



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

April 23, 2025

Micah Reynolds

Senior Managing Consultant for Happy Jack, Inc.

c/o Ramboll Americas Engineering Solutions, Inc.

4245 North Fairfax Drive, Suite 700

Arlington, VA 22203-1649

Subject: Label Amendment – Realign Original Product Label (2001) into Master Label Format & Approval of New Alternate Brand Name
Product Name: Sardex-II® Dog Mange Remedy
EPA Registration Number: 2781-51
Application Date: October 18, 2024
Action Case Number: 637818

Dear Micah Reynolds:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 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.

The alternate brand name, "***Sardex II® Dog Mange Remedy***" has been added to the product record.

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 FIFRA 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) lists 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 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 Carmen Rodia via e-mail at Rodia.Carmen@epa.gov.

Sincerely,



Tamica L. Cain, Product Manager 10
Invertebrate & Vertebrate Branch 2
Registration Division (7505T)

Enclosure: Stamped "Accepted" Master Label, April 23, 2025

{NOTE TO REVIEWER: Text in braces { } is for informational purposes and will not appear on the end-use label}
{NOTE TO REVIEWER: Text in brackets [] is optional, and may or may not appear on the end-use label}
{NOTE TO REVIEWER: Text in parentheses () will appear on the end-use label.}

Sardex-II[®] Dog Mange Remedy

[Alternate Brand Names: Sardex II[®] Dog Mange Remedy, Sardex II[®],
Sardex-II[®]]

An Effective Treatment for Sarcoptic Mange

For Dogs Only

ACTIVE INGREDIENT:

Benzyl benzoate	29.00%
OTHER INGREDIENTS:	71.00%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

NOTE TO PHYSICIAN

Vomiting may cause an aspiration pneumonia hazard. Contains petroleum distillate.

CONTENTS UNDER PRESSURE

[Refer to] [See] [back] [other] [side] [panel] [label] of Container and [Leaflet] [Booklet] for Complete
[Precautionary Statements] [and] [Directions for Use]

EPA Reg. No.: 2781-51

EPA Est. No.: _____

Net Contents: _____ OZ.

[Batch] [Lot] No: _____

{Note to reviewer: Batch or Lot code/number can
be printed on the label or directly on the container.}

[Manufactured] [Produced] [Sold] by:

Happy Jack, Inc.
P.O. Box 475
2122 Hwy. 258 S.
Snow Hill, NC 28580
[1-833-951-1615]

ACCEPTED

04/23/2025

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 2781-51

{NOTE TO REVIEWER: Text in braces { } is for informational purposes and will not appear on the end-use label}
{NOTE TO REVIEWER: Text in brackets [] is optional, and may or may not appear on the end-use label}
{NOTE TO REVIEWER: Text in parentheses () will appear on the end-use label.}

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Contains petroleum distillates. Harmful if swallowed, inhaled, or absorbed through skin. Avoiding breathing spray mist. Avoid contact with skin, eyes, or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL OR CHEMICAL HAZARDS

Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. **DO NOT** puncture or incinerate container. Exposure to temperatures about 130°F may cause bursting.

DIRECTIONS FOR USE

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

READ ENTIRE LABEL AND FOLLOW ALL DIRECTIONS ON THE LABEL BEFORE EACH USE

SHAKE WELL BEFORE USING

USE RESTRICTIONS

- **DO NOT** spray in or towards the eyes; affected areas around the eyes should be treated with care to avoid getting the product into the eyes.
- **THIS PRODUCT IS ONLY FOR USE ON DOGS**
- **DO NOT USE** on puppies younger than 12 weeks, nor on pregnant or nursing bitches. Consult a veterinarian before using this product on debilitated, aged or medicated dogs. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe the dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

PRODUCT INFORMATION

Sardex-II® Dog Mange Remedy kills mange mites, results in 5-7 days. Fights microscopic mange mites living on the dog's body and prevents mites from infecting other body parts or pets. For best results, clip hair around all affected areas; if necessary, clip entire body.

Apply **Sardex-II® Dog Mange Remedy** on the affected areas, rub in slightly, allow to dry and then apply a second time. Then wash animal thoroughly with soap and water, rinse and allow animal to dry or wipe dry before application. Repeat applications at 7-day intervals until the condition clears up.

Dogs under treatment should be fed an adequate diet containing all essential vitamins and minerals. To prevent reinfestation, change bedding daily. Wash bedding thoroughly after use.

STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store in a cool, dry area, away from heat or open flame. Exposure to temperature above 130°F may cause bursting.

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.

{NOTE TO REVIEWER: Text in braces { } is for informational purposes and will not appear on the end-use label}
{NOTE TO REVIEWER: Text in brackets [] is optional, and may or may not appear on the end-use label}
{NOTE TO REVIEWER: Text in parentheses () will appear on the end-use label.}

{Optional Marketing Statements, Logos, and Graphics}

[Product Name]

Dog mange remedy

Convenient
Stainless
Odorless

“Ask for Happy Jack...Your Dog Would!”

