

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

CASWELL FILE

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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

APR 20 1990

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OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. Nos.: 59-195 (EXPAR 3.2 EC) and 59-210 (EXPAR Insecticide Repellant for Dogs and Horses).
Permethrin: Review of a domestic animal (dog) safety study with the product EXPAR 3.2 EC.

TOX CHEM No.: 652BB
TOX PROJECT No.: 8-1215
Record No.: 231578

FROM: John Doherty *John Doherty 5/25/89*
Section I, Toxicology Branch I (IRS)
Health Effects Division (TS-769)

TO: George LaRocca
Product Manager #15
Registration Division (TS-767)

THROUGH: Edwin Budd *Edwin Budd 5/15/89*
Section Head
Section I, Toxicology Branch I (IRS)
Health Effects Division (TS-769)

*R. H.
7-10-90*

The Cooper's Animal Health Company (refer to letter from Donald A. Buss, dated July 14, 1988) is requesting that a animal safety study conducted with the product EXPAR 3.2 EC (EPA Reg. No.: 59-195) be reviewed and made a part of the file for this product. They are also requesting that this study be used to fulfill a domestic animal safety study request made by the Agency for the product EXPAR Insecticide Repellent for Dogs and Horses (EPA Reg. No.: 59-210)

The study submitted utilizes permethrin formulated as a dip product at 3.2% and the dogs were dipped at 1X and 4X the recommended rate or in bath containing 0.05% and 0.2% permethrin. No adverse effects were noted in the treated dogs under the test conditions employed.

EXPAR Insecticide Repellent for Dogs and Horses is a spray or wipe on product formulated at 1% permethrin. The use pattern of the Insecticide repellent is not the same as for dipping the dogs. Toxicology Branch I (TB-I) has determined, however, that the dipping of the dogs in the permethrin baths

should result in exposure to permethrin that is at least the same but more likely more that when spraying the dogs with the Insecticide repellent product.

Therefore TB-I concludes that the study submitted can be used to support the request for a domestic animal safety study with the product EXPAR Insecticide Repellent for Dogs and Horses.

The following comments, however, apply:

1. The label must be altered to read in essence that the product should not be used on animals more than once every seven days. The present label states that the product may be used as often as necessary. [Note: Since the dogs were dipped at weekly intervals in the study submitted to support its use on animals, there is no basis for the unrestricted application of this product.
2. The label statement reference to "non-burning" may be considered an example of misbranding the product. In particular, this represents a claim to safety which is not appropriate for labelling under Section 162.10(a)(5) Title 40. The use of this term in this label is also ambiguous because the user may interpret that the product is not flammable rather than not burning the eyes and skin of the treated dogs. TB-I advises that the term "non-burning" be deleted from the label.
3. TB-I has not reviewed the studies supporting the label signal word and precautionary statements for the product EXPAR Insecticide Repellent for Dogs and Horses. Of particular concern is that this product should be supported by a primary eye irritation study. The PM team should assure that these studies are available, have been reviewed and that the signal word and precautionary statements are appropriate
4. A recent (December, 1988) Peer Review meeting determined that permethrin is a Category C oncogen and that risk assessments for the individual uses of permethrin should be determined. In this regard, TB-I requests that the Product Manager arrange with Non-Dietary Exposure Branch to have exposure information related to users (applicators and dog/horse owners/handlers) of the product EXPAR Insecticide Repellent for Dogs and Horses generated. This information should be forwarded to TB-I after review by Non-Dietary Exposure Branch.

[Note: Mr. William Greear of TB-I/HED kindly provided useful comments and suggestions for this review.]

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Reviewed by: John Doherty *John Doherty* 5/25/89
Section I, Toxicology Branch I, (IRS)
Secondary reviewer: Edwin Budd *EB* 8/5/89
Section I, Toxicology Branch I, (IRS) *Act 13*

DATA EVALUATION REPORT

STUDY TYPE: Domestic Animal Safety

ACC. No.: 408067-01

TOX. CHEM. NO.: 652BB

TEST MATERIAL: EXPAR 3.2 EC (EPA Reg. No. 59-195)

SYNONYMS:

STUDY NUMBER(S): RA 53188

SPONSOR: Cooper's Animal Health, Inc.

