

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 17, 2001

RocCorp, Inc.
P. O. Box 785
Brunswick, OH 44212

361
17
5-600316

Attention: Mr. William Donze

Subject Hilo Ear Mite Remedy for Dogs and Cats
EPA Reg. No. 1452-17
Your letter of July 4, 2001

The name of record for this product is "Hilo Ear Mite Remedy for Dogs and Cats". Because you only market a "dog only" and a "cat only" product, we are stamping two labels under the additional brand names of "Ear Mite Remedy for Dogs" and "Ear Mite Remedy for Cats". If, in the future, you would like a combined label with both dogs and cats, you would need to submit for our review three (3) copies of revised labels with both claims on the label.

The labeling submitted with the above letter, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is acceptable, provided you submit one (1) copy of final printed labeling to us, with the following changes, before you ship your product. A copy of the stamped label is enclosed for your records.

Labeling changes A. Card Label

Revised the Ingredient Statement as follows:

The percentage of "Rotenone" and "Other Associated Resins" is "0.40%".

Labeling changes-cont.

B. Bottle Label

1. Revised the Ingredient Statement as follows:

The percentage of "Rotenone" and "Other Associated Resins" is "0.40%"

2. Align "ACTIVE INGREDIENTS" AND "INERT INGREDIENTS" to the same left margin.

Existing stocks of labels

Stocks of existing labels may be used for eighteen (18) months.


Consequence for non-compliance

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of this condition.

EPA contact

If you have any questions about this letter, please contact me by phone (703-305-5407), fax (703-305-6596), or E-Mail (peacock.dan@epa.gov).

Sincerely,



Daniel B. Peacock, Biologist
Insecticide-Rodenticide Branch
Registration Division (7504C)

Enclosure

1. Stamped label
2. Minimum Type Size Requirements for Final Printed Labeling

Letter location

A:\Rotenone\1452-17 July 2001.wpdJuly 17, 2001

HiLo Ear Mite

Remedy For Dogs



Effective in killing ear mites

HiLo
Ear Mite
 Remedy For Dogs
Effective in Killing Ear Mites
 ACTIVE INGREDIENTS: Rotenone 0.25%
 Other Associated Resins 0.50%
 INERT INGREDIENTS: 99.25%
 (Includes 2.5% Benzyl Alcohol)
CAUTION
 Keep Out Of Reach Of Children
 Not For Use In Pets
 LOT # EXP. DATE

ACTIVE INGREDIENTS:
 Rotenone..... 0.25%
 Other Associated Resins..... 0.50%
INERT INGREDIENTS..... 99.25%
 100.00%
 (Includes 2.5% Benzyl Alcohol)

CAUTION,
 Keep Out Of Reach Of Children.
 See back panel for additional
 precautionary statements.

ACCEPTED COMMENTS: EPA Reg. No. 1452-17 EPA Est. No. 1452-OH-1
 HiLo Corp Inc., PO Box 785, Brunswick, OH 44212

JUL 17 2001

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 as amended, for the pesticide
 registered under EPA Reg. No.
 1452-17



Ear Mite Remedy For Dogs

Effective in killing ear mites

RETAIN THIS CARD UNTIL BOTTLE IS COMPLETELY EMPTY.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

May be harmful if swallowed, absorbed through skin, or inhaled. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Avoid inhalation of spray. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash thoroughly before reuse.

FIRST AID

Have label with you when obtaining treatment advice.

If swallowed

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.

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 immediately for treatment advice.

If inhaled

- Move person to fresh air.
- If person is not breathing, call an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
- Call a poison control center or doctor immediately for treatment advice.

If in eyes

- 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 immediately for treatment advice.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not contaminate water when disposing of product.

DIRECTIONS FOR USE

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

PETS

PRETREATMENT DIRECTIONS

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS TO KILL EAR MITES. Do not use on animals under 12 weeks.

SPECIAL ANIMALS: Do not use this product on debilitated, aged, pregnant, nursing, or medicated pets.

ADVERSE REACTION INFORMATION

Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, consult a veterinarian immediately.

DIAGNOSIS FOR EAR MITES: Ear mites usually include the formation of a dry, dark brown, waxy exudate with crusts in the ears of dogs. Ear mites may be detected by placing some of the ear exudate on a dark surface and carefully watching for the movement of tiny white specks away from the exudate. Inflamed, watery, or blocked ear canals indicate a more serious condition which requires the services of a veterinarian.

APPLICATION DIRECTIONS: While holding pet firmly, fill each ear canal half full of Hilo Ear Mite Remedy for Dogs and massage base of ear to insure that insecticidal action penetrates ear wax.

REAPPLICATION DIRECTIONS: Do not reapply product for 1 day. Improvement is usually noted after two applications.

STORAGE AND DISPOSAL

Storage: Store only in original container, in a dry place inaccessible to children and pets.

Disposal: Do not reuse empty container. Securely wrap in newspaper and discard in trash.



Hip[®]
Ear Mite
 Remedy For Dogs

Effective in Killing Ear Mites

ACTIVE INGREDIENTS: Rotenone 0.25%
 Other Associated Resins 0.50%
 INERT INGREDIENTS: 99.25%
 (Includes 2.3% Benzyl Alcohol)

CAUTION
 Keep Out Of Reach Of Children
 Net Content: 1 fl. oz.

