

2781-39

4/10/2009

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms. Heather R Bjornson
Happy Jack Inc.
P.O. Box 475, 2122 Hwy 258
Snow Hill, NC 28580

APR 10 2009

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4 and 2007-1

Dear Registrant:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice.(PRN) 2007-4 and 2007-1 dated March 4, 2009 for:

EPA Registration 2781-39 Mitex

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and 2007-1, and finds that the label change(s) requested falls within the scope of PRN-2007-4 and 2007-1. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Banza Djapao of my staff at 703-305-7269.

Sincerely,

A handwritten signature in black ink, appearing to be "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

2096

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2781-39	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) MITEX	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Happy Jack Inc. PO Box 475, 2122 Hwy 258 Snow Hill, NC 28580 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: NOTIFICATION EPA Reg. No. _____ Product Name _____ APR 10 2009	

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.)
Notification if label changed per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4, and the requirements of EPA's regulations at 40 CFR §§156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	Other (Specify) _____	
		If "Yes" Package wgt	No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.5 and 1.0 oz.		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather R. Bjornson, hbjornson@tsgusa.com	Title Regulatory Assistant	Telephone No. (Include Area Code) (202) 828-8945
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 (Stamped)
2. Signature 	3. Title Regulatory Assistant to Happy Jack, Inc.	
4. Typed Name Heather R. Bjornson	5. Date March 23, 2009	

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WASHINGTON

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Richard Gebken
Registration Division (7504P)
Office of Pesticide Products
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

March 4, 2009

RE: MITEX™ (EPA Reg. No. 2781-39)

Notification per PR Notice 2007-4

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Dear Mr. Gebken:

Technology Sciences Group, Inc., on behalf of Happy Jack Inc., submits the enclosed notification to update the label per PR Notice 2007-4 and to correct the Happy Jack's address.

You will find the following in support of this notification:

- 1) Notification application form,
- 2) One redline version of the revised label, and
- 3) One clean version of the revised label.

Please do not hesitate to contact me with any questions and/or concerns.

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

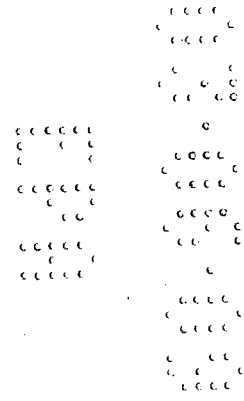
K1P 5H9

Telephone 613 247-6285

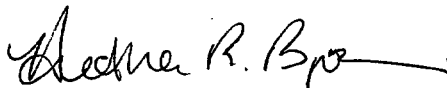
Fax 613 236-3754

Sincerely,

Heather R. Bjornson
Regulatory Assistant to Happy Jack, Inc.
Direct dial: (202) 828-8945
e-mail: hbjornson@tsgusa.com



Notification of label change relative to PR Notice 2007-1. This notification is consistent with the guidance in PR Notice 2007-1 and the requirements at 40 CFR 156.10 and 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 a violation of 18 U.S.C. Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the guidance of PR Notice 2007-1 and the requirements of 40 CFR 156.10 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.

 April 8 2009
Heather R. Bjornson
Regulatory Assistant to Happy Jack, Inc.

5096

[LOGO]

Happy Jack.

MITEX
PESTICIDAL
for the treatment
of ear mites in dogs and cats

ACTIVE INGREDIENTS

Pyrethrins 0.05%
Piperonyl butoxide* (tech)..... 0.50%

OTHER INGREDIENTS** 99.45%

* Equivalent to 0.04% [2-(2-butoxyethoxy)ethyl-6-propylpiperonyl ether] and 0.1% related compounds.

** Contains a Petroleum Distillate

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side panel for additional precautionary statements

NOTIFICATION

APR 10 2009

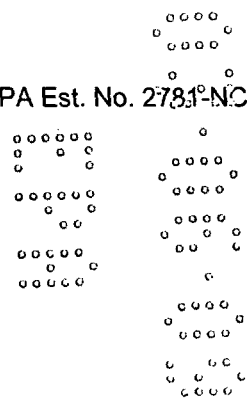
NET CONTENTS: ½ fl. oz. [14.5 ml]

EPA Reg No. 2781-39

EPA Est. No. 2781-NC-1

Manufactured by

HAPPY JACK INC.
PO Box 475
2122 Hwy 258
Snow Hill, N.C. 28580



Lot XXX

MITEX (EPA Reg. No. 2781-39)
March 4, 2009

60076

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Wash hands after using. Not for Human use. Do not use on animals under 12 weeks of age. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, wash ear with mild soap and consult your veterinarian

FIRST AID

IF SWALLOWED: ● Immediately call a poison control center or doctor for treatment advice. ● Do not induce vomiting unless told to do so by a poison control center or doctor. ● Do not give any liquid to the person ● Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN: contains petroleum distillate - vomiting may cause aspiration pneumonia.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool dry place away from heat and open flame.

PESTICIDE AND CONTAINER DISPOSAL: **if empty:** Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available. **if partly filled:** Call your local solid waste agency of 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

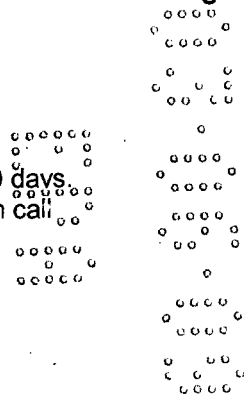
DIRECTIONS FOR USE

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 AND CATS

Cleanse ear. Place recommended drops in each ear daily for 7 - 10 days. Repeat treatment in two weeks if necessary. For further information call 1-800-326-5225.

Body Weight	Dosage
5 - 15 lbs	4 - 5 drops
15 - 30 lbs	5 - 10 drops
30 lbs or over	10 - 15 drops



MITEX (EPA Reg. No. 2781-39)

March 4, 2009