

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

January 5, 2024

Kathy Skates Regulatory Affairs Manager Y-TEX Corporation 1825 Big Horn Ave. Cody, WY 82414

Subject: Label Amendment - Registration Review Mitigation for Permethrin

Product Name: EQUANIMITY INSECTICIDE KIT

EPA Registration Number: 39039-13 Application Date: March 11, 2021

Decision Number: 572082

Dear Kathy Skates:

The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Permethrin Interim Decision, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

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 Assurance.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling

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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 12 months from the date of this letter. After 12 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.

If you have any questions about this letter, please contact Carolyn Smith by phone at 202-566-2273, or via email at smith.carolyn@epa.gov.

Sincerely,

Kelly Sherman

Chief, Risk Management & Implementation Branch 3

Pesticide Re-evaluation Division
Office of Pesticide Programs

ENCLOSURE: Stamped label

March 5, 2021

ACCEPTED

01/05/2024

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2000 40

39039-13

Master Label Text, EPA Reg. No. 39039-13 Page 1 of 7

PERMETHRIN GROUP 3A INSECTICIDE

Version: 0321

Tuttle's® Equanimity Insecticide for Horses

Active I	Ingredient

*cis/trans ratio: Min. 35% (±) cis and Max. 65% (±) trans. †Contains Petroleum Distillates6

- For both Indoor and Outdoor use
- Repels mosquitoes for up to 5 days, including those that may transmit Equine Encephalitis and West Nile Virus.
- Kills and repels Black Flies and Ticks, including those ticks that may transmit Lyme Disease.
- Reduces Bot Fly eggs laid on horses for up to 4 days.
- Precise dose directly from the container.
- · Rain-resistant formulation.

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Est. No. 39578-TX-01 EPA Reg. No. 39039-13 NET CONTENTS:

Manufactured for: Tuttle's Horse Care Division
Y-TEX CORPORATION • 1825 Big Horn Avenue • Cody • WY 82414

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS CAUTION

Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

FIRST AID		
IF SWALLOWED	Immediately call poison control center or doctor.	
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.	

NOTE TO PHYSICIAN: Contains petroleum distillates. May pose an aspiration pneumonia hazard. Have the product container or label with you when calling a poison control center or going for treatment. You may also contact 1-800-255-3924 (CHEM-TEL, INC.) for emergency medical treatment information.

Personal Protective Equipment (PPE) Applicators and other handlers must wear:

- · Long-sleeve shirt and long pants;
- · Shoes plus socks;
- Chemical-resistant gloves made of barrier laminate, nitrile rubber, neoprene rubber or viton.

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.

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 pesticide gets 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.

ENVIRONMENTAL HAZARDS

Version: 0321

This product is extremely toxic to aquatic organisms including fish and invertebrates. To protect the environment, do not allow pesticides to enter or to 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.

This pesticide is highly toxic to bees and other pollinating insects exposed to direct treatment or to residues in/on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area. Protect pollinating insects by following label directions intended to minimize drift and to reduce risk to these organisms.

PHYSICAL & CHEMICAL HAZARDS

Do not use or store near heat or open flame. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or 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 an absorbent material such as sand, sawdust, earth, fuller's earth, etc. Dispose of with chemical waste.

PESTICIDE DISPOSAL: Pesticide that cannot be used according to label instructions must be disposed of at or by an approved waste disposal facility. Do not pour or dispose down the drain or sewer. Call your local solid waste Agency for local disposal.



CONTAINER DISPOSAL:

Containers one gallon and smaller:

If empty: Non-refillable container. Do not reuse this container. Place in trash or offer for recycling, if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

NOTICE OF WARRANTY:

To the extent consistent with applicable law, Y-TEX CORPORATION MAKES NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PURPOSE, OR OTHERWISE, EXPRESSED OR IMPLIED concerning this product or its uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label, and in any case, is limited to replacement of product only.

READ ENTIRE LABEL BEFORE EACH USE DIRECTIONS FOR USE

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

Resistance-management Recommendations. For resistance management, Equanimity Insecticide for Horses contains a Group 3A insecticide. Any pest population may contain individuals naturally resistant to Equanimity Insecticide for Horses and other Group 3A insecticides. The resistant individuals may dominate the pest population if this group of insecticides are used repeatedly in the same herds. Appropriate resistance management strategies should be followed.

GENERAL PRECAUTIONS AND RESTRICTIONS

For both indoor and outdoor use.

Do not make applications during rain. Avoid making applications when rainfall is expected before the product has sufficient time to dry (minimum 4 hours).

Do not allow the product to enter any drain during or after application.

Do not apply or irrigate to the point of runoff.

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Do not allow the product to enter indoor or outdoor drains. No permita la entrada a desagües internos o externos.

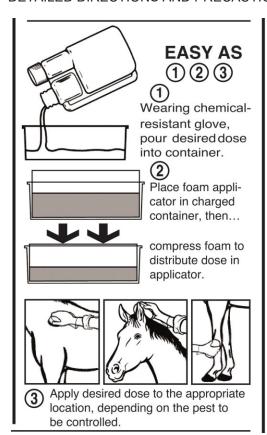
Follow proper disposal procedures on this label. Siga las indicaciones del etiquetado para el desecho apropiado del pruducto.



