



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

November 14, 2016

William Goodwine  
Director, Regulatory Affairs  
Janssen PMP  
1125 Trenton-Harbourton Road  
Titusville, NJ 08560

Subject: Label Amendment – Adding examples, intermediate directions, and textile uses  
Product Name: Zinc PYRION Powder Industrial Microbiostat  
EPA Registration Number: 43813-45  
Application Date: 10/14/16  
Decision Number: 522665

Dear Mr. Goodwine:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

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

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with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at [heffernan.aline@epa.gov](mailto:heffernan.aline@epa.gov).

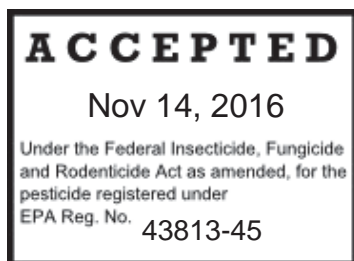
Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao".

Julie Chao, Product Manager 33  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: Accepted Label

# ZINC PYRION® POWDER INDUSTRIAL MICROBIOSTAT



Active Ingredient:		
Zinc pyrithione (Zinc, 2-pyridinethiol-1-oxide)	99%	
Inert Ingredients:	1%	
Total:	100%	

**KEEP OUT OF REACH OF CHILDREN**

## DANGER

<b>FIRST AID</b>	
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>-Call a poison control center or doctor immediately for treatment advice.</li> <li>-Have person sip a glass of water if able to swallow.</li> <li>-Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>-Do not give anything by mouth to an unconscious person.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>-Take off contaminated clothing.</li> <li>-Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>-Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>-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.</li> <li>-Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>-Move person to fresh air.</li> <li>-If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>-Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>HOT LINE NUMBER:</b>	
<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>	
<b>NOTE TO PHYSICIAN</b>	
<p>Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

Net Contents:

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 (i.e., goggles, safety glasses, or face shield) and protective clothing, including long sleeved shirt, long pants, socks, chemical resistant gloves, and chemical resistant footwear. Users must also wear a fit tested, NIOSH approved full-face respirator equipped with a combination organic vapor/P-100 pre-filter. When mixing and loading, or cleaning equipment, wear a chemical resistant apron. Remove and wash contaminated clothing immediately after use. Wash thoroughly with soap and water after handling, and before eating, drinking, or using tobacco.

**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 additional guidance on discharge of effluents containing this product contact your State Water Board or Regional Office of the EPA.

**CHEMICAL HAZARDS**

Handling conditions may form dust clouds that are susceptible to ignition by electrical (static) discharge. Ground the 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 and store container in open or well-ventilated area. Fumes caused by contamination may be hazardous.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or 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. Contact state and local waste authorities to obtain additional information on proper container disposal methods.

## **DIRECTIONS FOR USE**

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

**Overview:** Zinc PYRION Powder Industrial Microbiostat is an antimicrobial product for use in manufacturing of treated articles and substances. Zinc PYRION Powder Industrial Microbiostat is designed for commercial and industrial use. Zinc PYRION Powder Industrial Microbiostat suppresses the growth of bacteria, algae, yeasts, fungi, molds and mildew in treated substrates. Users should contact Janssen PMP to obtain assistance regarding appropriate concentrations for specific product applications.

Articles and substances containing Zinc PYRION may contain claims related to prevention, avoidance, and or mitigation of unpleasant odors, discoloration, or deterioration caused by antimicrobial activity in or on the treated article or substance, e.g., contains built-in antimicrobial product protection. Articles and substances incorporating Zinc PYRION Powder Industrial Microbiostat may not make any public health claims relating to control of antimicrobial activity without first obtaining an EPA registration. Zinc PYRION Powder Industrial Microbiostat also does not protect the product's users or others from food borne or disease causing organisms. Technical Bulletins that accompany treated articles and substances intended for further processing should identify the Zinc PYRION content so that finished products do not exceed permitted use levels. For further guidance on treated article claims, please refer to 40 C.F.R. § 152.25(a) and any additional guidance or policies issued by the U.S. Environmental Protection Agency.

Treated articles and substances incorporating Zinc PYRION Powder Industrial Microbiostat differ in composition, conditions of use, susceptibility to attack and performance expectations. Dose range tests up to the maximum permitted use rate are recommended to establish the most effective dose prior to commercial use.

## **PROTECTION OF FINISHED PRODUCTS**

Zinc PYRION Powder Industrial Microbiostat can be used as an antimicrobial additive to protect articles and substances at levels consistent with their listing below.

### **NON-FOOD CONTACT USES:**

#### **For the Preservation of Textiles Made of Natural and Synthetic Fibers, Fabrics and Blends:**

**Laundered Fabrics:** To inhibit the growth of microorganisms causing stain, odor, or product degradation, including degradation of physical properties of fabrics, such as 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, military, and related applications. The following are examples of laundered fabric products suitable for incorporation of Zinc PYRION Powder Industrial Microbiostat: hygienic next-to-skin clothing, uniforms, and underwear; bedding (e.g., sleeping bags, blankets, and pillow cases); and protective clothing such as gloves, helmet liners, and footwear components; used in military and related applications. For industrial use only; this use is not intended for residential, commercial, or institutional settings.

