



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 20, 2015

Mr. Micah T. Reynolds
Regulatory Consultant for
Happy Jack, Inc.
P.O. Box 475
Snow Hill, North Carolina 28580

Subject: Amended Reregistration Label
Product Name: Mitex
EPA Registration Number: 2781-39
Decision Number: 412070 & 410830

Dear Mr. Reynolds:

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

NOTE: This product is **not** 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 Any previously dated CSFs are superseded.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 February 16, 2011
- Alternate CSF 1, dated February 16, 2011

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.

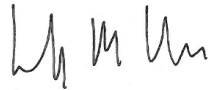
A copy of your label stamped "Accepted" is enclosed. Products shipped after 12 months from the date of this amendment or the next printing of the label, whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label

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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 about this letter, please contact Jennifer Urbanski by phone at 703 347-0156, or via email at Urbanski.Jennifer@epa.gov.

Sincerely,

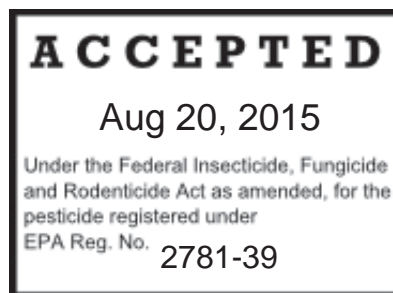
A handwritten signature in black ink, appearing to read 'Jennifer Urbanski', with a stylized, cursive script.

Jennifer Urbanski, PhD, Product Manager 4
Invertebrate and Vertebrate Branch 1 (IVB1)
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

[HAPPY JACK ICON]

**MITEX
PESTICIDAL**
For the treatment
of ear mites in dogs and cats



ACTIVE INGREDIENTS

Pyrethrins	0.05%
Piperonyl butoxide*	0.50%
OTHER INGREDIENTS**	99.45%
TOTAL	100.00%

* (butyl carbityl)(6-propylpiperonyl) ether and related compounds

** Contains a Petroleum Distillate

KEEP OUT OF REACH OF CHILDREN

CAUTION

See (back/side) panel for additional precautionary statements

NET CONTENTS: xx fl. oz. [xx ml]

EPA Reg No. 2781-39

EPA Est. No. [2781-NC-1]

Manufactured [by] [for]

HAPPY JACK Inc.
PO Box 475
Snow Hill, N.C. 28580

Lot: XXX

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION. Hazards to Humans: Harmful if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. 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. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Hazards to Domestic Animals: Do not apply to pets less than 12 weeks of age. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult your veterinarian immediately.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Do not give any liquid to the person.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
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.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• 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 1-800-222-1222 for emergency medical treatment information.	
NOTE TO PHYSICIAN: Contains petroleum distillates—vomiting may cause aspiration pneumonia.	

ENVIRONMENTAL HAZARDS

This product is toxic to fish. To protect the environment, do not allow product to enter or run off into storm drains, drainage ditches, gutters or surface waters.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

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 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

Not for use in outdoor residential misting systems.

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 Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY

To the extent consistent with applicable law, Happy Jack, Inc. makes no warranty of merchantability, fitness for any particular purpose, or otherwise, expressed or implied concerning this product or its uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label.