

4691-123

10/09/2003

Page 1810



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

OCT 9 2003

Ms. Angela Bishop
Boehringer Ingelheim Vetmedica, Inc.
15th & Oak Streets, P.O. Box 338
Elwood, KS 66024-0338

Subject: Amendments Updating First Aid and Respirator Requirement per PR Notices
2001-1 and 98-9; Revising the Basic Confidential Statement of Formula;
and Adding Pour-on Instructions for Livestock
Permethrin WS
EPA Registration Number: 4691-123
Your Submissions Dated July 17, 2003 and September 4, 2003

Dear Ms Bishop:

I. Revised Basic Confidential Statement of Formula:

The revised Confidential Statement of Formula (CSF), dated 7/17/03, referred to above and submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is not acceptable for the following reasons:

1. Only permethrin and piperonyl butoxide (PBO) source products with the same (or nearly the same) nominal concentrations should be included on the same CSF. Source products with different nominal concentrations (such as EPA Reg. Nos. 1021-974, an 80% PBO product, and 4816-699, a 90% PBO product) should be included on separate (alternate) CSFs, so that the amount of the source product and inert ingredients can be adjusted to account for the different concentrations of active ingredient in the source products.
2. The certified limits of the active ingredients must be the same regardless of the source product used to make the product, and they must be based on the nominal concentration of the active ingredients (8.5% permethrin and 4.25% PBO in this case).
3. The total weight in block 17 must be equal to the sum of the amounts in column 13a, and the percentages in column 13b must total 100.

2710

II. Label Amendment submitted September 4, 2003, incorporating revisions submitted July 17, 2003:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comment below. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. You must remove the new directions for "Pour-on" application under "Pests on Livestock: Beef Cattle, Lactating and Non-Lactating Dairy Cattle, Sheep, Goats and Swine" on page 4. Before we can approve these directions you must submit or cite data to support this application method, including efficacy and residue data. Alternatively, you may identify a substantially similar product with these use directions and use the "cite-all" method of data support, making appropriate offers to pay to companies on the data submitters' list for permethrin and piperonyl butoxide.

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,



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

Enclosure

3 7 10

**DRAFT LABEL
FRONT PANEL**

BI/LOGO

**PERMECTRIN WS
A WATER BASE, SYNERGIZED, CONCENTRATE INSECTICIDE WITH UP TO 30 DAYS RESIDUAL
EFFECTS ON INANIMATE SURFACES**

FOR AGRICULTURAL USE ONLY. NOT FOR HOUSEHOLD USE.

- °Broad Spectrum Insecticide/Acaracide
- °Synergized
- °Quick Knockdown
- °For Control of Insect Pests on Livestock, Poultry and Farm Premises
- °For Control of Insect Pests on Horses
- °For Control of Ticks Including Deer Ticks (carrier of Lyme Disease)
- °Pleasant Citrus Scent
- °Water Based

ACTIVE INGREDIENTS:

Permethrin (CAS # 52645-53-1)..... 8.50%
 Piperonyl Butoxide Technical (CAS # 51-03-6)..... 4.25%

OTHER INGREDIENTS:..... 87.25%
TOTAL 100.00%

Contains 80.4 g permethrin and 40.2 g piperonyl butoxide technical per quart.

**KEEP OUT OF THE REACH OF CHILDREN
CAUTION
SEE SIDE/BACK PANEL FOR
ADDITIONAL PRECAUTIONARY STATEMENTS**

Net Contents: 1 U.S. Quart (946ml)

CODE: _____ - _____

Bar Code Area

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

OCT 9 2003

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

4691-123

**DRAFT LABEL
SIDE/BACK PANEL**

PERMECTRIN WS

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

Causes moderate eye irritation. Harmful if swallowed or absorbed through the skin. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. When applying indoors as a space spray or fog wear a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P, or HE prefilter.

FIRST AID

If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If in eyes	<ul style="list-style-type: none"> • Hold eye 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 on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER

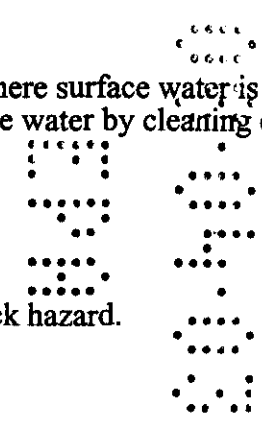
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-821-7467 for emergency medical treatment information.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS

Do not use this product in or on electrical equipment due to the possibility of shock hazard.



