HEC | 6 1991

306. 1510, 505 40051

Perycut-Chemie Ag % Ms. Olivia D. Laird Federal Regulatory Consultants Inc. 501 South Lincoln Avenue Sterling Park, VA 22170

Dear Ms. Laird:

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Subject: Amendment - Resubmission of Product Chemistry and Toxicity Data/Revised Labeling INSEKTEN KILLER - TOPICAL EPA Registration No. 50654-2 Your Submissions Dated July 18, 1991 and August 8, 1991

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes indicated below prior to release for shipment of product bearing the amended labeling.

1. Add the following precautionary statement under Hazards to Human and Domestic Animals:

Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Avoid contamination of feed and foodstuffs.

- 2. Add the heading **Statement of Practical Treatment** and the following statement:
 - IF ON SKIN Remove contaminated clothing and wash affected areas with soap and water.

The above comments were previously requested in the August 29, 1991 Notice of Registration and our August 1, 1990 letter.

3. The statement should read, "Do not use in food/feed areas of food/feed handling establishments..."

Submit five copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

In regards to the product chemistry and toxicity data submitted to support the registration of the product as a condition of registration outlined in the Notice of Pesticide dated August 29, 1990, we have the following comments:

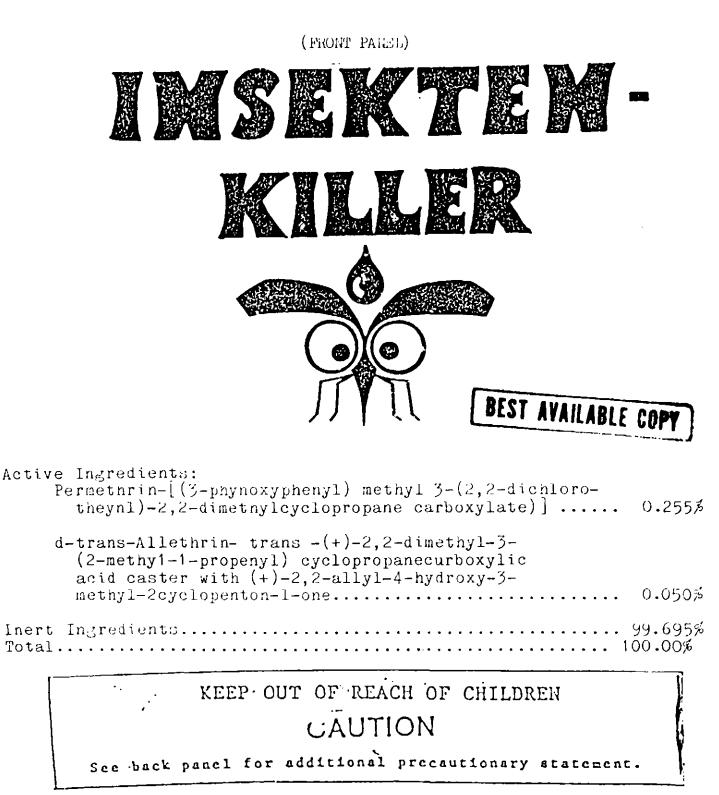
- 1. The Confidential Statement of Formula dated July 18, 1991 is acceptable and has been placed in the record file for the subject product. In the future, be aware that the upper and lower certified limits must be calculated based on the **pure active ingredients** rather than the technical or concentrate.
- 2. The storage stability statement is not acceptable. You must submit the **actual** data analyzing the percent active ingredient at time zero and during one year of storage. The method used for analysis must also be included.
- 3. We prefer the statement "Do not use this product in or on electrical ... " be retained on the label.
- 4. The dermal sensitization study submitted was acceptable and has been graded core guideline non-sensitizer.
- 5. The acute inhalation study submitted was considered supplementary but can be upgrade. In order to upgrade the study the following deficiencies must be addressed.
 - a. Missing particle sizing data: the volume of the sample taken; the rate of sampling.
 - b. It was not stated how the test material was delivered to the nebulizer and what were the "appropriate quantities" that were delivered to the nebulizer.
 - c. The position on the wall of the chamber of the sampling ports is not given.
 - d. The air flow values, how it was measured and how often, was not specified in accordance to guideline requirements.
 - e. There is no indication as to whether any of the equipment was calibrated or not.

f. The weights of the female rats are under the range suggested by the guidelines. There is a difference of 100 grams of weight between the male and female rats. The weight and age of the test animals have a direct bearing in the expressed toxicity.

