

43813-48

01/29/2009

1/7



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

JAN 29 2009
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. William Goodwine
Senior Director of Regulatory Affairs & Product Development for,
Janssen PMP
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Subject: Sodium Pyrion 40% Aqueous Solution
EPA Registration Number 43813-48
Your Amendment Dated October 8th, 2008
EPA Received Date October 10th, 2008

The amendment referred to above, submitted in connection with under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add additional use patterns to the product labeling, is acceptable.

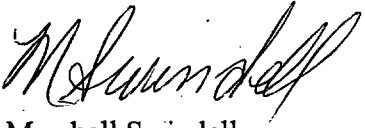
A stamped copy of the labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration /reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

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

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510P)

3/7

SODIUM PYRION® 40% AQUEOUS SOLUTION INDUSTRIAL FUNGICIDE & BACTERICIDE

Active Ingredient:
 Sodium pyrithione (Sodium 2-pyridinethiol-1 -oxide) 40%
 Inert Ingredients: 60%
 Total: 100%

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID	
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 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 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>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.</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	
<p>NOTE TO PHYSICIAN Convulsions, if persistent, may be controlled by careful intravenous use of short-acting barbiturates. Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

Net Wt:

EPA Reg. No.: 43813-48

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:

JAN 29 2009

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended for the purpose of
 registering under EPA Reg. No.

43813-48

4/7

ACCEPTED
with COMMENTS
in EPA Letter Dated:

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

JAN 29 2009
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the products,
registered under EPA Reg. No.

43813-48

May be fatal if absorbed through skin or inhaled. Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Remove contaminated clothing and wash clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT [PPE]

Applicators and other handlers must wear: goggles or face shield, long sleeved shirt and long pants, socks and shoes, chemical-resistant gloves (such as rubber or waterproof gloves).

USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. 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 our State Water Board or Regional Office of the EPA. This pesticide is a chelating agent and should not be used with other chelating agents or with chlorine.

CHEMICAL HAZARDS

Do not store or mix with strong oxidizing agents

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE & DISPOSAL: Do not store above 130°F (55°C). Keep container tightly closed when not in use. Do not store with strong oxidizing agents. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

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 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. 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.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons. Do not use for applications involving direct or indirect food/drinking water contact.

IN AQUEOUS BASED FLUIDS SUCH AS METAL WORKING, CUTTING, COOLING AND LUBRICATING FLUIDS

To inhibit the growth of fungi and bacteria causing stains, odors or degradation of the physical properties of the fluid, add an initial dose of up to 1250 ppm of this product (1.25 lbs. of this product to 1,000 lbs. of solution) to the solution by pouring from container and subsequent maintenance doses of up to 1250 ppm (1.25 lbs. of this product per 1,000 lbs. of solution) every 7-10 days or as needed. This product can be used at fluid to water ratios of 1:10 to 1:100. This product may be added to the fluid at the time it is prepared (diluted) or to the reservoir (sump) containing the fluid after it is put into use. If it is added to the reservoir, the fluid should be circulated after addition to ensure mixing. Contaminated fluid systems should be cleaned prior to the initial addition of this product. Drain the system, clean with cleaner designed for this purpose; rinse with water and refill with fresh fluid containing this product (up to 1250 ppm). Frequent checks (at least once a week) of the bacterial and fungal population in the system should be made using standard microbiological plate count procedures or any of the commercial "dip-stick" type devices. When the bacterial count reaches 10^7 and/or the fungal count reaches 10^3 organisms per ml, add additional product according to the above directions. If this does not reduce the bacterial and/or fungal count below the above value in 12-24 hrs., the fluid should be discarded and replaced after cleaning the system. Add this product to the fresh fluid according to the above directions. When adding fresh, diluted fluid to compensate for drag out or other losses, add this product to make-up fluid according to the above directions.

TO INHIBIT THE GROWTH OF BACTERIA AND FUNGI CAUSING STAINS, ODORS, OR DEGRADATION OF THE PHYSICAL PROPERTIES IN METALWORKING, CUTTING, COOLING AND LUBRICATING FLUID CONCENTRATES

Add an amount that will give up to a 1250 ppm solution. The amount required in the concentrate will depend on the end use dilution. For example: If the desired level of this product is 1250 ppm and the end use dilution of the fluid is 5%, then a 2.5% concentration of this product is required in the concentrate ($1250 \text{ ppm} / 0.05 = 25,000 \text{ ppm}$ or 2.5%).

FOR THE IN-CAN PRESERVATION OF LATEX EMULSIONS USED IN ADHESIVES, CAULKS, PATCHING COMPOUNDS, SEALANTS, PASTES AND GROUTS

To inhibit bacterial growth causing stains, odors or degradation of the physical properties in latex emulsions for a period of up to 1 year, a dosage of up to 1000 ppm of this product (1 lb. of this product per 1,000 lbs. of emulsion) is recommended. Product may be added at any time during the formulation procedure by pouring from the container.

IN AQUEOUS SYNTHETIC FIBER LUBRICANTS (SPIN FINISHES)

To inhibit the growth of bacteria and the formation of bacterial slime causing stains, odors or degradation of the physical properties in synthetic fiber lubricants (spin finishes) for periods of 2-4 weeks during use, add 1250 ppm (1.25 lbs. per 1,000 lbs. of lubricant) of this product to the diluted lubricant. This product may be used in lubricant solutions containing 5-10% lubricant concentrate (water to lubricant ratios of 20-1 to 10-1). This product should be added by pouring from the container to the diluted lubricant in the dilution tank.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 29 2009

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

43813-48

6/7

IN AQUEOUS BASED INKS

To inhibit the growth of bacteria and fungi causing stains, odors or degradation of the physical properties in inks, such as aqueous based inks, printing solutions, pigment slurries or press cake, add up to 1250 ppm of this product. While the inks are in use, a concentration of 0.125% w/w of this product is necessary. The amount of this product to be added at the time of manufacture of the ink to obtain the above concentrations, at the time of use, will vary with the shelf-life of the ink. The table below shows the relationship.