5 7 10

**DRAFT LABEL
SIDE/BACK PANEL**

PERMECTRIN WS

INDICATIONS

For use on Horses, Beef and Dairy Cattle, Swine, Sheep, Goats, Poultry, and their premises to Kill Flies, Fleas, Lice, Imported Fire Ants, Mites, and Ticks including Deer Ticks (carrier of Lyme Disease). Aids in Control of Cockroaches, Mosquitoes, Spiders and Crickets.

BUYER GUIDE: The following statements are made as a general guide to quantity of pesticide required for various applications. See Chart on inside of back panel for complete directions on dilution and use.

Premise Use as a Spray or Fog: Mix 1 qt. in 25 gal. of water to make a ready-to-use spray.

Livestock Use: Mix 1 qt. in 100 gal. of water to treat up to 400 animals.

Poultry Use: Mix 1 qt. in 50 gal. of water to treat up to 5,000 birds.

Horse Use: Mix 1.5 fl. oz. (45 mL) in 2 gal. of water for ready-to-use spray.

CONVERSION EQUIVALENTS: 1 fl. oz. = 30 mL = 2 tablespoons = 6 teaspoons

DIRECTION FOR USE

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

SHAKE WELL BEFORE USE.

Add the required amount of concentrate to water and blend thoroughly. Do not hold dilutions for more than 24 hours.

Mix **PERMECTRIN WS** and apply the use-diluted material to animals and pest breeding or resting surfaces at the rates shown on accompanying chart. These dilutions and rates will provide most efficient pest control under conditions of heavy pressure when good contact is achieved. Timing and frequency of application should be based on pest populations reaching nuisance levels, but accompanying manure removal and sanitation practices should precede sprays.

Do not spray feed, food or water. Retreat as needed, but not more often than once every two weeks. Wash udders thoroughly before milking. Do not use on sick, or debilitated animals.



6 7 10

DRAFT LABEL - SIDE/BACK PANEL

PERMECTRIN WS - DIRECTIONS FOR USE (CONT'D)

PESTS ON LIVESTOCK: BEEF CATTLE, LACTATING AND NON-LACTATING DAIRY CATTLE, SHEEP, GOATS AND SWINE
NOTE: For Swine allow 5 days between last treatment and slaughter

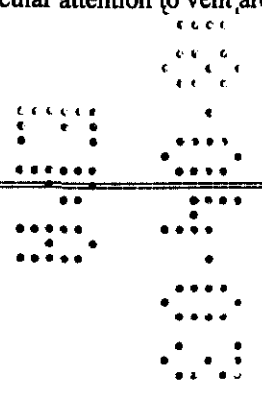
PESTS	DILUTIONS FOR USE	HOW TO APPLY
Horn Flies, Face Flies, Stable Flies, House Flies, Lesser House Flies, Horse Flies, Deer Flies, Black Flies, Mosquitoes, Eye Gnats, Blow Flies, Psoroptic (scabies) mites, Lice, Ticks including Deer Ticks (carrier of Lyme Disease), and Sheep Keds	Mix 1 part concentrate in 400 parts water (1 qt. in 100 gal. or 10 mL in 1 gal.). For severe infestations or for longer residual control, mix 1 part concentrate in 132 parts water [1 qt. in 33 gal. or 4 fl. oz. (120 mL) in 1 gal.].	High Pressure Spray: Spray to thoroughly wet entire animal (1-2 qts. per animal). For lice and mites, a second treatment is recommended in 14 days.
Horn Flies, Face Flies, Ear Ticks and Lice	Mix 7 fl. oz. (210 mL) in 1 gal. water.	Low Pressure Spray: For flies and lice, apply 4-5 fl. oz. (120-150 mL) along midline from face to tailhead. For ear ticks, spray directly onto each ear (1/2 fl. oz. per ear).
Horn Flies, Face Flies, Stable Flies, House Flies, Lesser House Flies, Horse Flies, Deer Flies, Black Flies, Mosquitoes, Eye Gnats, Blow Flies, Psoroptic (scabies) mites, Lice, Ticks including Deer Ticks (carrier of Lyme Disease), and Sheep Keds	Mix 1 part concentrate in 48 parts water (1 qt. in 12½ gal. or 4 oz. in 1½ gal. or 80 mL in 1 gal).	Pour-on: Apply up to 4 oz. of dilution down midline of back. Repeat application in 14 days if necessary.

