

43813-50

0810712009

1/8



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

43813-50

Date of Issuance:

AUG 07 2009

Term of Issuance:

Conditional

Name of Pesticide Product:

Zinc PYRION 48%
Aqueous Dispersion
Industrial Microbiostat

NOTICE OF PESTICIDE:

[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

William R. Goodwine
Janseen Pharmaceutica Inc.
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

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)(a) provided that you:

- 1. Submit and/or cite all data required for registration 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.
2. Make the labeling changes listed below before you release the product for shipment:
a. Revise the "EPA Registration Number to read, "EPA Reg. No. 43813-50".

Signature of Approving Official:

[Handwritten signature: M. Swindell]

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:

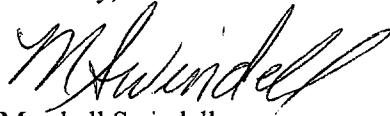
AUG 07 2009

Page 2
EPA Reg. No. 43813-50

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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 Demson Fuller at (703) 308-8062.

Sincerely,



Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: (Stamped Label)

ZINC PYRION® 48% AQUEOUS DISPERSION INDUSTRIAL MICROBIOSTAT

Active Ingredient:
 Zinc, 2-pyridinethiol-1-oxide 48.0%
Inert Ingredients: 52.0%
 Total: 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID	
If swallowed	-Call a poison control center or doctor immediately for treatment advice. -Have person sip a glass of water if able to swallow. -Do not induce vomiting unless told to do so by a poison control center or doctor. -Do not give anything by mouth to an unconscious person.
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 on skin or clothing	-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 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.
<p align="center">HOT LINE NUMBER:</p> <p>For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents) call the National Pesticide Telecommunications Information Center at 1-800-858-7378. For chemical emergency assistance (spill, leak, fire, or accident), call Chem Trec at 1-800-424-9300.</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p align="center">NOTE TO PHYSICIAN</p> <p>Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

Net Wt

EPA Reg. No.: 43813-

EPA Est. No.:

Manufactured for:

JANSSEN PMP
 a Division of Janssen Pharmaceutica NV
 1125 Trenton-Harbourton Road
 Titusville, NJ 08560

ACCEPTED
WITH COMMENTS
 in EPA Letter Dated
AUG 07 2009

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 registration of this pesticide is
 required by the EPA Administrator

43813-50

PRECAUTIONARY STATEMENTS:

ACCEPTED
 With COMMENTS
 In EPA Letter Dated
 AUG 07 2009
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 43813-50

HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER

Corrosive. Causes irreversible eye damage. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Do not breathe spray mists. Users must wear protective eyewear (goggles, safety glasses, or face shield), long sleeved shirt and long pants, socks, chemical resistant gloves and chemical resistant footwear. Users must wear a fit tested, NIOSH approved full-face respirator equipped with a combination organic vapor/P-100 prefilter. When mixing and loading, or cleaning equipment, wear a chemical resistant apron. Wash thoroughly after handling with soap and water, and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

CHEMICAL HAZARDS

Do not store or mix with strong oxidizing agents or strong (concentrated) acids. In case of contamination do not reseal container. If possible, isolate container in open or well-ventilated area. Fumes caused by contamination may be hazardous.

ENVIRONMENTAL HAZARD

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, ponds, streams, 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 our State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Do not freeze. Store above 50 degrees F. Keep container tightly closed when not in use. Do not store with strong oxidizing agents or strong (concentrated) acids.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticides, 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. Do not reuse empty container.

CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Offer for recycling if available 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. 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.

DIRECTIONS FOR USE

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

A minimum cost effective use level recommendation can only be established through testing of a specific formulation intended for use in a specific application. Formulations differ in their composition and as a result, of their susceptibility to microbial attack. Conditions of use and the performance expectations differ from product to product. For example, a warranted high performance preserved product that is under consideration for use in severe tropical environments is likely to need a high dose of biocide. Testing at biocide use levels would be recommended at 3000, 4000 and 5000 ppm. As the product adds cost to the formulation and as performance requirements need to be met, laboratory and field tests are conducted to establish the antimicrobial performance of this product. An unwarranted preserved product that is not intended for use in severe environments would likely need a lower dose. Again, a recommendation would be made for testing at lower concentrations based on formulation, performance and cost considerations. We recommend that users contact Janssen PMP for formulation assistance.

