

04/27/2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460United States  
Environmental Protection  
AgencyOffice of Pesticide ProgramsJanssen PMP, a Division of Janssen Pharmaceutica NV  
1125 Trenton-Harbouton Road,  
Titusville, NJ  
08560

APR 27 2011

Attention: William R. Goodwine

**Subject: Zinc PYR ION ® 48% Aqueous Dispersion Industrial Microbiostat**  
EPA Registration No: 43813-50  
Notification Dated March 21, 2011

This will acknowledge receipt of your notification to update the container handling statement per PR Notice 2007-4 and make other minor changes to the product label, submitted under the provision of FIFRA Section 3(c)(9).

**Proposed Notification:**

- To add the following statements under the direction of use

**General Comments:**

Based on a review of the submitted material, the following comments apply:

The Notification dated March 15, 2011 is acceptable, to add the following statements under the Directions for use. **“natural fiber”**, **“Toilet Seats”**, and **“Rubber Bands”**, **“ other non-food contact”** and to include powder coatings. A stamped copy of the label is enclosed.

If you have any questions concerning this letter, please contact Zebora Johnson at (703) 308-7080.

Sincerely

Marshall Swindell  
Product Manger (33)  
Regulatory Management Branch I  
Antimicrobial's Division (7501P)

Please read instructions on reverse before completing form.

Form Approved. O. No. 2070-0060

Print Form

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

**Application for Pesticide - Section I**

<b>1. Company/Product Number</b> 43813-50	<b>2. EPA Product Manager</b> Marshall Swindell	<b>3. Proposed Classification</b> <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
<b>4. Company/Product (Name)</b> Zinc PYRION 48% Aqueous Dispersion Ind. Microbiostat	<b>PM#</b> 33	
<b>5. Name and Address of Applicant (Include ZIP Code)</b> Janssen PMP, a Division of Janssen Pharmaceutica NV 1125 Trenton-Harbourton Road, Titusville, NJ 08560  <input type="checkbox"/> Check if this is a new address		<b>6. Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 1258-841  Product Name Zn Omadine 48% Aq. Disp. Ind. Microbiost

**Section - II**

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


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

Notification per PRN 98-10: 1) add "natural fiber" to Directions for Use, 2) add "toilet seats" & "rubber bands" to use site for use in treated articles made from Rubber & Plastics, 3) clarify dry film preservation as "other non-food contact" and to include powder coatings.

**Section - III**

<b>1. Material This Product Will Be Packaged In:</b>				<b>2. Type of Container</b>	
<b>Child-Resistant Packaging</b> <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	<b>Unit Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Water Soluble Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) <u>HDPE</u>
* Certification must be submitted		If "Yes" Unit Packaging wgt.    No. per container	If "Yes" Package wgt    No. per container		
<b>3. Location of Net Contents Information</b> <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		<b>4. Size(s) Retail Container</b> 66 lbs. (30 kg)		<b>5. Location of Label Directions</b> <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
<b>6. Manner in Which Label is Affixed to Product</b>				<input checked="" type="checkbox"/> Lithograph Paper glued Stenciled <input type="checkbox"/> Other _____	

**Section - IV**

<b>1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</b>		
<b>Name</b> William R. Goodwine	<b>Title</b> Director, WW Reg. Affairs	<b>Telephone No. (Include Area Code)</b> (609) 730-2607
<b>Certification</b> 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 or both under applicable law.		<b>6. Date Application Received (Stamped)</b>
<b>2. Signature</b> 	<b>3. Title</b> Director, WW Reg. Affairs	
<b>4. Typed Name</b> William R. Goodwine	<b>5. Date</b> March 21, 2011	



March 21, 2011

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

ATTN: Mr. Marshall Swindell (Product Manager – Team 33)

SUBJECT: Notification  
Zinc PYRION® 48% Aqueous Dispersion Industrial Microbiostat  
Reg. No. 43813-50

Dear Mr. Swindell:

Janssen PMP, a Division of Janssen Pharmaceutica NV is submitting the enclosed Notification for Zinc PYRION 48% Aqueous Dispersion Industrial Microbiostat, Reg. No. 43813-50. The Notification is submitted as per PR Notice 98-10 to:

- Add “natural fiber” to Directions for Use
- Add “Toilet Seats” & “Rubber Bands” to use site for use in treated articles made from Rubber & Plastics
- Clarify Dry Film Preservation as “other non-food contact” and to included powder coatings.

These changes appear on the Zinc Omadine 48% Aqueous Dispersion Industrial Microbiostat label, Reg. No. 1258-841 and were previously added to the label by notification.

