

2781-51

08/26/2013

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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Mr. Micah T. Reynolds  
TSG  
1150 18<sup>th</sup> Street, Suite 1000  
Washington, Dc 20036

AUG 26 2013

Subject: Label Notification(s) for Pesticide Registration  
Notice 98-10

Dear Mr. Reynolds:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice PRN 98-10 dated April 4, 2013 for the following product(s):

**Sardex II Dog Mange Remedy EPA Reg. No. 2781-51**

The Registration Division (RD) has conducted a review of this request for applicability under PRN 98-10 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please contact Linda A. DeLuise at 703-305-5428.

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda A. DeLuise".

*f*  
Richard J. Gebken  
Product Manager  
Insecticide Branch  
Registration Division (7504P)

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Please read instructions on reverse side before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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**Application for Pesticide – Section I**

1. Company/Product Number <b>2781-51</b>	2. EPA Product Manager <b>Richard Gebken</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Sardex II® Dog Mange Remedy</b>	PM# <b>10</b>	
5. Name And Address Of Applicant (Include ZIP Code) <b>Happy Jack, Inc. P.O. Box 475 Snow Hill, North Carolina 28580</b>	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ <b>NOTIFICATION</b> _____ Product Name _____ <b>AUG 26 2013</b> _____	
<input type="checkbox"/> Check if this is a new address		

**Section II**

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain Below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

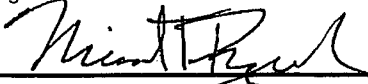
**Submission of Label Notification to update Storage & Disposal Language in accordance with per PR Notice 2007-4.**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Please confirm receipt with Micah Reynolds: [mreynolds@tsqusa.com](mailto:mreynolds@tsqusa.com), via phone (202) 828-8967, or via fax (202) 872-0745.

**Section III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes"      No. per Unit Packaging wgt.    Container If "Yes"      No. per Unit Packaging wgt.    Container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product				<input type="checkbox"/> Other _____	
				<input type="checkbox"/> Lithographed <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	

**Section IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name <b>Micah T. Reynolds, Technology Sciences Group, Inc.</b>	Title <b>Senior Regulatory Consultant</b>	Telephone No. (Include Area Code) <b>(202) 828-8967</b>
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received <b>(Stamped)</b>
2. Signature 		
3. Title <b>Regulatory Consultant to Happy Jack, Inc.</b>		
4. Typed Name <b>Micah T. Reynolds</b>		5. Date <b>April 4, 2013</b>

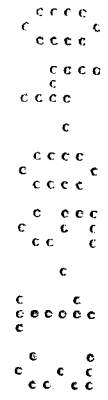


Technology Sciences Group Inc.  
1150 18<sup>th</sup> Street, Suite 1000  
Washington, DC 20036  
Direct: (202) 828-8967  
Fax: (202) 872-0745  
E-Mail: MReynolds@TSGUSA.com

Micah T. Reynolds  
Senior Regulatory Consultant

April 4, 2013

**Happy Jack, Inc.**  
**Submission of Label Notification for**  
**Sardex II® Dog Mange Remedy;**  
**EPA Reg. No. 2781-51**



Mr. Richard Gebken (PM-10)  
Insecticide Branch/Registration Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Document Processing Center  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202

Dear Mr. Gebken:

Technology Sciences Group, Inc., on behalf of Happy Jack, Inc., is submitting the enclosed label notification for the above referenced product to update the Pesticide Disposal and Container Handling instructions per PR Notice 2007-4. The product is an aerosol and instructions on container handling were updated accordingly to reflect product packaging. Further, label changes requested to be made in the Agency's Re-registration Notice, dated February 22, 2010, have been made to the revised version. It is important to identify that no text-based version of this label currently exists, so we are providing the enclosed marketplace container graphics. Please find enclosed the following documents supporting this submission:

- 1) EPA Notification Form (EPA Form 8570-1);
- 2) One copy of the EPA Stamped Accepted label for reference;
- 3) ~~Two~~ clean copies of the revised label.

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at [mreynolds@tsgusa.com](mailto:mreynolds@tsgusa.com).