DRY FILM PRESERVATION: THIS PRODUCT PROTECTS THE APPLIED DRY FILM ITSELF AND DOES NOT PROTECT THE UNDERLING SURFACE FROM ATTACK BY ALGAE, FUNGI, MILDEW OR BACTERIA.

For the Dry Film Preservation of Flooring, Adhesives, Caulks, Sealants, Grouts and Patching Compounds

Flooring Adhesives: For the control of fungi causing stains, odor or film degradation, add 1500 ppm of this product; for control of bacteria causing stain, odor and/or degradation of the physical properties of the film, add 4800 ppm. (Add 1.5 lbs. of this product to 1000 lbs. of adhesive to control these fungi and add 4.8 lbs. per 1000 lbs. of adhesive to control these bacteria).

Caulks/Sealants: For the control of fungi causing stains, odor or film degradation, add 4100 ppm of this product; for control of bacteria causing stain, odor and/or degradation of the physical properties of the film, add 10,000 ppm of this product. (Add 4.1 lbs. of this product per 1000 lbs. of caulk/sealant to control these fungi, add 10 lbs. of this product to control these bacteria).

Grouts/Patching Compounds: For the control of fungi causing stains, odor or film degradation, add 2000 ppm of this product; for control of bacteria causing stain, odor and/or degradation of the physical properties of the film, add 8000 ppm of this product. (Add 2 lb. of this product to 1000 lbs. of grouts/patching compounds to control these fungi and 8 lbs. of this product to control these bacteria).

ACCEPTED
 WITH COMMENTS
 MRLA Letter Dated
 AUG 07 2009

Under the Federal Insecticide,
 Fungicide, and Plant Growth Regulator Act and
 amended, for the...
 registered under...

43813-50

For the Dry Film Preservation of Aqueous Latex and Other Types of Architectural and Industrial Non-Marine Paints and Coatings:

Addition of up to 10000 ppm of this product can inhibit the growth of algae, bacteria causing stain, odor or degradation of the physical properties of the film, and fungi causing stains, odor or film degradation. It can be added at any time during the formulation procedure. For example, the dry film of a house paint having a density of 10 lbs. per gallon can be protected against the growth of these bacteria, fungi, and algae by the addition of 10000 ppm of this product. (Add 10 lbs. of this product to 100 gallons of wet paint).

For the Dry Film Preservation of Residential Latex Paints:

Use a minimum of 5000 ppm of this product. For maximum protection against the growth of algae and/or fungi causing stains, odor or film degradation, use 10000 ppm of this product. For control of bacteria, causing stain, odor or degradation of the physical properties of the dry paint film surface, use 5000 ppm of this product. (Add a minimum of 5 lbs. of this product to 100 gallons of wet paint, with a density of 10 lbs. per gallon, to control these fungi, bacteria, or algae. Add a maximum of 10.0 lbs. of this product to 100 gallons.)

For the Dry Film Preservation of Joint Compounds, Glazing Compounds and Wood Fillers:

Addition of up to 10000 ppm (10.0 lbs. of this product per 1000 lbs. of formulation) of this product will inhibit the growth of fungi causing stains, odor or film degradation, and bacteria causing stain, odor or degradation of the physical properties of the dry film. This product can be added at any time during the formulation procedure.

For the Control of Mildew and Bacteria in Styrene Butadiene Rubber and Thermoplastic Resins Used in the Manufacture of the Following Products:

Carpet Fibers; Carpet Backings; Rubber or Rubber Backed Bath Mats; Foam Underlay for Carpets; Synthetic, Non-Leather Materials; Foam Stuffing for Cushions and Mattresses; Wire and Cable Insulation; Vinyl, Linoleum and Synthetic Floor Coverings; Wall Coverings; Plastic Furniture; Athletic Flooring and Mats; Mattress Liners, Covers or Ticking; Molding; Mats; Gaskets; Weather Stripping; Coated Fabrics for Furniture Cushions, Boat Covers, Tents; Tarpaulins; Awnings; Non-Surgical Rubber Gloves; Garbage Bags, Refuse Containers; Bathtub Appliqués; Garden Hose; Non-Potable Water Pipe; Ductwork for industrial, hospital, or residential and commercial heating and cooling; Shower Curtains; Sponge or Fiber Mops; Household Use Sponges; Toilet Brush Receptacles, Toothbrush Receptacles (Non Bristle Contact); Non-Medical Scrub Brushes; Sink Mats and Drain Boards; Storage Containers; Soap Dish Holders; Towel Bars and Components of Footwear.

