



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

September 30th, 2024

Noelle Sanfilippo
Regulatory Affairs Specialist
Wellmark International
1501 E. Woodfield Rd
Schaumburg, IL 60173

Subject: Label Amendment - Registration Review Mitigation for Permethrin
Product Name: SANDOZ 9404 SPRAY
EPA Registration Number: 2724-483
Application Date: January 20th, 2021
Decision Number: 595988

Dear Noelle Sanfilippo:

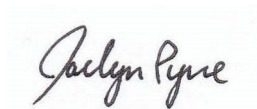
The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Permethrin Amended Interim Decision, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

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 Assurance.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling and must be used at your next label printing. 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 12 months from the date of this letter. After 12 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.

If you have any questions about this letter, please contact Samantha Carter by phone at 202-566-1179, or via email at carter.samantha@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Jaclyn Pyne". The signature is written in a cursive, flowing style.

Jaclyn Pyne, Team Leader
Risk Management and Implementation Branch 3
Pesticide Re-Evaluation Division
Office of Pesticide Programs

ENCLOSURE: Stamped label

[] indicates optional statements

SANDOZ 9404 SPRAY

[Treats 1500/2000 square feet]
[Part of the (Brand Name) [Step #][Guarantee] Pet Protection Program]
Contains the Synthetic Pyrethroid **PERMANONE™**
Contains [With] PRECOR® [VIGREN™] Insect Growth Regulator plus permethrin, an adulticide
Stops Hatching [flea] Eggs (Larvae) From Developing Into Adult Fleas For 210 Days [30 weeks][7 months]
Controls Residential, Industrial and Garden Insects
Kills [Controls] Both Adult and Preadult (Flea Eggs & Larvae) Fleas & Ticks for [7 months][210 days][30 weeks]
Contains an Insect Growth Regulator –
Kills Flea Eggs
Kills adult ticks
For Carpet/Upholstery
Satisfaction 100% guaranteed** **Or your money back
Kills Preadult (Larvae) Fleas Before They Grow Up to Bite You
Leaves No Lingering Odor (Bad Smell), No Stains, No Sticky Mess
Effectively Breaks The Flea Life Cycle
For Use On Dogs and On Premises to Control Fleas and Ticks
Controls Fleas and Ticks on Dogs for 14 Days
A Water Based Aerosol
Kills Lice and Their Eggs
For Use On Bedding Seams, Tufts and Edges, Furniture and Other Inanimate Objects Infested with Lice
Easy to Apply
Prevents Reinfestation and Flea Build-Up For 210 Days [30 weeks][7 months]
Not for Use on Humans

ACTIVE INGREDIENTS:

(S)-Methoprene (CAS #65733-16-6) 0.09%
Permethrin (CAS #52645-53-1) 0.50%

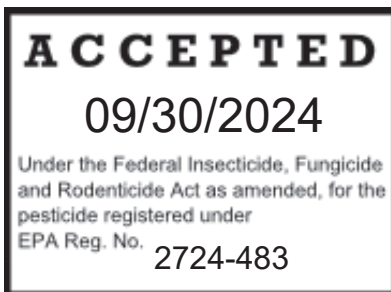
OTHER INGREDIENTS*: 99.41%
TOTAL: 100.00%

*Contains petroleum distillates

KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for additional precautionary statements

EPA Reg No. 2724-483
EPA Est No.
Net Contents: 12/16 fl oz



READ ENTIRE LABEL BEFORE USE

FIRST AID	
If on skin or clothing	<ul style="list-style-type: none">• 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.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1- 800-234-2269 for emergency medical treatment information.	
Note to Physician: Contains petroleum distillate. Vomiting may cause aspiration pneumonia. Treatment is supportive and may involve supplemental oxygen and/or mechanical ventilation. [Note: First Aid statement paragraph format may be used if space is limited.]	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Consult a veterinarian before using this product on debilitated, aged, pregnant, dogs on medication, or nursing dogs. Sensitivities may occur after using ANY pesticide product for dogs. If signs of sensitivity occur, bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. This product is potentially fatal to cats. Do not use on cats.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Applicators and other handlers must wear

- Long-sleeve shirt,
- Long pants,
- Shoes and socks
- Waterproof gloves

USER SAFETY REQUIREMENTS:

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product. Do not reuse them.

USER SAFETY RECOMMENDATIONS:

Users should remove clothing/PPE immediately if pesticide gets inside, Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS: This product is extremely toxic to aquatic organisms, including fish and invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are foraging in the treatment area.

PHYSICAL OR CHEMICAL HAZARDS: Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

Contains no CFC or other ozone-depleting substances. Federal regulations prohibit CFC propellants in aerosols.

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. For both indoor and outdoor use.

USE RESTRICTIONS:

INDOORS

For use as a surface spray: Do not allow adults, children, or pets to enter until sprays have dried. For use as a space spray: Do not allow adults, children or pets to enter until vapors, mists and aerosols have dispersed and the treated area has been thoroughly ventilated.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Remove pets and birds and cover and unplug aquariums before spraying.

Do not wet articles to the point of runoff or drip. Do not use treated article until spray has dried.

