

43813-45

12/9/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

DEC - 9 2008

Janssen PMP
a Division of Janssen Pharmaceutical NV
1125 Trenton-Harbourton Road
Titusville, N. J. 08560-0200

Attention: William R. Goodwine, Director
Regulatory Affairs and Product Development

Subject: Zinc PYRION Powder Industrial Microbiostat
EPA Registration No. 43813-45
Notification Dated November 4, 2008

This will acknowledge receipt of your notification of label change per PR Notice 2007-4 and PR Notice 83-3, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The Notification dated November 4, 2008 is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

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 (7510P)



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

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EPA	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration	OPP Identifier Number
		<input type="checkbox"/> Amendment	
		<input checked="" type="checkbox"/> Other	

Application for Pesticide - Section I

1. Company/Product Number 43813-45	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Zinc PYRION Powder Industrial Microbiostat	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Janssen PMP, a Division of Janssen Pharmaceutica NV 1125 Trenton-Harbourton Road Titusville, NJ 08560-0200 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label change per PR Notice 2007-4 and PR Notice 83-3. This notification is consistent with the guidance in PR Notice 2007-4, PR Notice 83-3, and EPA regulations at 40 CFR 152.10, 156.140, 156.144, 156.146, & 156.156. No other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with 40 CFR 152.10, 156.140, 156.144, 156.146, & 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted				Other (Specify) Fiber drum/plastic liner	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 55 lbs (25 kg)	5. Location of Label Directions <input checked="" type="checkbox"/> ON LABEL			
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name William R. Goodwine	Title Sr. Director, Reg. Affairs & Product Dev.	Telephone No. (Include Area Code) (609) 730-2607
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>William R. Goodwine</i>	3. Title Sr. Director, Regulatory Affairs & Product Development	
4. Typed Name William R. Goodwine	5. Date Nov. 4, 2008	

ZINC PYRION® POWDER INDUSTRIAL MICROBIOSTAT

Active Ingredient:
 Zinc pyrithione (Zinc, 2-pyridinethiol-1-oxide) 99.6%
Inert Ingredients: 0.4%
 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 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 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.
HOT LINE NUMBER:	
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.	
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.	

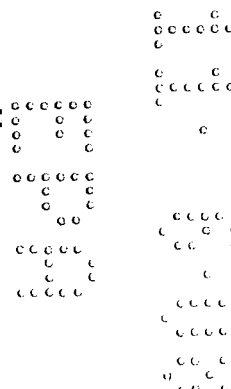
Net Wt.

EPA Reg. No.: 43813-45

EPA Est. No.:

Manufactured for:

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



PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes irreversible eye damage. May be fatal if swallowed. Harmful if absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Do not breathe dust. 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 with soap and water after handling, and before eating, drinking or using tobacco. Remove and wash contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARD

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, ponds, streams, estuaries, oceans or public 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.

CHEMICAL HAZARDS

Handling conditions may form dust clouds, which are susceptible to ignition by electrical (static) discharge. Ground container and personnel before transferring material. 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.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not store above 100°F. Keep container tightly closed when not in use. Do not store with strong oxidizing agents or strong (concentrated) acids.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then offer for recycling if available or dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

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. A warranted high performance preserved product, for example, 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.

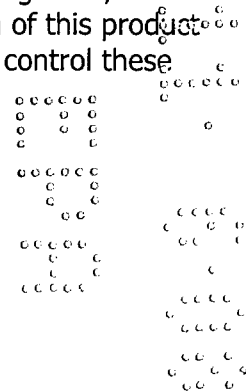
DRY FILM PRESERVATION: THIS PRODUCT PROTECTS THE APPLIED DRY FILM ITSELF, AND DOES NOT PROTECT THE UNDERLYING SURFACE FROM ATTACK BY ALGAE, FUNGI, OR BACTERIA.

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 750 ppm of this product; for control of bacteria causing stain, odor and/or degradation of the physical properties of the film, add 2400 ppm (add 0.75 lbs. of this product to 1000 lbs. of adhesive to control these fungi or add 2.4 lbs. per 1000 lbs. of adhesive to control these bacteria.)