Addition of up to 8000 ppm (8 lbs./1000 lbs. of formulation) of this product can inhibit the growth of fungi causing stains, odor or product degradation and bacteria causing stain, odor or degradation of physical properties in styrene butadiene rubber & thermoplastic resins such as vinyl chloride-vinyl acetate copolymers, polyurethanes, polyamides, polyolefins, polystyrene, polyesters and acrylonitrile copolymers. It can be added at a time during the formulation procedure that will ensure uniform distribution throughout the polymer system. Add by pouring or by use of metering equipment. For example, to inhibit these fungi in polyurethane footwear components, add 8000 ppm (4 lbs./1000 lbs. of formulation) of this product to the polyurethane for footwear.

Comments
Date
AUG 07 2009

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

For the In Can Preservation of Latex Emulsions, Clay, Mineral, Pigment and Guar Gum Slurries Used In the Manufacture of Adhesives, Caulks, Patching Compounds, Sealants and Grouts:

A dosage of up to 10000 ppm is recommended to control fungi causing stain, odor or and product degradation and bacteria causing stain, odor or degradation of physical properties. This dosage is equivalent to 10 lbs. of this product per 1000 lbs. of slurry. It may be added at any time during the formulation procedure.

For the Preservation of Dry Wall, Gypsum, Pearlite, Plaster-Like, Mineral Based, or Cellulose Derived Building Materials Used in the Manufacture of Ceilings, Ceiling Tile, Walls and Partitions:

Addition of up to 8000 ppm of this product (8 lbs. of product per 1000 lbs. of the formulation, i.e. wet slurry) will inhibit the growth of fungi causing stain, odor, and product degradation and bacteria causing stain, odor or degradation of physical properties. It can be added at any time during the formulation procedure. Alternatively the product may be added to latex or other types of coating systems routinely applied to the surfaces of walls, ceiling tiles, partitions, etc. at the same dosage as above.

Laundered Fabrics: To inhibit the growth of fungi causing stain, odor, or product degradation and bacteria causing stain, odor or degradation of physical properties of natural and synthetic fabrics, including polyamide, nylon, polypropylene, polyethylene, polyesters, wool, polybenzimidazole, polyparaphenylene phthalamides, cellulose and blends of these polymers, add 6-18 ounces of this product per 1000 lbs. dry weight of fabric, at a sour density of 8.3 pounds per gallon, to reach a use level of 38-112 ppm. Apply to the sour operation and run for a minimum of five minutes. Product is to be used in industrial applications. Product is not intended for use in residential, commercial or institutional settings.

INDIRECT FOOD CONTACT USES:

For the Preservation of Adhesives Used for Food Packaging:

For the control of fungi causing stain, odor, or product degradation and bacteria causing stain, odor or degradation of physical properties in food packaging adhesives, at use temperatures up to 120°F, and subject to Good Manufacturing Practices, including the conditions specified in 21 CFR 175.105 (a) and (b), add a dosage of 1500 ppm to a maximum of 2000 ppm of this product (1.5 to 2.0 lb. of this product per 1000 lbs. of food packaging adhesive) at a point where thorough mixing will take place.

NOTICE OF WARRANTY

Janssen PMP, a Division of Janssen Pharmaceutica NV warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with the directions under normal use conditions. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Janssen PMP. To the extent permitted by law, Janssen PMP disclaims any liability for consequential, special or indirect damages resulting from the use, handling, application, storage or disposal of this product or for damages in the nature of penalties, and the buyer and user waive any right that they may have to such damages. **To the extent consistent with applicable law, Janssen PMP makes no warranties of merchantability or of fitness for a particular use, other express or implied warranty except as stated above.**

Letter Dated

AUG 07 2009

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

117 217 50

