PMSD/ISB

0289-I

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

DEC 19 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. #4691-108 [RCB # ~~3119~~ 67] [Acc.#: None] — Permethrin: Amended Registration. New tail device for cattle.

FROM: William L. Anthony
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Hazard Evaluation Division (TS-769C)

TO: George T. LaRocca
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and

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THRU: Ed Zager, Section Head
Special Registration II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

Boehringer Ingelheim Animal Health, Inc., St. Joseph, MO requests an amended registration of their approved 10% EC insecticide, PERMETHRIN™-I (EPA Registration No. 4691-108).

The petitioner proposes a new trade name, MORMECTRIN™ and a new method of application, using a tail attachment device, TAT-L-TAIL™. As with PERMECTRIN™-II, MORMECTRIN™ is for use on beef, dairy cattle, and horses to aid in the control of flies, lice, mites, and ticks.

Tolerances for residues of permethrin, (3-phenoxyphenyl) methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate and its metabolites (DCVA, 3-PBA, 3-phenoxybenzoic acid) include

2 ppm for cattle fat, 1 ppm for cattle meat by-products, 0.15 ppm for cattle meat, and 3.75 ppm for milk fat (reflecting 0.15 ppm in whole milk) (40 CFR 180.378).

Manufacture and Formulation

(See Confidential Appendix)

Registered use for PERMECTRIN™

PERMECTRIN™-II is registered for use on beef and dairy cattle, and horses at the rate of 1 qt(94.6 gm ai) of the formulation in 200 gals water for whole body spraying not to exceed 1 to 1.5 gals of spray/animal or < 0.473 gms ai. For lice or mites, a second treatment is recommended 14 to 21 days later.

Proposed Use for MORMECTRIN™

The application will be made by dispersion from a device containing 3 ml of the formulation (0.3 g ai) attached to the animal's tail. The application will continue over a period of one month to several months. (Note: the formulation is on the inside of the device covered by porous tape.)

When retreatment is necessary the reservoir in the tail device may be refilled with 2.5 to 3.0 ml (0.25 to 0.30 gm ai) of the formulation (either MORMECTRIN™ or PERMECTRIN®-II)

Residue Data

No residue data were submitted with this action.

See PP#1F2564, J. Onley, February 25, 1982, for available residue data for dermal use of permethrin on cattle.

Lactating dairy cattle were sprayed with 2 quarts of a 0.05% ai solution every 2 weeks for about 8 months (18 total applications). This is equivalent to 0.034 oz (or 1.07 gms) ai/cow/treatment (about 0.8x the requested rate). In addition the premises were treated every 2 weeks at the then proposed rate and the cows were forced to pass under a permethrin treated back rubber each day. Only trace levels (< 0.01-0.02 ppm) of parent compound and the various metabolites were found in fat, liver, kidney, and muscle samples taken 1 and 5 days after the final dermal application. Milk collected throughout the study had a maximum of 0.017 ppm permethrin per se with metabolites ≤ 0.01 ppm. From that experiment it can be seen that the dermal and premise uses of permethrin result in very low residues in tissues and milk. Therefore, the requested use would not result in residues

exceeding the current tolerances for permethrin and its metabolites (DCVA, 3-PBA, and 3-phenoxybenzoic acid) on fat, meat, and meat by-products of cattle and horses at 2.0 ppm, 0.15 ppm, and 3.0 ppm, respectively; and 3.75 ppm for milk fat (reflecting 0.15 ppm in whole milk).

Conclusion

Residues from the proposed use of the tail device containing permethrin are not expected to exceed the established tolerance for milk and fat, meat, and meat by-products of cattle and horses. We have no objection to the use of this product, as proposed.

Attachment (Confidential Appendix): Reviewer: PM #15:PMSD/ISB: Amend. Files, RF, SF.
cc: R.F., Circu., S.F. (Permethrin), Amend. Files (Permethrin): PMSD/ISB:Reviewer

Permethrin residue chemistry review

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Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

___ A draft product label

_X_ The product confidential statement of formula

___ Information about a pending registration action

___ FIFRA registration data

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