LOT # EXP. DATE

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS

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

Hold pet firmly. Fill outer ear canal just full with EAR MITE REMEDY. Massage base of the ear to distribute solution into ear wax. Repeat every other day until condition is relieved. Symptoms of ear mite irritation are usually improved in two applications. Do not use on puppies less than 12 weeks old, sick, debilitated, aged, pregnant, medicated or nursing dogs. **NOT FOR USE ON HUMANS.**

See accompanying rack card for additional cautions and directions.

EPA Reg. No. 1452-17 EPA Est. No. 1452-34-1
 RocCorp, Inc., BRUNSWICK, OH 44222

Hip
Ear Mite
Remedy For Cats

Effective in killing ear mites

ACTIVE INGREDIENTS:
 Rotenone..... 0.25%
 Other Associated Resins..... 0.50%
INERT INGREDIENTS..... 99.25%
 100.00%
 (Includes 2.5% Benzyl Alcohol)

CAUTION
 Keep Out Of Reach Of Children.
 See back panel for additional precautionary statements.
 EPA Reg. No. 1452-17 EPA Est. No. 1452-OH-1
 RocCorp Inc., PO Box 785, Brunswick, OH 44212

ACCEPTED with COMMENTS:
 in EPA Letter Dated:

LOT # **EXP. DATE**

ACTIVE INGREDIENTS: Rotenone 0.25%
 Other Associated Resins 0.50%
INERT INGREDIENTS: 99.25%
 (Includes 2.5% Benzyl Alcohol)

CAUTION
 Keep Out Of Reach Of Children
 Net Content: 1 fl. oz.

JUL 17 2001

Under the Federal Insecticide, Fungicide, and Fertilizer Act, as amended for the pesticide registered under EPA Reg. No.

1452-17

Hilo[®]

Ear Mite Remedy For Cats

Effective in killing ear mites

RETAIN THIS CARD UNTIL BOTTLE IS COMPLETELY EMPTY.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

May be harmful if swallowed, absorbed through skin, or inhaled. Causes eye irritation. Avoid contact with skin, eyes, or clothing. Avoid inhalation of spray. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash thoroughly before reuse.

FIRST AID

Have label with you when obtaining treatment advice.

If swallowed

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.

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 immediately for treatment advice.

If inhaled

- Move person to fresh air.
- If person is not breathing, call an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
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If in eyes

- 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 immediately for treatment advice.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not contaminate water when disposing of product.

DIRECTIONS FOR USE

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

PETS

PRETREATMENT DIRECTIONS

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON CATS TO KILL EAR MITES: Do not use on animals under 12 weeks.

SPECIAL ANIMALS: Do not use this product on debilitated, aged, pregnant, nursing, or medicated pets.

ADVERSE REACTION INFORMATION

Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, consult a veterinarian immediately.

DIAGNOSIS FOR EAR MITES:

Ear mites usually include the formation of a dry, dark brown, waxy exudate with crusts in the ears of cats. Ear mites may be detected by placing some of the ear exudate on a dark surface and carefully watching for the movement of tiny white specks away from the exudate. Inflamed, watery, or blocked ear canals indicate a more serious condition which requires the services of a veterinarian.

APPLICATION DIRECTIONS:

While holding pet firmly, fill each ear canal half full of Hilo Ear Mite Remedy for Cats and massage base of ear to insure that insecticidal action penetrates ear wax.

REAPPLICATION DIRECTIONS:

Do not reapply product for 1 day. Improvement is usually noted after two applications.

STORAGE AND DISPOSAL

Storage: Store only in original container, in a dry place inaccessible to children and pets.

Disposal: Do not reuse empty container. Securely wrap in newspaper and discard in trash.



Hip®
Ear Mite
 Remedy For Cats
Effective in Killing Ear Mites

ACTIVE INGREDIENTS: Rosinone 0.25%
 Other Associated Resins 0.50%
 INERT INGREDIENTS 99.25%
 (Includes 2.5% Benzyl Alcohol)

CAUTION
 Keep Out Of Reach Of Children
 Net Content: 1 fl. oz.

LOT # EXP. DATE

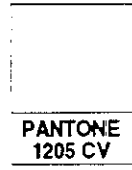
**READ ENTIRE LABEL BEFORE EACH USE
 USE ONLY ON CATS**

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

Hold pet firmly. Fill outer ear canal half full
 with EAR MITE REMEDY. Massage base of
 the ear to distribute solution into ear wax.
 Repeat every other day until condition is
 relieved. Symptoms of ear mite infestation
 are usually improved in two applications. Do
 not use on kittens less than 12 weeks old,
 sick, debilitated, aged, pregnant, medicated
 or nursing cats. NOT FOR USE ON HUMANS.

See accompanying rack card for
 additional cautions and directions.

EPA Reg. No. 1452-17 EPA Est. No. 1452-0H-1
 RocCorp, Inc., BRUNSWICK, OH 44212



PANTONE
 1205 CV



PANTONE
 Black CV

Use PANTONE MATCHING SYSTEM for
 accurate color representation.