Please contact me directly on all matters pertaining to this action.

Sincerely,

William R. Goodwine  
Sr. Director, Regulatory Affairs & Product Development  
Preservation & Material Protection Division  
Tel: 609/730-2607; Fax: 609/730-2202  
Email: [bgoodwi@its.jnj.com](mailto:bgoodwi@its.jnj.com)

Handwritten notations consisting of small circles and lines, possibly initials or a signature, located on the right side of the page.

4/9

# ZINC PYRION® 48% AQUEOUS DISPERSION INDUSTRIAL MICROBIOSTAT

Active Ingredient:  
 Zinc pyrithione,  
 Zinc, 2-pyridinethiol-1-oxide 48%  
Inert Ingredients: 52%  
 Total: 100%

**KEEP OUT OF REACH OF CHILDREN**

## DANGER

FIRST AID	
<b>If swallowed</b>	-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.
<b>If in eyes</b>	-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.
<b>If on skin or clothing</b>	-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.
<b>If inhaled</b>	-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><b>HOT LINE NUMBER:</b>            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><b>NOTE TO PHYSICIAN</b>            Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

Net Wt

EPA Reg. No.: 43813-50

EPA Est. No.:

Manufactured for:

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

ACCEPTED  
 with COMMENTS  
 EPA Letter Dated:  
 APR 27 2011

Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act as  
 amended, for the pesticide,  
 registered under EPA Reg. No. 43813-50

8/9

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

APR 27 2011

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 43813-5

**PRECAUTIONARY STATEMENTS:**

**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, chewing gum, using tobacco, or using the toilet. 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 HAZARDS**

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 your 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. Clean up spills immediately. Contain and absorb spills with inert material such as sand, calcium carbonate, clay or sawdust. Collect absorbed material by sweeping or shoveling into an appropriate waste disposal container. Wash spill area with water and absorb wash water in the same manner. Do not contaminate waterways. Dispose of waste in a manner approved by Local authorities. Avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes.

**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 promptly after emptying. Triple rinse as follows:

[For containers ≤ 5 gallons in size] – Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[For containers > 5 gallons in size] - Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ 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.

Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

ACCEPTED  
with COMMENTS  
EPA Letter Dated:  
APR 27 2011

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 43 813-50

.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....

**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.

**TEXTILES:** For the control of odor causing microorganisms on textiles made of natural and synthetic fibers, such as polyester and blends, add Zinc PYRION 48% Aqueous Dispersion Industrial Microbiostat at use rates such that the finished textile contains 0.14% - 0.71% by weight of this product.

The following are examples of textile products (substrates) suitable for finishing with Zinc PYRION 48% Aqueous Dispersion Industrial Microbiostat:

- Wearing apparel – work-wear, uniforms, sportswear, slacks, shirts, underwear, sweatshirts, sweatpants, socks, oven mitts, slippers, bathrobes, gloves, hats, scarves, jackets, incontinence pad cover stock, and washable incontinence briefs and panties.
- Household products – upholstery, curtains, wall coverings, mops, dishcloths, yarns, cords, towels, blankets, sheets, pillowcases, and non-food contact synthetic wipes, tissues and sponges.
- Seats and seat coverings (for transportation vehicles – auto, boat, train, plane).

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

**For the Dry Film Preservation of Flooring and Other Non-Food Contact 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 stains, 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 stains, 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 per 1000 lbs. of caulk/sealant 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 stains, 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 1000 lbs. of grouts/patching compounds to control these bacteria).

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

APR 27 2011

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

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

Addition of up to 10000 ppm of this product can inhibit the growth of algae and bacteria causing stains, 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 stains, 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 stains, 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:** Rubber Bands; 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, Components of Footwear and Toilet Seats.

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 stains, 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 4000 ppm (4 lbs./1000 lbs. of formulation) of this product to the polyurethane formulation.

**For the In Can Preservation of Latex Emulsions, Clay, Mineral, Pigment and 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 stains, odor and product degradation and bacteria causing stains, 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 stains, odor, and product degradation and bacteria causing stains, 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.

REGISTERED  
with DOCUMENTS  
EPA dated:

APR 27 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 49813-5D



**Laundered Fabrics:** To inhibit the growth of fungi causing stains, odor, or product degradation and bacteria causing stains, 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 stains, odor, or product degradation and bacteria causing stains, 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 purpose or any other express or implied warranty except as stated above.**

® PYRION is a registered trademark of Janssen Pharmaceutica NV

PMP 03/21/2011

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

APR 27 2011

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 43813-5D