Sincerely,

Regulatory Consultant to Happy Jack, Inc.

Enclosures  
CC: A. Exum (Happy Jack)

# PrimeSourceOPC

Revision Level: 3/2013  
 Part #/Name: HAP-174  
 Customer: Happy Jack

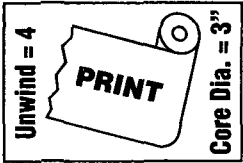
Art File No. 1303-017  
**PLEASE CHECK ONE**  
 Please resubmit new proof with changes noted  
 Approved / Proceed with order

Proof Approved by: \_\_\_\_\_  
 Approval Date: \_\_\_\_\_  
 Comments: \_\_\_\_\_

**PLEASE READ CAREFULLY!**  
 Please review this proof carefully, including all the copy. What you see on this proof is exactly what will be printed. We want everything right the first time. Please keep these facts in mind:  
 \*If an error to the copy is approved and printed, it will be necessary to charge you for the production costs.  
 \*Proofs returned quickly get the earliest press dates.  
 \*If no proof is returned within 90 days, we must invoice you for art charges.

Job Description: Sardex II LBL  
 Size (W x H): 4.4375" X 8.50" - Rectangle  
 Die #: R65300  
 Core Dia: 3"  
 Printing Method: Flexo  
 Material 1: 2.6Mil White Label-Lyte  
 Material 2: 1Mil Clear Polypropylene

Please inspect this proof and respond by fax to PrimeSourceOPC 336-661-3313.  
 Should you have any questions please call PrimeSourceOPC 336-661-3300.  
 Thank you.



- Black
- Cyan
- Magenta
- Yellow
- 340 Green

**NOTIFICATION**  
 1,000 Labels Per Roll  
 9.12" Finished Roll OD  
 AUG 26 2013

4 X CR  
 = .125"

**Happy Jack**  
**SARDEx II**  
 DogMange Remedy

AN EFFECTIVE TREATMENT FOR SARCOPTIC MANGE FOR DOGS ONLY

CONVENIENT STAINLESS COPPERLESS

ACTIVE INGREDIENT: Benzyl benzoate 28.00%  
 INERT INGREDIENTS: 71.00%  
 (Contains Petroleum Distillates) TOTAL 100.00%

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**  
 CONTENTS UNDER PRESSURE  
 SEE BACK PANEL FOR OTHER PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

**NET CONTENTS 9.5 OZ**

Dieline (Does not print)  
 Label Carrier (Does not print)

**DIRECTIONS FOR USE**  
 It is a violation of federal law to use this product in a manner inconsistent with its labeling.  
**READ ENTIRE LABEL BEFORE EACH USE**  
**USE ONLY ON DOGS**  
**SHAKE WELL BEFORE USING**

**DIRECTIONS:** Clip hair around all affected areas; if necessary, clip entire body. Then wash animal thoroughly with soap and water, rinse and allow animal to dry or wipe dry before application. Spray product on the affected areas, rub in slightly, allow to dry and then apply a second time. Repeat applications at 7-day intervals until the condition clears up. 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. 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.

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.

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**FOR USE ON DOGS ONLY**  
**CAUTION**  
 Contains petroleum distillate. Vomiting may cause aspiration pneumonia. Harmful if swallowed, absorbed through the skin or inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.  
**PHYSICAL AND CHEMICAL HAZARDS**  
 Flammable. Contents under pressure. Keep away from fire, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures about 130°F may cause bursting.

EPA Reg. No. 2781-51  
 EPA Est. No. is 7754-GA-1

**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 flame.  
**PESTICIDE DISPOSAL AND CONTAINER HANDLING:**  
 Do not puncture or incinerate if empty. Place in trash or other for recycling, if available. Thoroughly fill. Call your local solid-waste agency for disposal instructions.

Sold By:  
 Happy Jack, Inc.  
 POB 475  
 2122 Hwy. 268 S.  
 Snow Hill, NC 28580  
 1-252-747-2811

Happy Jack  
 "Ask for Happy Jack... Your Dog Would!"

www.happyjackinc.com  
 23851-01050-9  
 Made in USA

8.50"  
 8.625"

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