CONVERSION EQUIVALENTS: 1 fl. oz. = 30 mL = 2 Tablespoons = 6 teaspoons

PESTS ON POULTRY:

PESTS	DILUTIONS FOR USE	HOW TO APPLY
Chicken Mite, Northern Fowl Mite, Chiggers, Lice and Bed Bugs	Mix 1 part concentrate in 200 parts water (1 qt. in 50 gal. or 19 mL in 1 gal.) For severe infestation or for longer residual control, mix 1 part concentrate in 100 parts water (1 qt. to 25 gal. or 38 mL in 1 gal.).	High Pressure Spray: Spray 1 gal. of coarse spray per 100 birds paying particular attention to vent area.

CONVERSION EQUIVALENTS: 1 fl. oz. = 30 mL = 2 Tablespoons = 6 teaspoons



DRAFT LABEL - SIDE/BACK PANEL

PERMECTRIN WS - DIRECTIONS FOR USE (CONT'D)

PESTS ON FARM PREMISES: Barns, Loafing Sheds, Milking Parlors, Feed Lots, Stables, Paddocks, Poultry and Livestock Housing, Animal Hospitals and Outside Meat Processing Premises.

PESTS	DILUTIONS FOR USE	HOW TO APPLY
House Flies, Stable Flies, Lesser House Flies, other Manure Breeding Flies, Bed Bugs, Chicken Mites, Fleas, Mealworms, Lice, Mites, Ticks including Deer Ticks (carrier of Lyme Disease). Aids in control of Cockroaches, Ants, Spiders, Mosquitoes, Crickets, and Face Flies.	Mix 1 part concentrate in 100 parts water (1 qt. in 25 gal. or 38 mL in 1 gal.). For severe infestation or for longer residual control, mix 1 part concentrate in 33 parts water (1 qt. in 8-1/3 gal. or 115 mL in 1 gal.) The use of the higher concentration is recommended on painted wood surfaces.	SURFACE SPRAY: Spray all surfaces thoroughly with diluted emulsion using 1 gal. per 750-1000 square feet, but do not let runoff occur.

In mist blower or power fogger (non-thermal) mix 1 part concentrate in 20 parts water (1 qt. in 5 gal. or 189 mL in 1 gal).

INDOOR SPACE SPRAY: Apply as fog or fine mist until area is filled with mist, using 2 fl. oz. (60 mL) per 1000 cubic ft. (Can be used in Milk Rooms).

OUTDOOR SPACE SPRAY: Fill area with mist. Apply while the air is still.

CONVERSION EQUIVALENTS: 1 fl. oz. = 30 mL = 2 Tablespoons = 6 Teaspoons

DO NOT APPLY DILUTIONS FOR PREMISE TREATMENT DIRECTLY TO LIVESTOCK OR POULTRY. ENSURE THAT FEED AND WATER ARE NOT CONTAMINATED BY SPRAY DRIFT. FOR SPACE SPRAYING DO NOT REMAIN IN TREATED AREAS AND VENTILATE THE AREA BEFORE REOCCUPYING. REMOVE ANIMALS PRIOR TO TREATMENT. THE USE OF ANY RESIDUAL FLY SPRAY SHOULD BE SUPPLEMENTED WITH PROPER MANURE MANAGEMENT AND GENERAL SANITATION TO ELIMINATE FLY BREEDING SITES.

Fleas and Ticks on other outdoor Farm Premises.

Mix 3 fl. oz. (90mL) concentrate in 8 gal. water or 11 mL in 1 gal. water.

OUTDOOR PREMISE SPRAY:
Use enough finished spray to penetrate foliage, usually 50-100 gal. per acre. To prevent infestation of buildings, treat a band of vegetation 6-10 feet adjacent to the structure.

8710

DRAFT LABEL - SIDE/BACK PANEL

PERMECTRIN WS - DIRECTIONS FOR USE (CONT'D)

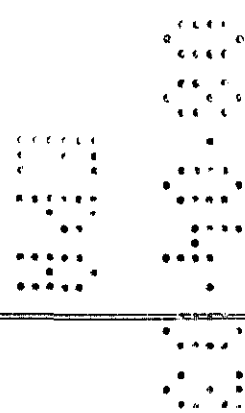
PESTS ON FARM PREMISES (CONT'D): Barns, Loafing Sheds, Milking Parlors, Feed Lots, Stables, Paddocks, Poultry and Livestock Housing, Animal Hospitals and Outside Meat Processing Premises.

PESTS	DILUTIONS FOR USE	HOW TO APPLY
Imported Fire Ants	Mix 14 fl. oz. (420mL) in 1 gal. water.	SPRINKLER CAN: Gently sprinkle one gal. over the surface of each mound. Thoroughly wet mound and surrounding area to a 4 ft. diameter. For best results, apply in cool weather 65-85° (early morning or late evening). Pressurized sprayers may disturb ants and cause migration, reducing product effectiveness.

