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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA File: #493-TT
[RCB#: 1513]
[Acc#: 265202]

Diazinon: Ear Tags on Beef and Nonlactating Dairy Cattle.

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THRU: Ed Zager, Section Head
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Fermenta Animal Health Company (SDS Biotech), Painesville, Ohio, requests registration of their new ear tag end-use product TERMINATOR (active ingredient diazinon) for use on beef cattle and nonlactating dairy cattle.

The product is to control horn flies, face flies, Gulf Coast ticks, spinose ear ticks, and as an aid to control lice, stable flies, and house flies.

There are established tolerances for residues of diazinon [O,O-diethyl-O-(2-isopropyl-6-methyl-4-pyrimidinyl) thioate] on fat, meat, and meat byproducts of cattle at 0.7 ppm [40 CFR 180.153].

For a recent review on ear tags containing diazinon on beef cattle, see memorandum, L. Cheng, 5/16/1986.

Manufacture of Formulation

(See Confidential Appendix)

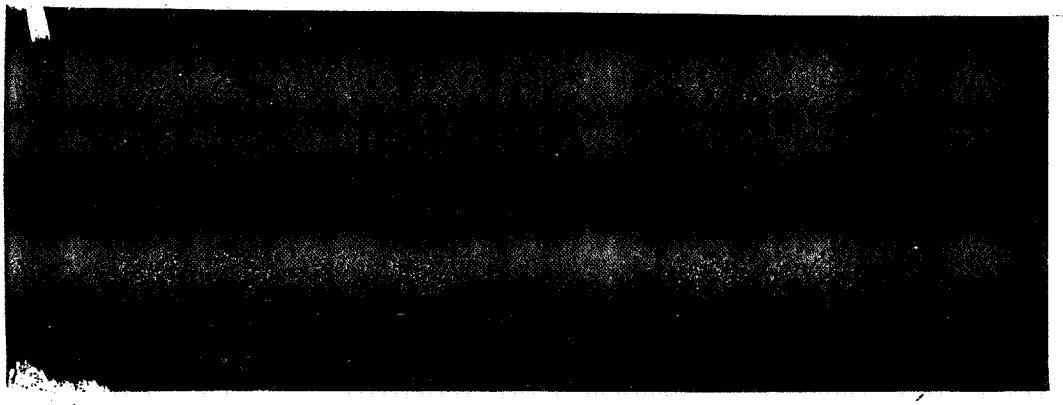
Confidential Statement of Formula

(See Confidential Appendix)

Proposed Use

One tag is to be applied to each ear of the beef or non-lactating dairy cattle. A single application is sufficient to obtain approximately 4 month pest control. The ear device is formulated to accomplish its purpose by slowly releasing the active ingredient, diazinon, in an adequate daily dose. Each ear tag weighs 15 g and contains about 3 g/ai.

Analytical Procedures (Method PMS 697/86; August 1986)



Residue Data

No new residue data on spraying or dipping of cattle was submitted with this request.

The registrants did, however, include the earlier residue studies on depletion release of diazinon from the ear tags drawn from PP#406, from which tolerances were established on fat, meat, and meat byproducts of cattle. This data were drawn from dermal application of diazinon:
Hereford weanlings (five treated and three controls) received 16 weekly dermal sprays of 0.05% dilution of diazinon. It was calculated that each treated animal received a total of 1.9 g/ai/gal/animal (500 lb)/application to runoff or a total of 30.4 g of diazinon for the 16-week period (112 days). From these data the average daily dose per treated animal would be 0.27 g of diazinon.

Duplicate fat samples from controls and weekly sprayed cattle were removed by omenectomy. Fat tissues were targeted for analysis because diazinon tends to accumulate more in fat than in other body tissues. These samples, as a result of 0.05% diazinon sprays and analyzed spectrophotometrically by

both Geigy labs and USDA labs, ranged from < 0.05 to 0.74 ppm residues when sampled 1 day after the 11th spray, and < 0.05 to 0.69 ppm residues when sampled 1 day after the 16th spray (all Geigy values). The values obtained by USDA labs were higher: 0.58 to 0.89 ppm and 0.77 to 0.87 ppm, respectively. Recoveries ranged from 90 to 129% (Geigy) and 92.5 to 102% (USDA). Spike levels were not given (memorandum: L. Cheng, May 16, 1986).

