



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 25, 2019

William R. Goodwine
Director
Janssen PMP, a division of Janssen
Pharmaceutical NV
1125 Trenton-Harbourton Rd.
Titusville, NJ 08560

Subject: Label Amendment – Amend the pesticide storage statement to
add phase “and direct sunlight”
Product Name: SANAFOR™ PO-5
EPA Registration Number: 43813-56
Application Date: March 6, 2018
Decision Number: 539757

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.

Page 2 of 2
EPA Reg. No. 43813-56
Decision No. 539757

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 with FIFRA section 6. If you have any questions, please contact Zebora Johnson by phone at (703) 308-7080, or via email at johnson.zebora@epa.gov.

Sincerely,



Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Accepted Label

A C C E P T E D

Mar 25, 2019

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 43813-56

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep in original container, and separate from food and feed items. Store in a cool, dry, well ventilated place, away from fire, open flames and direct sunlight. Keep product storage areas secure and clean. Clean up any spills promptly.

PESTICIDE DISPOSAL

To avoid waste, use all material in this container by application according to label directions. If waste cannot be avoided, offer remaining product to a waste disposal facility or waste disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container.

Completely empty bag into application equipment, then offer for recycling if available or dispose of liner in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SANAFOR™ PO-5

Active Ingredient:

Zinc pyrithione: Zinc, bis[1-(hydroxy-.kappa.O)-2(1H)-pyridinethionato-.kappa.S2]-, (T-4)- 5%

Inert Ingredients: 95%

Total: 100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If swallowed	<ul style="list-style-type: none">-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.
<p style="text-align: center;">HOT LINE NUMBER:</p> <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, 6:60 AM to 4:30 PM Pacific time, seven days a week. During other times, call the poison control center at 1-800-222-1222. 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>	

Net Weight: 55 lbs (25 kg)

EPA Reg. No.: 43813-56

EPA Est. No.:

Manufactured for:

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

DIRECTIONS FOR USE

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

SANAFOR™ PO-5 is an antimicrobial product for commercial use. It is designed to be incorporated into polyolefin and polyolefin co-polymeric materials during the manufacturing process to impart antimicrobial activity to manufactured and finished products. SANAFOR™ PO-5 suppresses the growth of bacteria, algae, yeasts, fungi, molds and mildew. If microbial activity in the manufactured or finished product could lead to unpleasant odors, discoloration or deterioration of the product, then such a claim may be made for the manufactured or finished product. Products incorporating SANAFOR™ PO-5 may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product which permits such claims. When incorporated into manufactured or finished products, SANAFOR™ PO-5 does not protect users of any such manufactured product or others against food borne or disease-causing bacteria, viruses, germs or other disease causing organisms. For further guidance on treated article label claims, please refer to 40 CFR § 152.25(a) and any additional guidance or policies issued by the U.S. Environmental Protection Agency.

SANAFOR™ PO-5 may be used in polyolefin and polyolefin co-polymeric materials manufactured or incorporated into finished products and applications listed below, such that the finished product (or finished coating, for all uses requiring coating type applications) contains 1% to 8% SANAFOR™ PO-5 by weight of finished product for non-food uses (equivalent to 500 - 4,000 ppm active ingredient) or 10 – 80 pounds (lbs.) of SANAFOR™ PO-5, respectively, by weight per 1,000 lbs. of product) or 1% to 2.0% SANAFOR™ PO-5 by weight of finished product for indirect food contact uses (equivalent to 500 – 1,000 ppm active ingredient) or 10 – 20 lbs. of SANAFOR™ PO-5 per 1,000 lbs. of product).

