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

Attention: Mr. William E. Donze

Subject: HiLo Dip

EPA Reg. No. 1452-3

Your amended applications of December 1, 1990, and

October 25, 1993

Your letter of June 27, 1995

In your letter of June 27, 1995, you requested us to determine the status of the above two amendments because you had not received written responses as yet.

We apologize for the delay in responding to your June letter. In reviewing the past history of these amendments, we discovered that our records were incomplete and, in some cases, inaccurate. However, with copies of missing documents supplied on your part and some detective work on our part, we now have a complete and accurate record of these actions. We appreciate your patience.

Status of December 1, 1990, Amendment

In 1990 California requested that all products containing 60% or more Pine Oil be labeling "DANGER" because of eye irritation. Subsequently, you verified this toxicity category in your own eye irritation study for this product.

On December 1, 1990, you submitted your eye irritation test (MRID No. 417247-01) to us for review as part of your amendment to change the signal word from "WARNING" to "DANGER". Two years later, on December 17, 1992, we faxed you a copy of the toxicity review, dated June 25, 1991, and promised to send you a letter in January 1993. No such letter was sent. We apologize for this oversight. As you see from our comments below, we are now able to accept, with comments, the labeling submitted with your December 1, 1990, amendment.

Status of October 30, 1993, Amendment

On October 30, 1993, you sent us an amendment, reducing the amount of Pine Oil in your product from 72% to 15% and changing the signal word from "DANGER" to "WARNING". In support of this amendment, you submitted four new studies on your new formula and cited an existing study on your old formula, as summarized below:

Test Name	Toxicity Category	MRID No.	Test Material
Acute Oral	3 .		1% Rotenone 72% Pine Oil
Acute Dermal	3	430305-03	1% Rotenone 15% Pine Oil
Eye Irrita- tion	2	430305-02	1% Rotenone 15% Pine Oil
Skin Irritation	3	430305-05	1% Rotenone 15% Pine Oil
Dermal Sensiti- zation	Not a sensitize		1% Rotenone 15% Pine Oil

In August of 1994, we sent these data for review. The normal processing time for packages of multiple toxicity studies is about one year. Therefore, we would expect a response by the end of next month. In view of the past delays with these two amendments, we will be sending a copy of this letter to our toxicity review section to insure that we meet our projected September 30, 1995 response date.

On October 17, 1994, we determined that your chemistry data for the new formula (MRID No. 430305-01) were acceptable.

^{1/}Our June 25, 1991, toxicity review, which was previously sent to you, indicated that we had reviewed previously submitted acute toxicity data under "EPA Accession No. 118214". This information was incorrect and resulted, in part, in the delay in responding to your letter. Actually, these were data conducted by EPA at its Beltsville, Maryland, laboratory in 1974 on your 1%Rotenone/72% Pine Oil formulation. The review should have indicated that the results were reported under EPA Enforcement Review ID Number 118214. For your records, we have enclosed a copy of these documents and our September 3, 1974, letter to the former registrant requesting labeling changes, including changing the signal word from "CAUTION" to "WARNING".

The labeling submitted with your December 1, 1990, amendment, in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you make the following labeling changes before you ship product:

- 1. On the Front Panel, change "WARNING" to "DANGER".
- 2. On the Back Panel, revise your use directions as follows:

DIRECTIONS FOR USE

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

Use Restrictions:

For use only on dogs to kill-fleas, lice, and ticks. DO NOT USE on cats, puppies less than 4 weeks old, nursing, sick, or debilitated pets. Do not use undiluted. Avoid contact of material with eyes, mouth, and nose of animal. SHAKE WELL BEFORE USING.

Application Directions:

For short-haired dogs:

To kill fleas and lice, mix 1/2 fluid ounce of Dip per gallon of water. To kill ticks, mix two fluid ounces of Dip per gallon. Saturate dog's coat thoroughly for several minutes and dry without rinsing.

For long-haired dogs:

To kill fleas and ticks, follow directions for short-haired dogs. To kill lice, first bathe dog with soap and water. Rinse out soap. Then follow directions for short-haired dogs as a final rinse.

Retreatment Instructions:

Retreat when necessary.

3. Structure your PRECAUTIONARY STATEMENTS as follows:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

WARNING

Corrosive. Causes irreversible eye damage and skin irritation [Burns]. Harmful if swallowed. No not get in eyes; on skin, or on clothing. Wear goggles, protective clothing and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Statement of Practical Treatment

IF IN EYES: Flush with plenty of water. Call a physician.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a physician or poison control center. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. Induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters.

4. Revise your "Storage and Disposal" text as follows:

STORAGE AND DISPOSAL

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

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

BEST COPY AVAILABLE

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 bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

Robert A. Forrest Product Manager (14) Insecticide-Rodenticide Branch Registration Division (H7504C)

Enclosure: 1) Stamped label

2) A-79 Enclosure

3) Results of 1974 EPA toxicity test

Peacock WP#6:A:ROTENONE\1452-3:305-5407,-6600:8/30/95

ACCEPTED with COMMENTS in EPA Letter Dated

SPECIMEN LABEL

FRONT

linder the Federal Insecticide, Fungicide, and Rodenticide Act as ancested, for the posticide registered under EPA Reg. No. HILO DIP KILLS FLEAS, TICKS AND LICE EACH OUNCE MAKES 2 GALLONS OF DIP SOLUTION WITH ROTENONE, A BOTANICAL INSECTICIDE

والمتحدث

CLEAN FRESH PINE FRAGRANCE RINSE AWAY FLEAS, TICKS ANC LICE

ACTIVE INGREDIENTS:

Other Associated Resins..... INERT INGREDIENTS.....

KEEP OUT OF REACH OF CHILDREN

WARNING

See Back Panel for Precautionary Statements

NET CONTENTS:

BEST COPY AVAILABLE

BACK

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DIRECTIONS FOR USE

SHAKE WELL BEFORE USING

It is a Violation of Federal Law to use this Product in a Manner Inconsistent with its labelling.

TO KILL FLEAS AND LICE: Pour one tablespoon (fl. oz.) of Dip into a gallon of lukewarm water. TO KILL TICKS, make solution four times as strong. Saturate dog's coat to the skin for several minutes and towel dry without rinsing. Repeat when necessary. To kill lice on long-haired dogs, bathe first with a pet shampoo and water. Rinse out shampoo and use diluted dip solution as a final rinse. DO NOT USE on cats, puppies less than 4 weeks old, nursing, sick or debilitated pets.

STORAGE & DISPOSAL: Do not reuse empty container. Wrap container and put

PRECAUTIONARY STATEMENTS WARNING HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes eye irritation. Do not get in eyes. Wear protective goggles when handling. Avoid contact with skin or clothing. In case of contact, flush eyes with water for 15 minutes. Wash with soap and water ofter handling. Remove contaminated clothing and wash before reuse.

HAZARDS TO THE ENVIRONMENT: This pesticide is extremely toxic to fish. For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water

STATEMENT OF PRACTICAL TREATMENT

- IF IN EYES: Flush with water for 15 minute. Contact physician if irritation
- IF ON SKIN: Wash with soap and water. Remove contaminated clothing and
- IF SWALLOWED: Contact physicial or poison control center. Promptly drink a large quantity of milk, egg whites, gelstin solution, or , if these are not available, large quantities of water. Avoid alcohol. Induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person. NOTE TO PHYSICIAN: Probable mucosal damage man contraindicate the use of gastric lavage,

Manufactured by:

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

EPA EST. NO. 1452-0H-1

EPA Reg. No. 1452-03

TEST OF AVAILABLE