In one feeding study (see Registration Standard for Diazinon, August 22, 1986, pp. 209 to 210), residues of diazinon were determined in various tissues of Angus steers. The steers (number unknown) received an oral dose of 5.30 mg/kg/ai for 14 consecutive days, followed by a 7-day pre-slaughter interval.

Tissue analyses were performed by the so-called "sulfide" technique (see PAM II, Method II(b), "Method for extracting diazinon from meat and fat prior to determination by the sulfide procedure," November 1, 1975). The results are shown below: Residues in control samples were all < 0.01 ppm.

DIAZINON RESIDUES (ppm)*

Tissue	
Fat	0.10–0.23
Heart	<0.01
Muscle	0.017–0.094
Liver	0.01–0.073
Brain	<0.01

RECOVERY

Tissue	Fortification (ppm)†	% Recovered
Fat	0.2–0.8	79–93
Heart	0.04–0.8	76–84
Muscle	0.2–1.0	19–66
Liver	0.2–0.8	85–104
Brain	0.2–0.8	46–98

* Range of two samples

† Three samples each

Depletion of Diazinon and [redacted] from Ear Tags

A field study was initiated by the registrants in Hawaii for analysis of tags worn by cattle. The results for diazinon were obtained by Method PMS 697/86 (see "Analytical Procedure" above); [redacted] (see Confidential Appendix).

Two tags were applied to each animal at day 0; after an elapsed time of 14, 35, 56, 84, 112, and 140 days, four tags were removed from the animals and each tag was analyzed in duplicate. (Note: Number of animals used in this study was not given.) Results obtained from the four values were then

averaged for each collection date. The cumulative loss of diazinon and the [redacted] were plotted vs. time (days).

The initial average weight of each ear tag was 15 g, of which about 3.03 gm were diazinon and [redacted]. Results indicated that after 14 days, 7.8% or 241 mg of diazinon had been depleted. Therefore, during the 14-day time period, the average daily depletion rate was 17.2 mg/day.

In comparison, when tags were removed after 140 days, the average daily depletion rate was about 11.2 mg/day.

Statistical regression value would indicate that an average of 10.15 mg of diazinon (20.30 mg for two ear tags) and [redacted] for two ear tags) is depleted daily over a 140-day period.

Depletion rate for the active ingredient and the [redacted] in this current study, is about half of the depletion rate shown in our RCB memorandum of May 16, 1986. The exposure of diazinon to cattle from ear tags is considerably less than exposure in spraying, dipping, or feeding.

We conclude that use of ear tags on beef cattle/nonlactating dairy cattle would not exceed the established tolerance for diazinon on fat, meat, or meat byproducts, when applied according to proposed use.

The company has requested an exemption from the requirement of a tolerance on the [redacted] RCB recommended against the requested exemption [redacted]

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Conclusion and Recommendation

Application of ear tags according to the proposed use will not exceed the established tolerance for active ingredient on fat, meat, and meat byproducts of beef cattle and nonlactating dairy cattle.

We recommend against the registration of TERMINATOR because [redacted] in the ear tags is not cleared under 40 CFR 180.1001(e).

Attachment(Confidential Appendix):Reviewer;PM#15;RF;PMSD/ISB;TOX.

cc: SF(diazinon);RF;Circu;PMSD/ISB;Reviewer.
RDI: LC,11/21/6;RDSchmitt,11/24/86.
TS-769;RCB;WAnthony;CM-2;Rm810;X4351

EPA Registration No. 56493-77

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Pages 5 through 7 are not included in this copy.

The material not included contains the following type of information:

_X_ Identity of product inert ingredients

___ Identity of product impurities

_X_ Description of the product manufacturing process

___ Description of product quality control procedures

_X_ Identity of the source of product ingredients

___ Sales or other commercial/financial information

___ A draft product label

___ 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.