses the growth of bacteria, algae, fungus, mold and mildew which cause odors, staining and discoloration."

i. Revise the third section in the "Directions for Use" to read: "...in-can processes and products listed on this label which do not come in contact with food to control the growth of bacteria and fungi which cause odors, staining and discoloration. For effective..." Also delete the word "Caution" from this section of the label.

j. Revise the Pulp and Paper section of the label to begin as follows: "For non-food contact pulp and paper products specified on this label."

7. Upon completion, submit a one year Storage Stability and Corrosion Characteristics Study to the Agency for review.

8. The submitted data matrix, dated March 5, 2009 has been corrected by changing the Group B chemistry guideline MRID to read 47389202. Make the same correction the matrix in your files and submit a revised hard copy to the Agency via front end processing.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Branch I

CONCURRENCES
Antimicrobials Division (7510P)

SYMBOL							
SURNAME							
DATE	Enclosure: (Stamped Label)						

ZeStat™ Preservative

An Antimicrobial Additive for the Control of Bacteria and Fungi in Industrial Applications as Specified in the Use Directions.

Active Ingredient:

Cetylpyridinium Chloride.....94.8%

Inert Ingredients..... 5.2 %

Total..... 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present after the first 5 minutes, 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 if possible. Call a poison control center or doctor for further treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

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

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9200 (Chemtrec) for emergency medical treatment information.

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

EPA Est. No. _____

Net Contents: _____

EPA Reg. No. _____

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR - 5 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 83402-2

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PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS

Corrosive. Causes irreversible eye damage. May be fatal if inhaled. Causes skin irritation. Harmful if swallowed. Do not breathe dust or spray mist. Wear goggles or face shield, rubber gloves, protective clothing and a dust/mist filtering respirator with any N-, R-, P or HE filter. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing.

ENVIRONMENTAL HAZARDS

This product 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 Systems (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 U.S. Environmental Protection Agency (EPA).

STORAGE AND DISPOSAL

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

Pesticide Storage: ~~Do not store in areas accessible to children.~~ Keep containers covered and away from water and excessive moisture or humidity. Store at ambient temperatures.

Pesticide Disposal: ~~Wastes from use of this product may be disposed of on-site or at an approved disposal facility.~~

Container Disposal: Nonrefillable container. Do not refill or reuse. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY STATEMENT

Vertellus warrants that the 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. To the extent consistent with applicable law, Vertellus makes no other express or implied warranties either of fitness or merchantability for a particular use. ~~Handling, storage and use of the product by buyer or user are beyond the control of Vertellus and seller.~~ Risks such as ineffectiveness or other unintended consequences resulting from, but no limited to, failure to follow label directions will be assumed by the buyer or user. In no case will Vertellus or seller be held liable for consequential, special or indirect damages resulting from the handling, storage or use of the product, to the extent consistent with applicable law.

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DIRECTIONS FOR USE

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

ZeStat™ Preservative is an antimicrobial powder for commercial use. It is designed to be incorporated into materials during the manufacturing process to impart antimicrobial activity to manufactured products. **ZeStat™ Preservative** suppresses the growth of bacteria, algae, fungus, mold and mildew. If microbial activity in the manufactured product could lead to unpleasant odors, discoloration or deterioration of the product, then such a claim may be made for the manufactured product. Manufactured products incorporating **ZeStat™ Preservative** may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product which permits such claims. When incorporated into manufactured products, **ZeStat™ Preservative** does not protect users of any such manufactured product or others against food borne or disease causing bacteria, viruses, germs or other disease causing organisms.

ZeStat™ Preservative may be used in materials that may be incorporated into the manufactured products listed below. The final article (or finished coating for all uses requiring coating type applications) may contain from 0.02% to 0.5% by weight, except as specifically noted.

General Preservative

ZeStat™ Preservative may be used as a preservative (inert ingredient) in water-based products and systems, including industrial, institutional and consumer in-can processes and products which do not come in contact with food to control the growth of bacteria and fungi. For effective preservation, add **ZeStat™ Preservative** in concentrations not to exceed 0.5% by weight of the total formulation, except as noted below. Mix uniformly. ~~Caution~~ **ZeStat™ Preservative IS A CATIONIC MATERIAL. DO NOT MIX WITH SOAP OR OTHER ANIONIC MATERIALS.**

Construction Materials

To increase shelf life and use life of caulking, grouting, and spackling compounds and joint cements add 0.06% to 0.5% **ZeStat™ Preservative** by weight of the formulation. Method of application depends on the type of formulation and may be added as a powder or as an aqueous solution.

