

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 14, 2012

Mr. Micah Reynolds Agent for Intervet, Inc. c/o Technology Sciences Group, Inc. 1150 18<sup>th</sup> S. NW, Suite 1000 Washington, DC 20036

Subject:

Amended Reregistration Label

Product Name: Saber Extra Insecticide Ear Tags

EPA Registration Number: 773-75 EPA Decision Number: 411156

Dear Mr. Reynolds:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the **Piperonyl Butoxide** RED and has concluded that your submission is acceptable.

NOTE: This product is **not** being reregistered under sections 3(c) 5 and 4(g) of FIFRA at this time.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated 3/7/11
- Alternate CSF, dated 3/7/11

Please note that, should you wish to add/retain a reference to the company's website on your label, the website becomes labeling under FIFRA and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not be substantially differ from those claims approved through the registration process. Therefore, should the Agency find, or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on <u>non-refillable</u> containers. The code may appear either on the label or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact either Melody Banks at (703) 305 5413 or via e-mail at *Banks Melody@epa.gov*.

Sincerely yours,

Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7505P)

Enclosures: Label stamped "Accepted," dated 12/14/12

Product Chemistry Review, dated 9/2/11 Acute Toxicity Review, dated 10/13/10

EPA Reg No: 773-75

Amended Label: Version 1.1

"Master Label": This master label includes text for different size packages and application rates specific to

pet's age and body weight.

#### PRIMARY CARTON FRONT PANEL STATEMENTS

0061-5019-02

# SABER Extra INSECTICIDE EAR TAGS

For up to 5 months control of horn flies and up to 4 months control of face flies (Use two tags per head) on beef and non-lactating dairy cattle and calves ACTIVE INGREDIENTS:

Picture of Cow with Calf

# KEEP OUT OF REACH OF CHILDREN CAUTION

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 773-75

EPA Est. No. 618-LA-1



Net Wt: 9.5 grams per tag

Contents: 20 tags and buttons

Treats 10
Head
Of Cattle



DEC 1 4 2012

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide Registered under EPA Reg. No. 723-75

<sup>\* (</sup>butyl carbityl)(6-propylpiperonyl) ether and related compounds.

DATED: 13Dec2012

Page 2 of 4

#### PRIMARY CARTON BACK PANEL STATEMENTS

### SABER Extra INSECTICIDE EAR TAGS

#### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS **CAUTION**

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing.

FIRST AID	
IF SWALLOWED:	• Call a poison control center or doctor immediately for treatment advice. • Have a person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison
	control center or doctor. • Do not give anything by mouth to an unconscious person.
If ON SKIN OR	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20
<b>CLOTHING:</b>	minutes. • Call a poison control center or doctor for treatment advice.
IF IN EYES:	Hold eyes open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
	HOT LINE NUMBER
	ontainer or label with you when calling the poison control center or doctor or going for treatment. act the Rocky Mountain Poison Center at 1-303-595-4869 for emergency medical treatment

#### **ENVIRONMENTAL HAZARDS**

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.

#### Personal Protection Equipment (PPE)

Applicators and other handlers must wear: Long-sleeved shirt and long pants, Shoes, socks and Chemical-resistant gloves made of any waterproof material.

#### **User Safety Requirements**

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

#### User Safety Recommendations

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. User should remove clothing/PPE immediately if pesticides get inside. Then wash thoroughly and put on clean clothing. User should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Amended Label: Version 1.1

DATED: 13Dec2012 Page 3 of 4

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This labeling must be in the possession of the user at the time of pesticide application. Avoid contamination of food or feedstuffs. Wear rubber or nonpermeable protective gloves when applying or removing tags.

Figure 1

Figure 2

Figure 3

Figure 4

Place male button onto pin until it projects through the tip.

Dip tag button into disinfectant solution

Press female tag under the clip by depressing

Apply through ear between second and third rib, halfway between ear tip and head.

For optimum control and to minimize development of insect resistance, use two tags per animal (one in each ear). All animals in the herd should be tagged. Apply when flies first appear in the spring. Replace as necessary. Apply with ALLFLEX®\* Tagging System. Tags remain effective up to 5 months. Remove tags in the fall.

Continual exposure of horn flies to a single class of insecticides (eg. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticides. In order to reduce the possibility of horn flies developing resistance, it is important to rotate the class of insecticide used and/or the method of horn fly control on a seasonal basis. For advice concerning current control practices with relation to specific local conditions, consult resources in resistive management programs and/or your Cooperative Agricultural Extension Service.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in cool place away from direct sunlight. Pesticide Disposal: Remove tags before slaughter. Tags may be disposed of on site or at an approved waste disposal facility. Container Disposal: Nonrefillable container. Do not reuse or refill this container. Dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

#### NOTICE OF WARRANTY

MERCK ANIMAL HEALTH 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 ACCORDANCE WITH THE STATEMENTS ON THIS LABEL.

Copyright ® 1998, Intervet Inc d/b/a Merck Animal Health, Summit, NJ 07901 \*ALLFLEX is a registered trademark of Allflex USA, Inc.

Rev. 09/12

Aménded Label: Version 1.1

### Left and Right Side Panels

# SABER Extra INSECTICIDE EAR TAGS

Top and bottom Flap Panels

## SABER Extra INSECTICIDE EAR TAGS

Treats 10 Head Of Cattle