Caulks/Sealants: For the control of fungi causing stains, odor or film degradation, add 2083 ppm of this product; for control of bacteria causing stain, odor and/or degradation of the physical properties of the film, add 5000 ppm of this product (add 2.083 lbs. of this product per 1000 lbs. of caulk/sealant to control these fungi or add 5.0 lbs. of this product to control these bacteria.)

Grouts/Patching Compounds: For the control of fungi causing stains, odor or film degradation, add 1000 ppm of this product; for control of bacteria causing stain, odor and/or degradation of the physical properties of the film, add 4000 ppm of this product (add 1 lb. of this product to 1000 lbs. of grouts/patching compounds to control these fungi or 4 lbs. of this product to control these bacteria.)



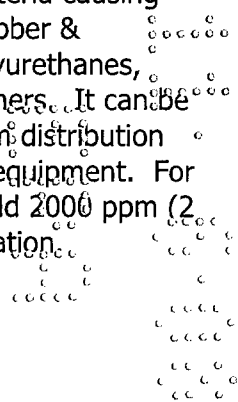
For the Dry Film Preservation of Architectural and Industrial Non-Marine Paints and Coatings: Addition of up to 5000 ppm of this product can inhibit the growth of algae, bacteria causing stain, odor or degradation of the physical properties of the film, and fungi causing stains, odor or film degradation. 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 5000 ppm of this product. (Add 5 lbs. of this product to 100 gallons of wet paint.)

For the Dry Film Preservation of Residential Paints: Use a minimum of 2500 ppm of this product. For maximum protection against the growth of algae and/or fungi causing stains, odor or film degradation, use 5000 ppm of this product. For control of bacteria, causing stain, odor or degradation of the physical properties of the dry paint film surface, use 2500 ppm of this product. (Add a minimum of 2.5 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 5.0 lbs. of this product to 100 gallons.)

For the Dry Film Preservation of Joint Compounds, Glazing Compounds and Wood Fillers: Addition of up to 5000 ppm (5.0 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 Preservation of 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, air filters, air filtration components and air filtration media for industrial, hospital, residential, and commercial heating and cooling; conveyor belts; 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 4000 ppm (4 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 insure 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 2000 ppm (2 lbs./1000 lbs. of formulation) of this product to the polyurethane formulation.



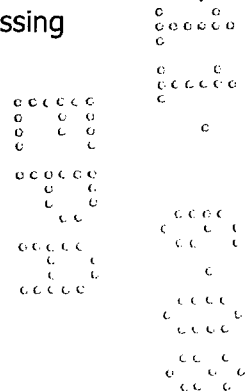
For the In Can Preservation of Latex Emulsions, Clay, Mineral, Pigment and Guar Gum Slurries Used in the Manufacture of Adhesives, Caulks, Patching Compounds, Sealants and Grouts: A dosage of up to 5000 ppm is recommended to control fungi causing stain, odor or and product degradation and bacteria causing stain, odor or degradation of physical properties. This dosage is equivalent to 5 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 4000 ppm of this product (4 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 fabrics, including nylon, polypropylene, polyethylene, polyesters, cellulose and blends of these polymers, add 3-9 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 19-56 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:

Food Contact Surfaces Made from Polymers: For the control of fungi causing stain, odor, or product degradation and bacteria causing stain, odor or degradation of physical properties in polymers used in food contact, add 750 ppm to a maximum of 1000 ppm of product (0.75 to 1.0 lbs. of this product per 1000 lbs. of polymer) at a point where thorough mixing will take place. Do not incorporate this product into any food contact polymer unless the subject food contact polymer is approved and listed in 21 CFR, Parts 174 through 186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System". Restricted to use applications at or below room temperature. Any incorporation of this product into any food contact substance (including but not limited to non-polymer substances) other than an approved and listed food contact polymer is prohibited. For incorporation into articles made from, or coated with FDA approved polymers. Applications include food processing equipment, conveyor belts, utensils, and storage containers.



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 750 ppm to a maximum of 1000 ppm of this product (0.75 to 1.0 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 purpose or any other express or implied warranty except as stated above.**

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PMP 11/08