For feed/feed handling and service area use: Do not apply when food is present. Do not use in food areas of food handling establishments, restaurants or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared foods are served such as dining rooms, but excluding areas where foods may be prepared or held. In the home, cover all food processing surfaces and utensils during treatment or thoroughly wash before use. Cover or remove exposed food.

Application is prohibited directly into sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur. Do not allow the product to enter any indoor or outdoor drains. *(No permita la entrada a desagües internos o externos.)* Follow proper disposal procedures on this label. *(Siga las indicaciones del etiquetado para el desecho apropiado del producto.)*



When used in dairy barns or facilities: Close milk bulk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milking utensils before application. Wash teats of animals before milking.

Not for broadcast use on carpets, floors, floor coverings or similar sites. Only for use as crack and crevice or spot treatments on these sites.
Do not use in aircraft.

OUTDOORS

For outdoor residential use:

Not for use in outdoor residential misting systems.

All outdoor spray applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses

- 1. Application to pervious surfaces such as soil, lawn, turf, and other vegetation;
- 2. Perimeter band treatments of 7 feet wide or less from the base of a man-made structure to pervious surfaces (e.g., soil, mulch, or lawn);
- 3. Applications to underside of eaves, soffits, doors, or windows permanently protected from rainfall by a covering, overhang, awning, or other structure;
- 4. Applications around potential exterior pest entry points into man-made structures such as doorways and windows, when limited to a band not to exceed one inch;
- 5. Applications to vertical surfaces (such as the side of a man-made structure) directly above impervious surfaces (e.g., driveways, sidewalks, etc.), up to 2 feet above ground level;
- 6. Applications to vertical surfaces directly above pervious surfaces, such as soil, lawn, turf, mulch or other vegetation) only if the pervious surface does not drain into ditches, storm drains, gutters, or surface waters.
- Spot treatments must not exceed two square feet in size (for example, 2 ft. by 1 ft. or 4 ft. by 0.5 ft.).
- For soil or foliar applications, do not apply by ground within 25 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds.
- Do not spray the product into fish pools, ponds, streams, or lakes. Do not apply directly to sewers or storm drains, or to any area like a drain or gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur.
- Do not allow the product to enter any drain during or after application.
- Do not apply directly to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack-and-crevice treatment.
- Treat surfaces to ensure thorough coverage but avoid runoff.
- To treat insects harbored in voids and cracks-and-crevices, applications must be made in such a manner to limit dripping and avoid runoff onto untreated structural surfaces and plants.
- Do not apply or irrigate to the point of run-off. Do not make applications during rain. Avoid making applications when rainfall is expected before the product has sufficient time to dry (minimum 4 hours). Rainfall within 24 hours after application may cause unintended runoff of pesticide application.

SHAKE WELL BEFORE USING

USE INFORMATION: This product is not for use on humans.

A single can (12/16 oz.) treats 1,500/2,000 square feet. Remove protective cap, hold container *upside down* and spray from a distance of 2 - 3 feet.

INDOORS

Houseflies, Mosquitoes, Gnats, Wasps, Hornets, Bees, Black Flies, Skipper Flies, Blow Flies and Small Flying Moths: Close all doors and windows and spray room at the rate of 2 to 3 seconds per 1,000 cubic feet. Direct spray to all parts of the room, especially windows and other light sources which attract these insects. Keep nozzle in constant motion.

Cockroaches, Waterbugs, Palmetto Bugs, Silverfish, Firebrats, Crickets, Scorpions, Spiders, Millipedes, Centipedes, Sowbugs and Pillbugs: Spray into hiding places such as cracks, crevices, behind sinks, cabinets, along baseboards and floors, around drains and plumbing, hitting insects with spray whenever possible.

Ants: Spray trails, nests and points of entry. Spray on ants where possible.

Indian Meal Moths, Angoumois Grain Moths: Close doors and windows, direct spray into all parts of room especially around stored food product containers, pallets and darkened areas. Spray 7 to 10 seconds for each 1,000 cubic feet of space. Keep area closed for 15 minutes following treatment.

Exposed stages of Confused Flour Beetles, SawToothed Grain Beetles, Red Flour Beetles, Rice Weevils, Granary Weevils, Grain Mites: Spray into cracks and crevices, processing and handling equipment, around cartons or containers or other areas where these insects tend to congregate. Spray 30 seconds for each 100 square feet of surface. Keep area closed for 45 minutes to 1 hour after treatment. Dispose of infested stored food products in the home.

Carpet Beetles: Spray directly on beetles, cracks, baseboards and shelves. Spot treat floors and carpets.

Clothes Moths and Carpet Beetles on wool and other proteinaceous fibers: Remove infested articles from storage, brush thoroughly, and air for several hours in sunlight, if possible. Apply spray liberally to empty chests, closets, bureaus and other storages directing the spray into cracks, joints and crevices. After airing, infested articles may be treated by spraying lightly, keeping nozzle at least three feet from fabric to avoid staining.

