

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 29, 2022

Charles Levey
NA Regulatory Lead
Bayer Environmental Science
5000 Centregreen Way, Suite 400
Cary, NC 27513, USA

Subject: Label Amendment – Added label language related to Butoxypolypropylene

Glycol Interim Registration Review Decision (Case # 3123) dated February 2021

Product Name: Pyrenone Stabilene Horse Insecticide

EPA Registration Number: 432-995

Application Date: 07/13/2020, 06/08/2021

Decision Number: 569723, 586349

Dear Mr. Ovilla:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act 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 FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list 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 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 the EPA's Office of Enforcement and Compliance.

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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 Registration Review of the above referenced product in connection with the Butoxypolypropylene Glycol Interim Registration Review Decision, and has concluded that your submission is acceptable.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact Robert Mitchell at 202-566-2842 or via email at <a href="mailto:mitchell.robert@epa.gov">mitchell.robert@epa.gov</a>.

Sincerely,

Elizabeth Fertich Product Manager 4

Invertebrate-Vertebrate Branch 1

Registration Division

Office of Pesticide Programs

Enclosure

# PYRENONE® STABILENE®

## Horse Insecticide

- FOR USE ON HORSES ONLY.
- KILLS AND REPELS STABLE FLIES, HORN FLIES, HOUSE FLIES, FACE FLIES, HORSE FLIES, DEER FLIES, MOSQUITOES, AND GNATS ON HORSES.
- ALSO A GROOMING AID AND COAT CONDITIONER FOR HORSES WITH A PLEASING CITRONELLA SCENT
- CONTAINS PYRENONE®, STABILENE®, AND LANOLIN.

ACTIVE INGREDIENT:	
Pyrethrins	0.1%
Piperonyl Butoxide,	1.0%
Butoxypolypropylene Glycol	
*OTHER INGREDIENTS	<u>.83.9%</u>
TOTAL:	100.00%
*Contains Petroleum Distillates	
EPA Reg. No. 432-995	EPA Est. No.

# KEEP OUT OF REACH OF CHILDREN CAUTION

PARA EL USUARIO: Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you.)

See [Back][Side] Panel for First Aid Instructions and [Leaflet][Booklet] for Complete Precautionary Statements and Directions for Use. (Note to reviewer: Location of additional precautionary statements, directions for use will vary between those listed, depending on container type/size.)

For <u>MEDICAL</u> And <u>TRANSPORTATION</u> Emergencies <u>ONLY</u> Call 24 Hours A Day 1-800-334-7577 For PRODUCT USE Information Call 1-800-331-2867

### ACCEPTED

07/29/2022

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No.

432-995

FIRST AID	
	Take off contaminated clothing.
IF ON SKIN OR CLOTHING:	Rinse skin immediately with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.
	Hold eye open and rinse slowly and gently with water for 15-20 minutes.
IF IN EYES:	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 SWALLOWED:	Immediately call a poison control center or doctor for treatment advice.
	Do not induce vomiting unless told to do so by a poison control center or doctor.
	Do not give any liquid to the person.
	Do not give anything by mouth to an unconscious person.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

Note to Physician: Contains petroleum distillates. May pose an aspiration pneumonia hazard.

#### PRECAUTIONARY STATEMENTS

## HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequent skin contact may cause allergic reactions in some individuals.

#### **USER SAFETY RECOMMENDATIONS**

Users should wash hands with plenty of soap and water before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

#### **ENVIRONMENTAL HAZARDS**

This product is toxic to aquatic organisms, including fish and invertebrates. Do not contaminate water when disposing of equipment washwater or rinsate. Do not apply directly to or near water. Drift or run-off may be hazardous to fish in water adjacent to treated areas. See Directions for Use for additional precautions and requirements.

#### PHYSICAL AND 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.

For use on horses only.

Not for use on horses under six weeks of age or those intended for slaughter.

Remove feed and water prior to treatment.

The minimum retreatment interval is 24 hours.

PYRENONE® STABILENE® Horse Insecticide has been especially developed for use on horses only. It provides a protective hair coating against flies while imparting a high sheen to the hair when brushed out. 1 - 2 ounces per head per day gives adequate protection. Apply by either soft cloth or fine mist spray.

The preferred application time is at the end of the day, once the animal is ready to rest. If used during the day, allow PYRENONE STABILENE Horse Insecticide to dry, before turn-out of the horse.

Avoid applying PYRENONE STABILENE Horse Insecticide if you expect the animal to be outdoors during a heavy rain.

#### **USE RESTRICTIONS:**

- · Do not apply this product in a way that will contact adults, children, or pets, either directly or through drift.
- Do not allow adults, children, or pets to enter the treated area until sprays have dried.
- Do not allow product to contact animal's eyes, nose, mouth, or sores during application.
- Not for use on horses under six weeks of age or those intended for slaughter.

**USE TO WIPE ON:** Use only for direct application to horses, indoors or outdoors in close proximity to the stable. First, brush animal to remove excess dirt and dust. Moisten (but do not wet to the point of dripping) a soft cloth and rub over the hair. It is best to apply by rubbing against the hair growth. Give special attention to the legs, shoulders, shanks, neck, and facial areas where flies most often are seen.

Use only for direct application to horses, indoors or in close proximity to the stable.

Only a light application is required. Avoid using an excessive amount on your horses. Do not wet skin.

After application, brush out thoroughly to bring out bright sheen on the coat.

Repeat daily or as required.

**USE AS A SPRAY:** PYRENONE STABILENE Horse Insecticide may be used only for direct application to horses, indoors or in close proximity to the stable, or to indoor premises (stables). Do not wet horse's skin or exceed two ounces per application

#### STORAGE AND DISPOSAL

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

**Pesticide Storage And Spill Procedures:** Store upright at room temperature. Avoid exposure to extreme temperatures. In case of spill or leakage, soak up with absorbent material such as sand, sawdust, earth, fuller's earth, etc. Dispose of with chemical waste.

**Pesticide Disposal:** Pesticide, spray mixture, or rinse water that cannot be used according to label instructions may be disposed of on site or by an approved waste disposal facility.

#### **Container Handling:**

If empty: Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available.

**If partly filled**: Call your local solid waste agency or toll free at 1-800-334-7577 for disposal instructions. Never place unused product down any indoor or outdoor drain.

#### CONDITIONS OF SALE AND LIMITATIONS OF WARRANTY AND LIABILITY

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

**CONDITIONS**: The directions for use of this product must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, plant injury, other property damage, as well as other unintended consequences may result because of factors beyond the control of Bayer CropScience LP. Those factors include, but are not limited to, weather conditions, presence of other materials or the manner of use or application. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience LP is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

**LIMITATIONS OF LIABILITY:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE LP'S ELECTION, THE REPLACEMENT OF PRODUCT.

#### PRODUCED FOR



Bayer Environmental Science A Division of Bayer CropScience LP 5000 CentreGreen Way, Suite 400 Cary, NC 27513

PYRENONE® STABILENE® Horse Insecticide (PENDING) 04/15/2019, 06/17/2019, 07/01/2020, 07/12/2020, 08/31/2020, 09/02/2020, 07/26/2021