Sincerely yours,

George T. LaRocca Product Manager 13 Insecticide-Rodenticide Branch Registration Division (H7505C)

Enclosure



For Use Outdoors and in Homes, Kennels, and Non-Food/Feed Areas of Commercial Buildings, Warehouses, Theaters, Office Buildings, Motels, Hotels, and Food/ Feed Processing Establishments. "Not for Use in USDA Meat and Poultry Plants"

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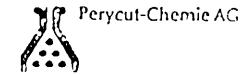
Manufactured for: PERICUT-CHEMIE AG WEHRENBACHHAIDE 54 CH - 8053 ZURICH, SWITZERIAND

EFA REG. 197 50694-2 MAT CONTARCS:

3)A 32. RM. 50654-AT-01



506.54-2



INJEKTENKILLER - TOPICAL (Multiple-purpose insect spray)

KEEP OUT OF REACH OF CHILDREN

CAUTION

(See back panel for additional precationary statements)

NET WT.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION:

Avoid contact with skin or clothing. In case of contact, wash skin with plenty of soap and water. Avoid contamination of feed and foodstuffs.

DIRECTIONS: FOR USE:

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

READ ENTIRE LABEL. USS STRICTLY IN ACCORDARSS WITH LABEL PRECATIONARY STATEMENTS AND DIRECTIONS.

SHARE WELL BEFORE USING:

Point Valve attachment from the pump toward target area. Do not remain in treated area. Ventilate the area after treatment is completed. NOTE: Do not contaminate food, utensils, dishes or drinking water. Do not use in food/feed handling establishments, restaurants or other areas where food/feed is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared foods are served such as dining rooms but excluding areas where foods may be prepared or held.

Non-food/feed areas:

garbage rooms, lavatories, floor drains (to sewer entries and vestibules), offices, locker rooms, machine rooms, garages, mop closets and storage (after canning or bottling). In the home cover all food handling surfaces and cover or remove all food and cooking utensils, or wash thoroughly after treatment. Remove pets, birds and cover fish aquariums before spraying. Do not spray on furniture.

INDOORS - FOR HOUSE FLIES, MOSQUITOS, AND GNATS:

Close all doors and windows. Adjust spray nozzle for fine mist and point upward. Direct spray mist to all parts of the room, especially near windows and other light sources which attract these insects. After the room is filled with the mist, leave the treated area. Keep the room closed for at least 15 minutes. Ventilate the room when treatment is completed.

INDOORS - FOR CRAWLING INSECTS:

Roaches, fleas, silverfishes, earwings, sowbugs, mites, spiders and centipedes: Adjust spray nozzle for course spray droplets. Spray thoroughly toward hiding places, such as cracks, crevices, moist areas, firewood piles, openings around pipes and sink, under refrigerators, baseboards and storage areas. Spray direstly is insects where possible, depent as decreasing. INDOORS - ANTS: Spray trails, nest and points of entry. Spray on ants where possible. Repeat as necessary.

INDOORS - DOG FLEAS: To reduce reinfectation of areas infested with dog and cat fleas, thoroughly spray the animal's bedding and other resting areas. Treat these areas at the rate of 2 seconds per linear foot while spraying at a distance of 12 to 18 inches from target. Also spray entire inside service of dog houses. Repeat as necessary.

OUTDOORS - TO KILL FLYING INSECTS - Adjust spray nozzle for fine mist. Spray areas infested with mosuitoes, gnats (midges), house flies, biting flies and pyralid and noctuid flying moths. Follow precautions listed above. Hold nozzle 18 to 24 inches from shrubs, bushes, and grassy areas. Spray these areas with a slow sweeping motion at the rate of from 1 to 3 seconds per cubic yard of space while moving away from treated areas. To reduce annoyance from these flying insects, treat open porches and patios in a similar manner. Spray only when the air is still. Allow spray to dissipate before occupying the treated area. Repeat as necessary.

OUTDOORS - ANTS: Spray trails, nests and point of entry. Spray on ants where possible. Repeat as necessary.

OUTDOORS - SPIDERC: Direct snort bursts of gray on spiders and repeat as necessary.

OUTBOORD - WASPS: Application should be made in late evening when insects are at rest. Spray liberally into hiding and breeding places, contracting as many insects possible. Repeat as necessary.

DISPOSAL:

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Do not reuse empty pesticide containers otherthan the application equipment. Wrap the container and put into trash collection.

PHYSICAL/CHEMICAL HAZARDS:

Do not use this product in or on electrical equipment due to the possibility of shock hazard.

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.