TESTING FACILITY: Cooper's Animal Health Inc., Kansas City, Ks.

TITLE OF REPORT: Results of a study to determine the safety
of permethrin in dogs.

AUTHOR(S): J.G. Gladney and J.E. Dyer

REPORT ISSUED: May 31, 1988

CONCLUSIONS: Dipping dogs in EXPAR 3.2 EC at 1X and 4X (0.05% and 0.2% permethrin) the usage rate did not result in any noticeable adverse reactions in the appearance or behavior of the treated dogs.

Classification: ACCEPTABLE.

Special Review Criteria (40 CFR 154.7): N/A

Quality Assurance Statement:

A Statement signed by S.L. Hall was provided. Mr. Hall attested that he participated (as QA officer) in the study up until the completion of the second dipping. There was no indication that Mr. Hall verified the final report of the study.

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REVIEW

In this study, 12 dogs (described as mixed beagle, mixed hounds and mixed breed) reported as being of 3-4 months old and weighing 6-21 pounds were dipped in tanks containing the permethrin shampoo product at 0, 0.05% and 0.2%. They were reported as being held in the tanks for "a minimum of five seconds". Two dogs served as untreated (undipped) controls and five dogs were dipped at each concentration level. Their whole bodies were immersed except for their faces. After dipping, the dogs were returned to their cages and allowed to air dry. They were observed for reactions at two, four, six and eight hours after treatment and daily thereafter for four days. After one week, the dogs were again dipped in the permethrin containing baths and the process of observation was repeated.

Results.

No evidence of adverse reactions were reported as being noted in any dog at anytime throughout the experiment.

Conclusion.

This study is ACCEPTABLE. The study demonstrates that dipping dogs in 0.05% and 0.2% permethrin wash prepared from EXPAR 3.2 EC does not result in any observable effects on the health of the treated dogs. These concentrations represent 1X and 4X the recommended label instructions for the product EXPAR 3.2 EC.

NOTE: This study contained a comprehensive blood analysis of the dogs used in the study that was taken before dipping. Although the data are useful for evaluating the health of the dogs prior to dipping, these data are useless in evaluating the effects of permethrin treatment.

(ALL COPY BLACK EXCEPT AS INDICATED)

Label - Expar[®] Insecticide/Repellent For Dogs and Horses

(PMS PROCESS BLUE BACKGROUND)

(Front Panel)

505230

(WHITE REVERSE TYPE)

Expar[®] Insecticide/Repellent For Dogs and Horses

- For control of fleas, ticks and lice on dogs for up to 28 days after application.
- Controls fleas on premises for up to ten weeks.
- Repels* and controls gnats, mosquitoes, biting flies, house flies and ticks on dogs and horses.
- Controls cockroaches**, fleas, ticks, silverfish** and spiders** on premises.

Active Ingredient

Permethrin (3-phenoxyphenyl) methyl (±)-cis, trans-3-

(2,2 dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate*** 1.0%

Inert Ingredients 99.0%
100.0%

***cis/trans ratio: Max 55% (±) cis and min 45% (±) trans

KEEP OUT OF REACH OF CHILDREN
CAUTION
SEE BACK FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 31 1987

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

59-210

Net contents one U.S. pint (473 ml)

EPA Est. 6175-LA-1

EPA Reg. 59-210



Coopers Animal Health Inc.

Kansas City, KS 66103-1438 U.S.A.

*U. S. Patent No. 4,020,181

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(PMS RED-185 PARENTHESIS)

4510PFR

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(ALL COPY BLACK EXCEPT AS INDICATED)

(Back Panel)

Expar[®] Insecticide/Repellent For Dogs and Horses

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

For animal use only. **DO NOT USE ON CATS.** Not for use on humans. Harmful if swallowed. Avoid breathing spray mist. Avoid contact with eyes, skin or clothing. Avoid contamination of food. Wear gloves when applying this pesticide product. Wash thoroughly with soap and water after handling. Do not allow children or pets to contact treated surfaces until surfaces are completely dry.

