JAN 2 6 2005

Ms. Angel Bishop Boehringer Ingelheim 15th & Oak Street Elwood, Kansas 66024-0338

Dear Ms. Bishop:

Subject: Amendment- Label and Confidential Statement of Formula

(CSF) - basic and alternates (a and b)

Ear Force Tags

EPA Registration Number 4691-113

Your submissions dated October 6, 2004

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(a), is acceptable provided that you:

- Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA section 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.
- 2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
- a) Based on the toxicity profile for this type product you may delete the If on shin and If swallowed first aid statements. Likewise replace the first statement under Hazards to Humans to, "Causes moderate eye irritation" and delete "skin and" in the second statement.
- b) Delete "Reformulation or repackaging of this product is prohibited". This statement is in conflict with the data compensation provisions of FIFRA.
- c) Specify a specific time interval (based on efficacy data) when to replace tag. The term "Replace as necessary is non-specific.
- 3. Submit three (3) copies of your final printed labeling before you release the product for shipment.

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 constitutes acceptance of these conditions.

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

Your basic and two alternate Confidential Statement of Formula (CSF) dated October 5, 2004 have been reviewed and are acceptable and will supercede the currently acceptable CSF for the basic.

Sincerely,

George T. LaRocca Product Manager 13 Insecticide Branch Registration Division (7505C)

Enclosure

EAR FORCETM TAGS

FOR USE ON DRY OR LACTATING DAIRY AND BEEF CATTLE AND CALVES TO CONTROL HORN FLIES, FACE FLIES, GULF COAST TICKS, SPINOSE FARPTED TO CONTROL HUKN FLIES, FACE FLIES, GOLL COAST. TO COAST.

KEEP OUT OF REACH OF CHILDREN **CAUTION**

See side and end panels for additional directions for use. amended, for the problem of the probl

registered ;	91-113
	10.00%
	<u>90.00%</u>

TOTAL 100.00%

*Cis/trans ratio: Min. 35% (\pm) cis and max. 65% (\pm) trans isomers.

Permethrin* (CAS No. 52645-53-1) Other Ingredients

Net Weight:

ACTIVE INGREDIENTS:

10 Grams Per Tag

Contents:

24 Tags

FIRST AID
e off contaminated clothing. se skin immediately with plenty of water for 15-20 minutes.
a poison control center or doctor for treatment advice
d eye open and rinse slowly and gently with water for 15-20 utes.
nove contact lenses, if present, after the first 5 minutes, then tinue rinsing eye.
a poison control center or doctor for treatment advice.
l a poison control center or doctor immediately for treatment ice.
re person sip a glass of water if able to swallow.
not induce vomiting unless told to do so by a poison control ter or doctor.
not give anything by mouth to an unconscious or convulsing son.
t

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-821-7467 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if absorbed through the skin or if swallowed. Avoid contact with skin and eyes. Wash thoroughly with soap and water after handling and before eating or smoking. Wear non-permeable gloves when applying tags.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not apply directly to water. Do not contaminate water by disposal of used tags.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

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

Reformulation or repackaging of this product is prohibited.

For adequate control of horn flies, attach one tag per animal. For optimum control of flies, Gulf Coast ticks, spinose ear ticks, and as an aid in the control of lice, stable flies, and houseflies, attach one tag to each ear (two per animal). Replace as necessary. Apply as indicated (Figures 1-5). Calves less than 3 months of age should not be tagged as ear damage may result. Remove tag prior to slaughter.

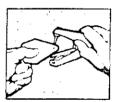


Figure 1. Place female tag under clip by depressing lever. Collar on tag must be pointing down.



Figure 2. Slide rivet on pin. Align tip of rivet with female portion of tag. Tag and rivet are now ready for application.





Figure 3 and Figure 4. Position tag on the inner flat surface in center of ear. Do not allow shaft of the male rivet to penetrate any cartilage rib or blood vessel or ear damage may result. We recommend that tag be rotated at a 90° angle (Fig. 3) for ease of application. Tag may also be extended outward from the plier in a straight manner (Fig. 4).



Figure 5. When properly positioned, the tag should hang as shown.

DIRECTIONS FOR USE (For Duflex Tagging System)

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

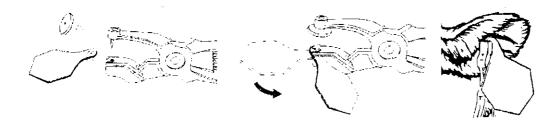
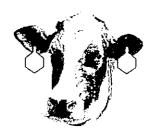


Figure 1: Place female tag under clip by depressing lever. Collar on tag must be pointing down.

Figure 2: Slide male stud on pin until it is firmly seated. Tag and stud are now ready for application. Disinfect pliers and tags prior to application.

Figure 3: Position tag on the flat surface in center of ear. Do not allow shaft of the male stud to penetrate any cartilage rib or blood vessel. Ear damage may result. When properly positioned, the tag should hang down as shown.



STORAGE AND DISPOSAL

Store in a cool place in original container.

Opened pouches containing ear tags should be resealed for storage. Do not contaminate water, food, or feed by storage or disposal.

<u>Pesticide Disposal</u>: Waste (spent tags) resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

<u>Container Disposal</u>: Dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND LIMITATION OF DAMAGES

Seller warrants that this material conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use and Buyer assumes the risk of any use contrary to such directions. Seller makes no other express or implied warranty, including any other express or implied warranty of Fitness or of Merchantability, and no agent of Seller is authorized to do so except in writing and with a specific reference to this warranty. In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which a claim is made.

Boehringer Ingelheim Vetmedica, Inc. St. Joseph, MO 64506 U.S.A. (800) 821-7467

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