

43813-50

2/23/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460



Office of Pesticide Programs

FEB 23 2012

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

Attention William R Goodwine Director

Subject Zinc PYRION® 48% Aqueous Dispersion Industrial Microbiostat
EPA Registration No 43813 50
Amendment Dated January 9 2012

The amendment submitted in connection with registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) as amended is acceptable

Proposed Amendment

To include Incontinence care products under the heading Textiles
Rubber/wood flour composite and wood plastic composite products (non food) uses
under the heading For the Preservation of Styrene Butadiene Rubber and
Thermoplastic Resins used in the Manufacture of the following products

General Comments

A stamped copy of the accepted product label is enclosed for your records

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)

Enclosure

**ZINC PYRION® 48% AQUEOUS DISPERSION
INDUSTRIAL MICROBIOSTAT**

Active Ingredient	
Zinc pyrithione,	
Zinc, 2-pyridinethiol-1-oxide	48%
<u>Inert Ingredients</u>	<u>52%</u>
Total	100%

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
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 50

EPA Est No **ACCEPTED**
w/ **COMMENTS**
EPA Label Dated

Manufactured for

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

FEB 23 2012

the Federal Insecticide
and Fungicide Act as
amended by the Pesticide
Control Act under EPA Reg No 43813 50

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ACCEPTED
IN COMMENTS
Letter Dated

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

FEB 23 2019
Federal Insecticide
Fungicide and Rodenticide Act as
amended under EPA Reg No
43 813 51

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 cause l 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

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[For containers > 5 gallons in size] 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

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 Local Dated

FFB 23 02

Under the Federal Inoculation
Program and the 1974 Act
as amended to the Act
registered under EPA Reg No 43813 50

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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

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, and incontinence care products such as incontinence pad cover, stock, 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 add 8 lbs of this product to 1000 lbs of grouts/patching compounds to control these bacteria.)

ACCEPTED
with COMMENTS
EPA Letter Dated

FEB 23 2011

U.S. Federal Insecticide
and Fungicide Act as
amended
Registered under EPA Reg No 43813-5D

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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 Rubber/Wood Flour Composite Wood Plastic Composite Products (non food) Uses, 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 Appliques, 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 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 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.

ACCEPTED WITH COMMENTS

FEB 23 2012

Federal insecticide, rodenticide, etc.

4381350

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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 (h) add a usage 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 01/09/2012

**ACCEPTED
with COMMENTS
EPA Letter Dated**

FEB 23 2012

Under the Federal Insecticide
Fungicide and Rodenticide Act
Registration No. 438135D