STATEMENT OF PRACTICAL TREATMENT

If Swallowed: Call a physician immediately. **DO NOT INDUCE VOMITING** unless under medical attention.

If On Skin: Remove contaminated clothing and wash skin thoroughly with soap and water.

If In Eyes: Immediately flush eyes with plenty of water. Get medical attention if irritation persists.

Note To Physician: This product contains petroleum distillates. Vomiting may cause aspiration pneumonia.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not add directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes.

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use spray
insects
or more
of floor

(ALL COPY BLACK EXCEPT AS INDICATED)
DIRECTIONS FOR USE

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

Not for use on horses intended for human consumption.

Expar Insecticide/Repellent For Dogs and Horses is ready-to-use. No mixing necessary. The non-burning water-base formulation has been developed to use full strength and may be applied directly with trigger spray applicator or as a wipe-on.

Expar Insecticide/Repellent For Dogs and Horses kills fleas, ticks and lice on dogs. Expar also repels and controls house flies, stable flies, horn flies, face flies, horse flies, deer flies, mosquitoes and gnats on dogs and horses; also kills fleas, ticks, cockroaches, silverfish and spiders around premises. Repels flies, mosquitoes and gnats for 3-5 days on horses.

SHAKE WELL BEFORE USING

FOR USE ON DOGS: Remove cap and insert sprayer. Cover animal's eyes with hand, and using a firm fast stroke to get a proper spray mist, spray head, ears and chest until damp. With gloved hand rub into face around mouth, nose and eyes. Then spray neck, middle and hindquarters, finishing legs last. For best penetration of spray to the skin, direct spray against the lay of the hair. On long haired dogs rub your hand against the lay of hair spraying the ruffled hair directly behind the hand. Make sure spray thoroughly wets ticks.

Old bedding of pets should be removed and replaced with clean fresh bedding after treatment. Expar Insecticide/Repellent for Dogs and Horses provides up to 28 days residual protection against fleas, ticks and lice on dogs and up to 10 weeks residual protection against fleas in carpets. This product may be used as often as necessary.

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(ALL COPY BLACK EXCEPT AS INDICATED)

FOR USE ON HORSES: AS A SPRAY: First, remove excess dirt and dust by brushing. Apply spray to animal paying special attention to legs, shoulders, and neck. For head and eye area, dampen an applicator mitt, cloth or toweling (Turkish) with Expar Insecticide/Repellent For Dogs and Horses and wipe over face. Be especially careful not to get in eyes. Do not soak hair or skin. Repeat as necessary. **AS A WIPE-ON:** First, remove excess dirt and dust by brushing. Dampen an applicator mitt, cloth or toweling (Turkish) with Expar Insecticide/Repellent For Dogs and Horses. Rub over hair with special attention to the legs, shoulders, neck and facial areas where flies tend to congregate. Be especially careful not to get in eyes. Repeat as necessary.

SURFACE SPRAY FOR CONTROL OF FLEAS AND TICKS: Thoroughly spray infested areas such as pet's bed and resting areas, along baseboards and localized areas of floor and floor coverings (such as carpeting) where pests may be present. Treatment of all infested areas is desirable. Pet's bed and resting areas should be sprayed to dampness. This application will control fleas up to 10 weeks. Apply spray uniformly to other localized areas; as a guide, 16 oz will cover 200 sq. ft. Allow sprayed areas to dry thoroughly.

SURFACE SPRAY FOR CONTROL OF COCKROACHES, SILVERFISH** AND SPIDERS**:** Spray baseboards, corners, cracks, crevices and other harborage areas where these pests frequent and hide. Assure that food, feed and food utensils are not contaminated by spray or spray drift.

**Not approved for control in California.

STORAGE AND DISPOSAL

Storage: Store in cool, dry place. Protect from freezing.

Pesticide Disposal: Securely wrap original container in several layers of newspaper and discard in trash.

Container Disposal: Do not reuse empty bottle. Wrap bottle and put in trash.

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NOTICE OF WARRANTY

COOPERS ANIMAL HEALTH 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.