FOOD CONTACT USES

SANAFOR™ PO-5 may be used for incorporation into articles made from, or coated with polyolefin and polyolefin co-polymeric polymers as an antimicrobial additive in repeat-use polyolefin and polyolefin co-polymeric food contact materials that are used for manufacturing, transporting, handling and/or holding food, if such use is not intended to have any microbial effect in/on the food itself, but rather control fungi, bacteria, yeasts and algae causing stain, odor, and/or product degradation, including change or loss of physical and/or chemical properties of the polymer. Do not incorporate SANAFOR™ PO-5 into any food contact polyolefin polymer or copolymer unless that polymer and use conditions are approved and listed in 21 CFR 174-186 (inclusive), or in the United States Food and Drug Administration's (FDA's) "Food Contact Substance Notification System," or FDA has determined it has no objection to the proposed use in response to a Generally Recognized as Safe (GRAS) Notification. Use is restricted to applications at or below room temperature. Any incorporation of SANAFOR™ PO-5 into any food contact substance other than an approved, listed, or no-objection GRAS notified food contact polymer is prohibited. Applications include, but are not limited to, food processing equipment, conveyor belts, utensils, cutting boards, and storage containers.

Use Rates: 1.0% to 2.0% SANAFOR™ PO-5 by weight of finished product.

NON-FOOD CONTACT USES

SANAFOR™ PO-5 may be incorporated into manufactured products listed below for non-food contact uses for the control of fungi, bacteria, yeasts and algae causing stain, odor, and/or product degradation, including change or loss of physical and/or chemical properties of the polymer:

Use Rates: 1% to 8% SANAFOR™ PO-5 by weight of finished product.

Plastics, Foam, Films, Coatings and Laminates	
Appliances	Foam Insulators and weather stripping
Automotive and vehicular parts	Kitchen and bathroom hardware and fixtures: Towel racks, toilet brush receptacles, tooth brush receptacles, soap dishes
Awnings	Liners
Bags, including garment, garbage, bedding and vacuum cleaner bags	Mats, yoga, exercise, door mats, sink and bathtub mats, drain boards, and placemats
Barrier fabric	Molding
Bed pans, spit cups, wash basins and trays	Mops
Broom and brush handles and bristles, excluding toothbrush bristles	Packaging materials
Building materials and components (excluding roofing shingles), residential and commercial siding, wood plastic composite products	Paper products (wipes and tissues, wall covering, towels, book covers)
Buckets	Plastic film
Carpet padding, backing and foam underlay	Plumbing supplies and fixtures
Carts	Portable toilets
Collection and storage containers and equipment (including piping systems, silos, tanks and processing vessels)	Protective covers, table cloths
Conveyor belts	Razor handles
Credit, debit and membership cards	Refuse containers: Waste baskets, garbage cans, garbage bags
Ear plugs	Respirator components
Films for fabrics	Shower curtains
Floor drains	Sinks, toilets
Floors and Floor covering	Sponges
Foam filters	Sports equipment: Helmets, handles, weights, exercise machine components
Footwear and footwear components	Stuffing for cushions and mattresses
Furniture	Tape
Gas filters	Tarpaulins
Gaskets	Tools
General purpose containers	Tubing, hoses, pipes (non-potable water and non-food items), drainage & sewer, garden hoses
Grease traps	Vacuum cleaner bags
Hand dryers	Water containers, non-potable

Industrial equipment	Writing instruments
Insulation for wire and cable	

Fibers and Fabrics – polyolefins and blends	
<u>Apparel</u> : Uniforms, outerwear, gloves, aprons, coats, sportswear, sleepwear, stockings, socks, hosiery, caps, undergarments, jacket linings, shoes, helmet liners	
Artificial leather	Mattress linings, pads, covers and ticking
Automotive convertible tops	Mops
Automotive trunk and interior liners	Packaging
Awnings	Ropes and cordage
Bags – Laundry, totes, luggage, handbags	Sails
<u>Bedding</u> : Blankets, sheets, pillow cases, fiberfill for quilts, pillows and sleeping bags	
Book covers	Sponges
Brush bristles	Tarpaulins
Carpet, rugs and underlay	Tents
<u>Cloths and wipes</u> : Table cloths, napkins, dish towels, bath towels, wash cloths and wipes	
Curtains, draperies	Umbrellas
Filters	<u>Upholstery and padding</u> : Furniture, automotive, truck, boat and aircraft
Footwear and footwear components	Vehicle and boat covers
	Wall coverings

Heating, Ventilation and Air Control (HVAC) equipment and related materials	
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 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.	

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.**