DIRECTIONS FOR USE

For dirty horses, shampoo, rinse and allow to dry thoroughly. Wear chemical-resistant glove provided. Shake well before using. Do not treat foals under 12 weeks of age.		
TARGET INSECTS	APPLICATION INSTRUCTIONS	
For control of mosquitoes, black flies, face flies,	Apply once every 7 days as a whole body wipe	
lice & ticks.	with foam applicator to horses and ponies at the	
Aids in control of stable flies, deer flies, house flies,	Max. Rate of 6 ml per 200 lbs. body weight to a	
bot flies and eye gnats.	Max. Dose of 30 ml. per animal.	

FOR IMPROVED RESULTS AGAINST SPECIFIC PESTS SEE INSIDE BOOKLET FOR MORE DETAILED DIRECTIONS AND PRECAUTIONARY STATEMENTS.



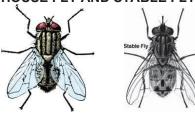
To apply EQUANIMITY to foam applicator, loosen cap over measuring chamber only, and hold bottle upright.

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- 1. While wearing a chemical-resistant glove, squeeze bottle to fill chamber with required dosage. Remove that cap and pour dosage into the plastic container provided.
- 2. Place the foam applicator (gray side down) into the container. Place the applicator and container on a firm surface and press down on the applicator to distribute the product evenly throughout the gray foam.
- 3. Apply this product to the horse in the desired location on its body. Do not exceed Max. Rate of 6 ml/200 lbs. body wt. per horse per week or Max. Dose of 30 ml per horse per week. Replace the foam applicator into the container when finished.



HOUSE FLY AND STABLE FLY



House flies do not bite but cause annoyance by persistent feeding around the eyes, muzzle and wounds. **Stable flies** are very aggressive blood feeding flies with a painful bite. They feed primarily on the lower legs and sometimes the flanks. Horses seen frequently stomping their feet are usually being attacked by stable flies.

Both house flies and stable flies breed in decaying organic matter. House flies will breed in any matter with greater than 40% moisture. Stable flies prefer a mixture of manure and vegetation of similar moisture content.

APPLICATION OF EQUANIMITY

House flies: apply 1 ml/200 lbs. body weight once every 3-4 days to the face, being careful to avoid getting in the eyes.

Stable flies: apply 3 ml/200 lbs. body wt. once every 3-4 days to the legs, belly and chest.

Additional Strategies to Aid in Control of the House Fly and Stable Fly

Eliminating as many breeding sites as possible is important. Remove manure, bedding and other organic matter at least every 3 to 4 days. Release of parasitic wasps that attack the pupal stage can be beneficial.

FACE FLY AND HORN FLY





Face flies do not bite but feed like house flies around the eyes, muzzle and wounds. They are similar in size and appearance. Their feeding is more irritating than that of the house fly thus causing greater annoyance.

Horn flies are blood feeding flies, taking several blood meals a day. They are about half the size of a house fly and are usually found in clusters on the body of the horse.

Both face flies and horn flies breed in fresh, undisturbed cattle manure pats primarily on pastures.

APPLICATION OF EQUANIMITY

Face flies: apply 1 ml/200 lbs. body wt. once every 3-4 days to the face, being careful to avoid getting it in the eyes.

Horn flies: apply 6 ml/200 lbs. body weight once every 7 days as a whole body wipe. For horn flies only, apply 30 ml as pour-on over the withers once every 2 weeks. Do not ride for 24 hrs.

Additional Strategies to Aid in Control of the Face Fly and Horn Fly

See your local county Cooperative Extension Service agent for assistance.

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HORSE FLY AND DEER FLY



Horse flies are large, aggressive, blood feeding flies with a very painful bite. They feed primarily on the neck, back and rump but will bite horses anywhere, including the legs.

Deer flies are generally much smaller than horse flies but similar in appearance. They too are aggressive blood feeders with a painful bite. They feed primarily on the head and ears but will bite horses anywhere, including under the flanks.

Both horse flies and deer flies breed in wet bottom lands and wooded areas. Horse flies and deer flies have been implicated as the primary vectors for equine infectious anemia.

APPLICATION OF EQUANIMITY

For both horse flies and deer flies: apply 3 ml/200 lbs. body wt. once every 3-4 days over the whole body paying particular attention to where the flies are biting. Some species prefer to feed on certain areas of the body.

Additional Strategies to Aid in Control of the Horse Fly and Deer Fly

Horse flies and deer flies are some of the most difficult pests of horses to control. Mechanical traps are available to reduce adult populations. Neither horse flies nor deer flies come inside buildings so providing covered shelter can supply some relief during high populations of these pests.

