

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 22, 2016

James McFadden, Ph.D. Director, Regulatory Affairs Wellmark International 1501 E. Woodfield Rd Suite 200W Schaumburg, IL 60173

Subject: Amended Reregistration Label/PRIA Label Amendment – change in Signal Word Product Name: Sandoz 9404 Spray EPA Registration Number: 2724-483 Application Date: 8/18/2016 Decision Numbers: 520697, 413632

Dear Dr. McFadden:

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

NOTE: This product is <u>not</u> yet being reregistered under section 4(g) of FIFRA.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated 9/19/2014
- Alternate CSF 1, dated 5/7/2015

A copy of your label stamped "Accepted" is enclosed. This labeling supersedes all previously accepted labeling. Products shipped after 12 months from the date of this amendment or the next printing of the label, whichever occurs first, must bear the new revised label. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling.

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

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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 bearing the amended label 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 Autumn Metzger at 703-919-7453, or <u>Metzger.autumn@epa.gov</u>.

Sincerely,

Kable Bo Davis, Product Manager 3 Invertebrate and Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

Enclosure

[] 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[®] [VIGRENTM] 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 weeks1 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*:	
TOTAL:	100.00%

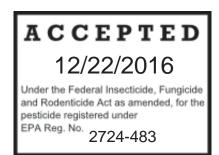
*Contains petroleum distillates

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	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.

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 drain during or after application.

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.

OUTDOORS

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

- Treatment to soil or vegetation around structures,
- Applications to lawns, turf, and other vegetation,
- Applications to building foundations, up to a maximum height of 3 feet.

Other than applications to building foundations, all outdoor applications to impervious surfaces such as sidewalks, driveways, patios, porches and structural surfaces (such as windows, doors, and eaves), are limited to spot and crack-and-crevice applications only. Do not use in aircraft.

For outdoor residential use: Do not water the treated area to the point of runoff. Do not make applications during rain. Not for use in outdoor residential misting systems.

SHAKE WELL BEFORE USING

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

A single can (12/16 oz.) treats 1500/2000 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 1000 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 1000 cubic feet of space. Keep area closed for 15 minutes following treatment.

Exposed stages of Confused Flour Beetles, Saw-Toothed 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. Bedbugs: 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. 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.

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 1000 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 Bedbugs 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: 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 disposal instructions.

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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