**Textiles:** To inhibit the growth of microorganisms causing stain, odor, and product degradation, including degradation of physical properties of textiles. Apply at rates such that the finished product contains 0.07 to 0.34% by weight of this product. Refer to the table below for textile products suitable for finishing with this product. Applying Zinc PYRION Powder Industrial Microbiostat to textiles via an intermediate formulation of Zinc PYRION Powder Industrial Microbiostat and dyes, bonding agents, and other substances requires obtaining an EPA registration for the formulation.

**For the In-Can Preservation of Solutions, Emulsions, and Dispersions, and 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 microorganisms causing stain, odor, or product degradation including 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 microorganisms causing stain, odor, and product degradation, including degradation of physical properties.

**PROTECTION OF FINISHED PRODUCTS AND INTERMEDIATE CONCENTRATES:**

Zinc PYRION Powder Industrial Microbiostat can also be used as an antimicrobial additive in (1) finished products and formulations listed below at levels consistent with their listing; and (2) intermediate concentrations up to 25% by weight (250 lbs. of product per 1000 lbs. (*i.e.*, as a master batch) in substrates intended for further processing in an industrial environment into the finished products and formulations listed below consistent with the permitted finished product concentration. This rate applies only to intermediate manufacturing/industrial uses.

**NON-FOOD CONTACT USES:**

**For the Preservation of Rubber and Plastics Used in the Manufacture of the following Products:**

Addition of up to 4000 ppm (4 lbs./1000 lbs. of formulation) of this product can inhibit the growth of microorganisms causing stains, odor or product degradation, including degradation of physical properties in rubber (such as natural, ethylene propylene diene monomer, styrene butadiene, acrylonitrile butadiene, silicone and other elastomer rubber compounds), styrene based polymers (such as acrylonitrile butadiene, polystyrene, styrene acrylonitrile and others) and plastic resins and blends, including but not limited to vinyl chloride-vinyl acetate copolymers, polyurethanes, polyamides, polyolefins, polyesters, polycarbonate, 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.

<b>Plastics, Foam, Films, Coatings and Laminates</b>	
Appliances (non-food contact) and touch surfaces of food contact appliances	Kitchen and bathroom hardware and fixtures: towel bar/racks, toilet brush receptacles, tooth brush receptacles, soap dishes, dish drainer, bath seats, soap dispenser, paper towel dispenser, bath seats, splash guards & screens
Automotive and vehicular parts	Liners
Awnings	Litter boxes
Bags, including garment, garbage, bedding, and vacuum cleaner bags	Luggage
Barrier fabric	Mats, incl. yoga, exercise, door mats, sink and bathtub mats, placemats, and drain boards.
Bed pans, spit cups, wash basins, commodes	Molding
Blinds, window/picture frames	Mops, mop boards
Broom and brush handles and bristles (non-medical), excluding toothbrush bristles, combs	Packaging materials
Building materials and components (excluding roofing shingles), residential and commercial siding, trim, wood plastic composite products	Paper products - wipes and tissues (excluding baby and cosmetic wipes), wall covering, towels, book covers)
Buckets	Plastic film
Carpet padding, backing and foam underlay	Plumbing supplies and fixtures
General Purpose Cart and Cart linings or sealants.	Portable toilets
Collection and storage containers and equipment (including piping systems, silos, tanks and processing vessels)	Protective covers, table cloths
Containers, general purpose and cosmetics	Razor handles
Conveyor belts	Refuse containers: waste baskets, garbage cans, garbage bags
Counter and table tops	Respirator components
Credit, debit and membership cards	Railings, grab bars, pulls and handles
Crutches, canes, walkers, wheel chairs,	Rubber/wood flour composite



transfer benches & boards	
Dental & orthodontic appliance cases for retainers, aligners, mouth guards, bleaching trays , toothbrushes	Rubber gloves (non-surgical)
Ear plugs	Sharps containers
Films for fabrics	Shopping carts, baskets and handles
Fixtures, switches, switch/push plates	Shower curtains
Floor drains	Sinks, toilets, bathtubs, showers
Floors and Floor covering (vinyl, linoleum and other synthetics)	Sponges
Foam filters	Sports/physical therapy equipment: helmets, handles, weights, exercise machine components, lockers, massage tables
Foam Insulators and weather stripping	Stuffing for cushions and mattresses
Footwear and footwear components	Swimming pool and spa construction material/liners, and equipment
Furniture, Beds	Tape
Gas filters	Tarpaulins, vehicle and boat covers
Gaskets	Tools
Grease traps	Trays, general purpose and medical/dental
Hand dryers	Tubing, hoses, pipes (non-potable water and non-food items), drainage & sewer, garden hoses
Industrial equipment	Water containers, non-potable
Insulation for wire and cable	Weather stripping
	Writing instruments, and office supplies