UPC Code

Odorless & Stainless Itch Relief for Skin Irritations Including Severe Mange, Hot Spots, Fungi, Allergies, Eczema.

Got mange?

Formulated to Specifically Soothe and Relieve Itch from Severe Mange

Fast and Effective (5-7 days)!

Fast Acting Formula (5-7 days)

Results typically in 5-7 days*

*Duration of treatment depends on severity of ailment

Stainless and Greaseless

Spot treatment for affected area

Soothe their itch, ease their pain

Mange treatments that comforts your dog, soothes his itch, and alleviates the distress of mange...by eliminating mange mites – fast (5-7 days)!

Relieves extreme itchiness
Relieves redness & rash
Relieves crusty skin
Stops hair loss
Stops mange from spreading

Kills mange mites, results in 5-7 days*. Fights microscopic mange mites living on the dog's body and prevents mites from infecting other body parts or pets

Soothes irritated skin. Effectively relieves itching from severe mange, fungi, falling hair, itching eczema, allergies, hot spots, moist feet and ears and pus pimples.

Odorless, stainless, greaseless. Simply spray onto affected areas, rub in and allow to dry. Kills those itch

{NOTE TO REVIEWER: Text in braces { } is for informational purposes and will not appear on the end-use label}

{NOTE TO REVIEWER: Text in brackets [] is optional, and may or may not appear on the end-use label}

{NOTE TO REVIEWER: Text in parentheses () will appear on the end-use label.}

causing mange mites and brings much needed relief to your dog. Fast-acting formula works on stubborn cases.

Since 1946. Made in USA. Trust the name that has provided the best in effective mange control for over 70 years.

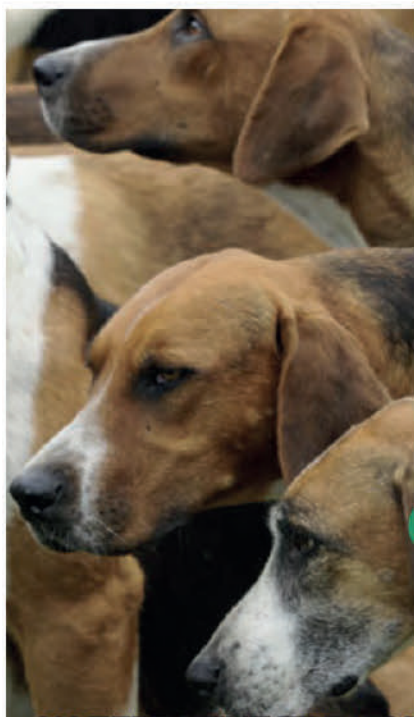
Trust the brand that has specialized in mange treatments since 1946

Trusted by professional dog breeders & kennels

{Optional graphics}



{NOTE TO REVIEWER: Text in braces { } is for informational purposes and will not appear on the end-use label}
{NOTE TO REVIEWER: Text in brackets [] is optional, and may or may not appear on the end-use label}
{NOTE TO REVIEWER: Text in parentheses () will appear on the end-use label.}



{NOTE TO REVIEWER: Text in braces { } is for informational purposes and will not appear on the end-use label}
{NOTE TO REVIEWER: Text in brackets [] is optional, and may or may not appear on the end-use label}
{NOTE TO REVIEWER: Text in parentheses () will appear on the end-use label.}

Stainless and Greaseless



- ✓ Spot treatment for affected area
- ✓ Fast-acting formula in 5-7 days



Directions

Application

1. Clip hair around affected area.
2. Wash pet thoroughly with soap and water. Rinse allow dog to dry or wipe dry.
3. Spray on affected area, rub in slightly, and allow to dry. Do not wash off.
4. Apply a second time.

1x Day

- 1x every 7 days (1 x in a week)
- 1x a day for 7 days (7 x in a week)

Apply once a day until small hairs grow and skin returns to a healthy pink color.
Duration of treatment depends on severity of ailment)



{NOTE TO REVIEWER: Text in braces { } is for informational purposes and will not appear on the end-use label}

{NOTE TO REVIEWER: Text in brackets [] is optional, and may or may not appear on the end-use label}

{NOTE TO REVIEWER: Text in parentheses () will appear on the end-use label.}



Soothe Their Itch, Ease Their Pain

Mange treatments that comforts your dog, soothes his itch, and alleviates the distress of mange....by eliminating mange mites – fast!

- ✓ Relieves extreme itchiness
- ✓ Relieves redness & rash
- ✓ Relieves crusty skin
- ✓ Stops hair loss
- ✓ Stops mange from spreading

The bottom right corner of the advertisement features the Happy Jack logo (a beagle's head in a green circle, the brand name "Happy Jack" in a green, cursive script, and a cartoon beagle head with a wide smile) next to a close-up photograph of a beagle's head. The beagle has its tongue out and is looking towards the camera.