Wallboard (Gypsum board)

To protect wallboard from fungal growth, specifically molds and mildew, add 0.01% to 0.1% **ZeStat™ Preservative** based on the dry weight of the gypsum in the board. **ZeStat™ Preservative** can be present in the gypsum core and/or on or in one or both of the paper facings. If needed, a solution of **ZeStat™ Preservative** with a solvent such as water, alcohol or glycol may be used to apply **ZeStat™ Preservative** to the paper facing.

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Paints

To preserve cellulose-thickened latex paints in the can, add 0.05% **ZeStat™ Preservative** by weight of the formulation. Add dry or as an aqueous solution during any step of the formulating process with other aqueous phase ingredients.

Latex Emulsions

To prevent bacterial deterioration during manufacture, transit and storage of raw emulsions, add 0.05% to 0.5% **ZeStat™ Preservative** by weight of the final emulsion. Add as an aqueous solution.

Adhesives

To prevent pH change, odor, change in viscosity and loss of adhesive strength during manufacture, storage and use, add 0.05% to 0.5% **ZeStat™ Preservative** by weight of the formulation. Add to the aqueous phase as the powder or as an aqueous solution.

For use in the following types of adhesives:

Starch-based (corn tapioca, sago, potato, etc.) -- Add 0.01% to 0.2% **ZeStat™ Preservative** by weight as a concentrated aqueous solution.

Protein-derived (animal glues such as hide, bone, fish, blood, and gelatin) -- Add 0.1% to 0.5% **ZeStat™ Preservative** by weight as a concentrated aqueous solution.

Natural Gums (Arabic, guar, and tragacanth) -- Add 0.05 to 0.2% **ZeStat™ Preservative** as a concentrated aqueous solution. Highly concentrated gums do not readily support bacterial or fungal growth; consequently, higher concentrations of product are required in the less concentrated gum solutions.

Natural Rubber Latex -- Add 0.05% to 0.15% **ZeStat™ Preservative** by weight as a concentrated aqueous solution.

Polyvinyl Acetate Emulsions -- Add 0.05% to 0.15% **ZeStat™ Preservative** by weight as a concentrated aqueous solution.

Synthetic Gums (e.g., methylcellulose gums and other synthetic-based adhesives) -- Add 0.05% to 0.15% **ZeStat™ Preservative** by weight as a concentrated aqueous solution.

Floor Wax Emulsions and Floor Polishes

To preserve water-based waxes and polishes during storage, add 0.05% to 0.15% **ZeStat™ Preservative** by weight of the formulation. Add as an aqueous solution.

Inks

To increase the shelf life of fountain pens, fabric and paper printing inks, add 0.15% to 0.2% **ZeStat™ Preservative** by weight of the ink. Add as an aqueous solution.

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Pulp and Paper

For non-food contact pulp and paper products only. To protect coatings, finishes, and printing colors based on starch and latex, both natural and synthetic, from non-public health bacterial and fungal attack. Only for use when these coatings, finishes, and printing colors are applied to the following pulp and paper products: toilet and facial tissue, pulp and or paper products used to make wallboard backing, paperboard, printing paper stock, newsprint, magazine, kraft paper, non-food packaging material, wallpaper, cardboard. Add 0.1% to 0.2% **ZeStat™ Preservative** by weight of the formulation. Add as an aqueous solution. The higher concentration is required for preservation beyond 3 to 6 days.

Textiles

For treatment of textile materials used to make, awnings, carpet backing, cordage, curtains and sails, to prevent spoilage of spinning emulsions for rayon and finishing solutions and to prevent viscosity and pH changes in printing pastes caused by bacteria and fungi. Add 0.1% to 0.2% **ZeStat™ Preservative** by weight of the formulation. Add as an aqueous solution.

Vertellus Health & Specialty Products LLC
215 N. Centennial Street
Zeeland, Michigan 49464
616-772-2193/800-223-0453