CONVERSION EQUIVALENTS: 1 fl. oz. = 30 mL = 2 Tablespoons = 6 Teaspoons

PESTS ON HORSES:

PESTS	DILUTIONS FOR USE	HOW TO APPLY
Horse Flies, Deer Flies, Stable Flies, House Flies, Horn Flies, Face Flies, Black Flies, Mosquitoes, Eye Gnats, Mange Mites, Lice and Ticks.	Mix 1.5 fl. oz. (45 mL) concentrate in 2 gal. water <u>or</u> 23 mL in 1 gal. water.	SPRAY OR SPONGE ON: Thoroughly wet animal to skin with spray or sponge.
	Mix 7 fl. oz. (210 mL) concentrate in 3 qts. water <u>or</u> 70 mL in 1 qt. water.	LOW PRESSURE SPRAY OR WIPE ON Spray or wipe on 1-2 fl. oz. per animal. Pay particular attention to treat back, face, legs, and ears.



9 8 10

DRAFT LABEL - SIDE/BACK PANEL

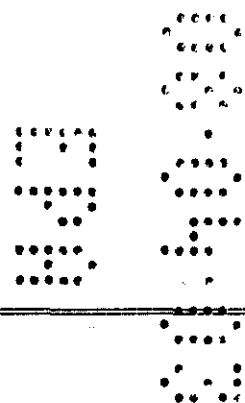
PERMECTRIN WS - DIRECTIONS FOR USE (CONT'D)

PESTS ON EQUINE PREMISES: Barns, Stables, Paddocks, and Animal Hospitals.

PESTS	DILUTIONS FOR USE	HOW TO APPLY
House Flies, Stable Flies, Lesser House Flies, other Manure breeding Flies, Bed Bugs, Chicken Mites, Fleas, Mealworms, Lice, Mites, Ticks (including Deer Ticks, Carrier of Lyme Disease). Aids in control Of Cockroaches, Ants, Spiders, Mosquitoes, Crickets, and Face Flies.	Mix 1 part concentrate in 100 parts water (1 qt. in 25 gal. <u>or</u> 38 mL in 1 gal.). For severe infestation <u>or</u> for longer residual control, mix 1 part concentrate in 33 parts water (1 qt. in 8-1/3 gal. <u>or</u> 115 mL in 1 gal.)	SURFACE SPRAY: Spray all surfaces thoroughly with diluted emulsion using 1 gal. per 750 – 1000 square feet, but do not let runoff occur.
	In mist blower or power fogger (non-thermal mix 1 part concentrate in 20 parts water (1 qt. in 5 gal. <u>or</u> 189 mL in 1 gal.)	INDOOR SPACE SPRAY: Apply as fog or fine mist until area is filled with mist, using 2 fl. oz. (60 mL) per 1000 cubic ft.
		OUTDOOR SPACE SPRAY: Fill area with mist. Apply while the air is still.

CONVERSION EQUIVALENTS: 1 fl. oz. = 30 mL = 2 Tablespoons = 6 Teaspoons

DO NOT APPLY DILUTIONS FOR PREMISE TREATMENT DIRECTLY TO HORSES. ENSURE THAT FEED AND WATER ARE NOT CONTAMINATED BY SPRAY DRIFT. FOR SPACE SPRAYING DO NOT REMAIN IN TREATED AREAS AND VENTILATE THE AREA BEFORE REOCCUPYING. REMOVE ANIMALS PRIOR TO TREATMENT. THE USE OF ANY RESIDUAL FLY SPRAY SHOULD BE SUPPLEMENTED WITH PROPER MANURE MANAGEMENT AND GENERAL SANITATION TO ELIMINATE FLY BREEDING SITES.



10 7 10

**DRAFT LABEL
SIDE/BACK PANEL**

PERMECTRIN WS

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **KEEP CONTAINER SEALED WHEN NOT IN USE. PROTECT FROM FREEZING.**

Pesticide Storage: Store upright at room temperature. Avoid exposure to extreme temperatures.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Do not reuse empty container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or 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 reasonable 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 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.

EPA Reg. No.: 4691-123

EPA Est. No.: 4691-KS-01

Manufactured by:
Boehringer Ingelheim Vetmedica, Inc.
2621 North Belt Highway
St. Joseph, MO 64506-2002
1-800-821-7467