HORSE BOT FLIES



Horse bot flies are the adult stages of three species of stomach bots, which are serious internal parasites of horses. The common bot fly is the most prevalent throughout the U.S. Its appearance is similar to that of a honey bee. It lays its light yellow eggs on the forelegs, belly, flanks and shoulders of horses. After incubation period of 7-10 days the eggs hatch when licked by the horse. The larvae are picked up on the tongue. The larvae attach to the stomach lining where they over winter and are passed out in the feces the following spring or summer to start the life cycle over.

APPLICATION OF EQUANIMITY

Common bot flies: apply 3 ml/200 lbs. body wt. once every 3-4 days to the legs, chest, belly and flanks.

Additional Strategies to Aid in Control of Horse Bot Flies

After the first killing frost horses should be given a broad-spectrum boticide and anthelmintic for control of all internal parasites.

MOSQUITOES



Several species of mosquitoes will feed on horses. Their feed activity is greatest in the late evening and early morning, although they are active throughout the night. They may transmit equine encephalitis (sleeping sickness) and West Nile virus.

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Mosquitoes breed in standing water. Old automobile tires, cans, or any container that holds water can breed large numbers of mosquitoes. Larger bodies of standing water such as swamps, lagoons, ponds and back water of lakes can breed large numbers of mosquitoes. Adults rest in tall vegetation near feeding and breeding sites.

APPLICATION OF EQUANIMITY

Mosquitoes: apply 6 ml/200 lbs. body wt. once every 7 days as a whole body wipe. For improved control, apply 3 ml/200 lbs. body wt. once every 3-4 days as a whole body wipe.

Additional Strategies to Aid in Control of Mosquitoes

Removal of all objects that could hold stagnant water is critical to reducing adult populations. Removal of tall grass and weeds near horse barns and pastures can help reduce adult populations. Adult mosquitoes are attracted to lights at night so turn lights off in barns and stables. Installing lights away from buildings instead of over doorways will help attract mosquitoes away from buildings.

BLACK FLIES AND EYE GNATS





Black flies are small blood feeding flies that feed in the ears, under the neck and along the midline of the belly, depending on the species. During high populations the ears can become sore and irritated. Black flies can produce large sores on the chest and midline of the belly, cause bite reactions to their saliva and they transmit the microfilaria of Onchocerca nematodes.

Eye gnats are small flies that feed around the corners of the eye.

APPLICATION OF EQUANIMITY

Black flies: apply 6 ml/200 lbs. body wt. once every 7 days to inside surface of the ears, throat area and mid-line of the belly. For improved results apply 3 ml/200 lbs. body wt. once every 3-4 days. Eye gnats: apply 1 ml/200 lbs. body wt. once every 3-4 days around the eye being careful not to get product in the eye.

Additional Strategies to Aid in Control of Black Flies and Eye Gnats

See your local county Cooperative Extension Service agent for assistance.

TICKS AND LICE





Ticks are blood sucking arthropods that may transmit diseases such as Lyme disease. The adult stages have eight legs. There are several different species inhabiting a variety of habitats. The species that are the most problem to horses are those that live in woodland habitats. Ticks have four life stages: egg, larvae (seed ticks), nymphs (yearlings) and adult. The seed ticks are frequently found in large clusters of several thousand. Nymphs and adults are usually found individually.

Lice are either sucking (blood feeding) or chewing (non-blood feeding). They are transmitted by direct contact with infested animals.

APPLICATION OF EQUANIMITY

Ticks and Lice: apply 6 ml/200 lbs. body wt. once every 7 days as a whole body wipe, paying particular attention to those areas of the body that are most heavily infested. Depending on the species, that may be between the front and hind legs, in the mane and tail, or in the ears for some species of ticks. Lice should be eliminated by 3 weekly treatments.

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Additional Strategies to Aid in Control of Ticks and Lice

Keeping horses out of tick habitat and/or tick habitat reduction can help reduce you and your horses' exposure to ticks. Fence horses out of wooded areas. Keep fencerows and other areas of the pasture clear of tall grass, weeds and brush. To protect your horse from lice, prevent contact with infested horses and examine all new horses for infestation.

Additional information for Equanimity Insecticide Kit – not part of Directions for Use.

INTEGRATED PEST MANAGEMENT (IPM)

Effective pest control on horses first requires a basic understanding of the different pests involved. The preferred feeding site on the animal, breeding sites for immature stages and resting sites for the adults all must be considered when designing an Integrated Pest Management program (IPM). An IPM program should involve every aspect of your horse facility starting with the design and construction of the entire facility.

The three components of an IPM program are chemical, cultural, and biological. Insecticides applied directly to horses are an important component of chemical control and for certain pests the only practical strategy. Cultural control means removal of breeding sites for immature stages and resting sites for adults. Cultural control also includes the use of mechanical control such as screens and air blast fans that prevent flying insects from entering barns. Biological control means the protection and/or release of beneficial insects. This strategy requires the judicious use of premise insecticides.

The enclosed label will tell you how to use EQUANIMITY as part of the chemical component in an IPM program. In addition, it will help identify the pests and list additional strategies to aid in control of pest problems. To develop an effective integrated Pest Management program, contact your local county Cooperative Extension Service office for assistance.