Shelf-Life Ink (months)	% Sodium PYRION 40%
36	1.25
24	0.65
18	0.475
12	0.3125
8	0.25

To inhibit the growth of bacteria causing stains, odors or degradation of the physical properties in neutral or slightly acidic aqueous based jet-printer inks for periods of up to 4 weeks while the inks are in use, add 0.75% w/w of this product to the ink at the time of manufacture. To avoid decomposition of this product during shelf-life of the ink, airtight packaging must be used. In all cases, this product may be added to the ink at any point in the manufacturing process by pouring from the container.

FOR THE DRY FILM PRESERVATION OF NATURAL AND SYNTHETIC ADHESIVES, LATEXES, URETHANE FOAMS, CAULKS, PATCHING COMPOUNDS, SEALANTS, ARCHITECTURAL PAINTS, INDUSTRIAL PAINTS AND COATINGS (Including wood coatings), PASTES AND GROUTS Addition of up to 5000 ppm (5 lbs. of this product per 1000 lbs. of formulation) of the active ingredient can inhibit the growth of bacteria and fungi causing stains, odors or degradation of the physical properties of the dry film of these products. This product can be added at any time during the formulation procedure. For example, sheet vinyl adhesives used in the installation of vinyl flooring can be preserved by the addition of 2100 ppm of this product (2.1 lbs. per 1000 lbs. of adhesive).

FOR THE IN-CAN PRESERVATION OF LAUNDRY RINSE ADDITIVES, LAUNDRY DETERGENTS, CARPET CLEANERS, SURFACE CLEANERS, FLOOR CLEANERS: To inhibit the growth of bacteria and fungi causing stains, odors or degradation of the physical properties in these products for periods of up to one year, add 0.16% w/w (1600 ppm or 1.6 lbs. of this product per 1000 lbs. of formulation). This product can be added at any time during the formulation procedure.

FOR THE IN-CAN PRESERVATION OF WATER BASED CHEMICAL OR MINERAL ADD MIXTURES THAT ARE USED IN CONCRETE: Addition of up to 1000 ppm of this product can inhibit the growth of bacteria and fungi causing stains, odors or degradation of the physical properties of the *add mixtures*. *Add mixtures* can be preserved by addition of 1000 ppm of this product (1.0 lb. of this product per 1000 lbs. of *add mixture*).

FOR THE PRESERVATION OF AQUEOUS ANALYTICAL AND DIAGNOSTIC REAGENTS USED IN CHEMICAL AND CLINICAL ANALYSIS: Addition of up to 1250 ppm of this product can inhibit the growth of bacteria and fungi causing stains, odors or degradation of the physical properties in aqueous analytical and diagnostic reagents (1.25 lbs. of this product per 1000 lbs. of reagent).

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 29 2009

Under the Federal Insecticide,
Fungicide, and Herbicide Act as
amended, for the protection of
registered users of this product.

43813-4A

7/7

FOR THE PROTECTION OF GYPSUM WALLBOARD: Addition of up to 9600 ppm of this product (9.6 lbs. of product per 1000 lbs. of the formulation, i.e., wet slurry) will inhibit the growth of fungi causing stains, odors or degradation of the physical properties on or in gypsum wallboard. Sodium PYRION 40% Aqueous Solution can be added at any time during the formulation procedure. For example, to control the growth of these fungi in gypsum & drywall add a minimum of 1000 ppm of this product (1.0 lb. of product per 1000 lbs. of formulation).

Preservation of Carrageenan Based Gels Used to Produce Solid Air Fresheners.

Add 0.03 – 0.1% of this product (0.03 – 0.1 lb./100 lbs. of formulation) to control the growth of fungi causing stains, odors or degradation of the physical properties of the gels. Add this product into the gel formulation prior to cooling.

To Protect Dry Wall and 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 9600 ppm of this product (9.6 lbs. of product per 1000 lbs. of the formulation, i.e., wet slurry) will inhibit the growth of bacteria and fungi causing stains, odors or degradation of the physical properties of the building materials. 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.

LEATHER PRESERVATION: Sodium PYRION 40% Aqueous Solution is used at treatment rates

of 0.02% to 1.0%, based on the weight of the leather stock, to prevent the growth of bacteria or fungi causing stains, odors or degradation of the physical properties of the hides and skins. The application level is dependent on the type of hide or leather to be protected, the length of protection desired, and the presence of other constituents in the processing formula. The optimum addition should be determined by trial for each individual application. For soaking raw hides, this product should be added to the water to be used for soaking. For treating hides cured with dry salt, this product should be applied to the hides or should be mixed with the salt before it is applied to the hides. This product can be used for the protection of wet leather stock such as pickled, chrome, chrome alternative, metal free, and vegetable tanned leathers from mold and mildew during in-tannery wet processing and for the protection of wet-blue during long storage and transportation times. Treatment rates should be calculated based on the wet white weight or wet blue weight, and compatibility with chrome solutions or other treatment chemicals should be confirmed prior to trial.

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 10/08

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 29 2009

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

4383-40