Bed bugs: Apply as a spot treatment to mattress seams, tufts and edges of bed only. Do not spray the entire surface area of mattress. Allow mattress to dry thoroughly before replacing pillows and or bed linens. Take beds apart and spray into all joints. Treat baseboards, moldings and floors.

In Animal Quarters and Milk Rooms: For rapid control of House flies, Mosquitoes, Gnats, Wasps, Hornets, Bees and Small-flying Moths, close windows and doors and spray at the rate of 2 seconds per 1,000 cubic feet of space. For best results, keep area closed for 10 minutes after spraying. Do not remain in treated area and ventilate after treatment is completed.

To Treat Livestock: To protect beef cattle, dairy cattle, goats, sheep, hogs and horses from attacks of Stable Flies, Horse Flies, Deer Flies, Face Flies, House Flies, Horn Flies, Mosquitoes, and Gnats: Spray about 3 seconds on each side being careful to spray back, withers and forelegs thoroughly. To protect from Face Flies, spray the face and head, but do not spray into eyes.

Repeat treatment when flies are troublesome. For Swine: Do not ship animals for slaughter within 5 days of treatment. When used in dairy barns or facilities: Close milk bulk tank lids to prevent contamination from pesticide spray.

To control Blood Sucking Lice: Apply to the infested areas of the animal, using a stiff brush to get the spray to the base of the hair. Repeat every 3 weeks if required. To control Poultry Lice, spray roosts, walls and nests or cages thoroughly. This should be followed by spraying over the birds with a fine mist.

For control of Bed bugs and Mites in poultry houses, spray crevices of roost poles, cracks in walls, and cracks in nests where the bedbugs and mites hide.

FOR USE IN THE HOME

Fleas (Adults and Larvae) and Ticks (Adults):

For best results, pay special attention to areas your pets frequent. Avoid thoroughly wetting the area that needs treating.

To kill adult fleas, flea larvae and adult ticks in your home, hold container upside down 2-3 feet from surface, point actuator towards the surface and push button.

For Surface / Carpet Spray:

Vacuum thoroughly before spraying.

Make a test application to upholstery or drapery fabrics in an inconspicuous place before use. Apply as a spot treatment only to rugs, carpets, drapes and surfaces of upholstered furniture.

For Use in Pet Areas:

Pay special attention to areas where pets frequent, such as in and around sleeping and resting areas. Treat pet bedding and other pet resting areas as these are primary hiding areas for fleas/ticks. For best results, treat pets before they return to the treated areas.

To Kill Lice and Louse Eggs: Spray in an inconspicuous area to test for possible staining or discoloration. Inspect again after drying, then proceed to spray entire area to be treated. Hold container upright with nozzle away from you. Depress valve and spray from a distance of 8 to 10 inches. Spray each square foot for three seconds. Spray only those garments and parts of furniture that cannot be either laundered or dry cleaned. Spray mattress tufts, seams and edges only. Do not spray entire mattress. Allow all sprayed articles to dry thoroughly before use. If lice infestations occur on humans, use an EPA-registered product labeled for use on humans. If lice infestations occur on humans, consult either your physician or pharmacist for a product for use on humans. Not for broadcast use on carpets, floors, floor coverings or similar sites. Only for use as crack and crevice or spot treatments on these sites.

FOR USE ON DOGS

To Control Fleas, Ticks and Lice on Dogs: Application of product on pets must only be done indoors. Use only on dogs. Starting at the tail, stroke against the lay of the hair, spraying the parted fur in short bursts, directly behind the hand to insure penetrating the coat. Dampen the fur up to the head. Do not treat face, eyes or genitals. Repeat application weekly if necessary to control infestations. **Restriction:** Do not use on puppies under 12 weeks old. This product is potentially fatal to cats. Do not use on cats.

OUTDOORS

FOR THE CONTROL OF GARDEN INSECTS: For use on roses, dahlias, asters and other ornamentals to kill Japanese Beetles hit by spray, as well as Whiteflies, Aphids, exposed Thrips, Spiders, Red Mites and Leafminers. May be used on plants, as well as a multi-purpose spray in small gardens and for spot treatments of incipient insect infestations to prevent spreading in large garden areas.

May also be used on other plants such as African violets, azaleas, begonias, camellias, carnations, chrysanthemums, delphiniums, dogwood, English Ivy, euonymus, fuschia, geraniums, crassula, grape vine, Kentia palm, laurel, marigolds, rhododendrons, rubber plants, snapdragons, stocks, wandering Jews and zinnias.

Effective when used as directed against Whiteflies, Aphids, Spiders and Red Mites, exposed Thrips, Lace Bugs, Japanese Beetles, Pavement Ants, Clover Mites and Army Worms. When spraying plants, do not operate closer than 18 inches. Use sweeping motion. Spray in one second bursts. Be cautious about wetting tender foliage, young plants and new growth. Do not spray plants when temperatures exceed 90 F. Contact spray insects directly whenever possible.

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

Pesticide Storage: Store in a cool, dry area. Do not transport or store below 32° F.

Pesticide Disposal and Container Handling: Do Not Puncture or Incinerate! **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for local disposal options. Do not dispose of down-the-drain or sewer.

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

For information or in an emergency call 1- 800-234-2269

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