<b>Textiles – natural and synthetic fibers, fabrics and blends</b>	
Apparel: uniforms, outerwear, gloves, aprons, coats, sportswear, sleepwear, stockings, socks, hosiery, caps, undergarments, jacket linings, shoes, helmet liners, incontinence pad cover stock.	
Artificial leather, synthetic non-leather materials	Footwear and footwear components
Automotive convertible tops	Mattress linings, pads, covers and ticking
Automotive trunk and interior liners	Mops
Awnings	Packaging
Bags – Laundry, totes, luggage, handbags	Ropes and cordage
<u>Bedding</u> : Blankets, linens/sheets, pillow cases, fiberfill for quilts, pillows and sleeping bags	Sails
Book covers	Sponges
Brush bristles	Tarpaulins, vehicle and boat covers
Carpet/rug fibers and underlay	Tents
<u>Cloths and wipes</u> : table cloths, napkins, dish towels, bath towels, wash cloths and wipes (excluding baby and cosmetic wipes).	Umbrellas
Curtains, draperies	<u>Upholstery and padding</u> : Furniture, automotive, truck, boat and aircraft

Fibers and fabric	Vacuum cleaner bags
Filters	Wall coverings

<b>Heating, Ventilation and Air Control (HVAC) equipment and related materials</b>	
Adhesives	Filters
Air handlers	Fins
Air purifiers	Fixtures and gaskets
Coils and tubing	Insulation
Diffusers	Plenums
Drain pans	Rigid and flexible ducts
Duct support mechanisms	
Air filtration components and air filtration media for industrial, hospital, residential, and commercial; supplemental articles used in the assembly of HVAC systems, such as gaskets, fixtures, sealants, adhesives, and HVAC reinforcing as well as parts and components thereof. These articles could be constructed of fibrous materials (textiles), non-woven, plastic or coated metal material.	

<b>Electronics and Appliances</b>	
ATM machines, cash registers	Plastic casings for electronics
Cell phones, covers and cases	Plastic components in humidifiers
Computers, keyboards, mouse	Public and residential phones
Control cabinets	Remote controllers
Liners	TV's
Microphones and head phones	Vacuum cleaners
	Vending machines (non-food contact)

**NOTE: The addition of Zinc PYRION Powder Industrial Microbiostat into products classified by FDA as medical devices may require prior clearance by FDA.**

**DRY FILM/PRODUCT PRESERVATION (for protection of the applied dry film/product itself; does not protect the underlying surface):**

**For the Dry Product Preservation of Flooring Adhesives, Caulks, Sealants, Grouts, Patching Compounds, Joint Compounds, Glazing Compounds, and Wood Fillers.**

For the control of microorganisms causing stains, odor or film degradation, including degradation of the physical properties of the film. Add at a point in the manufacturing process where thorough mixing will take place and uniform distribution will occur.

Caulks, Sealants, Joint/Glazing Compounds, and Wood Fillers - add up to 5000 ppm of this product by weight of the formulation (i.e. 5 lbs. of this product per 1000 lbs. of formulation)

Flooring Adhesives – add up to 2400 ppm of this product by weight of the formulation (i.e. 2.4 lbs. of this product per 1000 lbs. of adhesive).

Grouts and Patching Compounds - add up to 4000 ppm of this product by weight of the formulation (i.e. 4 lbs. of this product per 1000 lbs. of formulation)

**For the Dry Film Preservation of Residential, Architectural, and Industrial (non-marine) Paints, Foams, and Coatings, including Powder Coatings:**

To inhibit the growth of microorganisms causing stain, discoloration, odor and/or degradation of the physical properties and/or function of the film, add 2,500 – 5,000 ppm of this product at any time during the formulation procedure. This can be achieved, for example, by the addition of 2.5 – 5.0 lbs. of this product to 100 gallons of wet paint with a density of 10 lbs. per gallon. Coatings may be applied to any of the products in the above table.

**INDIRECT FOOD CONTACT USES:**

**Indirect Food Contact Surfaces Made from Polymers:** For the control of microorganisms causing stain, odor, or product degradation including 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 in the manufacturing process where thorough mixing will take place and uniform distribution will occur. Do not incorporate this product into any food contact polymer unless the subject food contact polymer is approved and listed in 21 C.F.R., Parts 174 through 186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System". Restricted to repeat 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 treated articles made from, or coated with FDA approved polymers.

Indirect food contact material applications include:

- Food processing equipment
- Conveyor belts
- Utensils
- Refrigerator and kitchen appliances
- Kitchenware
- Cutting boards
- Storage containers
- Food trays

**For the Preservation of Adhesives Used For Food Packaging:** For the control of microorganisms causing stain, odor, or product degradation including 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 C.F.R. 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.**

®PYRION is a registered trademark of Janssen Pharmaceutica NV

Ver. 11/09/2016