

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 7, 2016

Veronica Semetis Lawless Regulatory Affairs Specialist Central Garden & Pet 1501 E. Woodfield Rd., Suite 200 W Schaumburg, IL 60173

Subject: Label Amendment – Revising the directions for use, precautionary language, and

marketing claims.

Product Name: RF2118 Equine Pesticide EPA Registration Number: 89459-5 Application Date: November 30, 2015

Decision Number: 511614

Dear Ms. Lawless:

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. 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.

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

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with FIFRA section 6. If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

Laura N. Bacon, Acting Product Manager 4 Invertebrate & Vertebrate Branch 1 (IVB1) Registration Division (7505P)

Office of Pesticide Programs

Enclosure



RF2118 EQUINE PESTICIDE

PROTECTS HORSES FROM TICKS, FLIES, GNATS, MOSQUITOES AND OTHER LISTED BITING INSECTS

DO NOT USE ON CATS

ALTERNATE BRAND NAMES: (May be preceded by [Farnam] and use Roman Numeral II)

EQUI-SPOT - SPOT-ON CONTROL FOR HORSES

EQUI-SPOT - SPOT-ON FLY CONTROL FOR HORSES

EQUI-SPOT - SPOT-ON TICK CONTROL FOR HORSES

EQUI-SPOT - SPOT-ON MOSQUITO CONTROL FOR HORSES

EQUI-SPOT SPOT-ON PROTECTION FOR HORSES

EQUI-PEN SPOT-ON PROTECTION FOR HORSES EQUIPEN SPOT-ON PROTECTION FOR HORSES

EQUI-SPOT - SPOT-ON BITING INSECT CONTROL FOR HORSES

TICKS B GONE - SPOT-ON TICK CONTROL FOR HORSES TICKS AWAY - SPOT-ON TICK CONTROL FOR HORSES

FLIES B GONE - SPOT-ON FLY CONTROL FOR HORSES FLIES AWAY - SPOT-ON FLY CONTROL FOR HORSES

MOSQUITOES B GONE - SPOT-ON MOSQUITO CONTROL FOR HORSES MOSQUITOES AWAY - SPOT-ON MOSQUITO CONTROL FOR HORSES

Applicator name options (applicator is used in text)

Applicator

Tool

Device

Application Pen

Applicator Pen

Applicator Device

Application Tool

Easy App Pen

EZ Tool

Easy Tool

ACCEPTED

09/07/2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 20450.5

89459-5

HORSE CLAIMS

- PROTECTS HORSES FROM HOUSE FLIES, STABLE FLIES, FACE FLIES, HORN FLIES, EYE GNATS, AND TICKS
- Protects/Defends Your Horse from Ticks [that may transmit Lyme disease, anaplasmosis/equine ehrlichiosis, or equine piroplasmosis] [for up to 14 days/2weeks]
- AIDS IN THE CONTROL OF HORSE FLIES, DEER FLIES, MOSQUITOES AND BLACK FLIES ON HORSES
- Aids in protection against mosquitoes on horses
- Aids in the Defense of your horse from Mosquitoes [that may transmit West Nile virus and eastern and western encephalitis] [for up to 14 days/2weeks]
- Protects/Defends [horses] [from Flies and Ticks] [for up to 14 days/2weeks]
- PROTECTS/DEFENDS (HORSES) FROM HOUSE, STABLE & FACE FLIES THAT MAY CAUSE SUMMER SORES
- AIDS IN THE CONTROL OF MOSQUITOES THAT MAY TRANSMIT WEST NILE VIRUS AND EASTERN AND WESTERN ENCEPHALITIS
- AIDS IN THE CONTROL OF MOSQUITOES ON HORSES
- PROTECTS AGAINST MOSQUITOES ON HORSES
- PROTECTS AGAINST TICKS ON HORSES
- PROTECTS AGAINST FLIES [ON HORSES]
- PROTECTS AGAINST FLIES, TICKS, MOSQUITOES AND OTHER LISTED BITING INSECTS
- PROVIDES PROTECTION AGAINST TICKS [ON HORSES]
- PROVIDES PROTECTION AGAINST FLIES ON HORSES
- PROVIDES PROTECTION AGAINST FLIES, TICKS, MOSQUITOES AND OTHER LISTED BITING INSECTS
- Protects/Defends Your Horse from Flies, Ticks, Mosquitoes, & Gnats & other listed biting insects for up to 14 days/2 Weeks
- PROTECTS/DEFENDS YOUR HORSE FROM FLIES THAT MAY TRANSMIT THE EQUINE INFECTIOUS ANEMIA VIRUS (EIAV).
- PROTECTS/DEFENDS YOUR HORSE FROM FLIES, TICKS, MOSQUITOES, GNATS, & OTHER LISTED BITING INSECTS THAT PROVIDE ENTRY POINTS FOR INFECTION
- Protects/Defends Your Horse from listed Biting Insects
- Protects/Defends Your Horse from listed Biting Insects
- Protects/Defends Your Horse from listed biting insects
- Protects/Defends Your Horse from ticks, mosquitoes, flies & other listed biting insects
- Protects/Defends Your Horse from flies that may transmit the EIA virus
- PROTECTS HORSES FROM TICKS
- Protects horses from ticks, mosquitoes, flies and other listed biting insects
- PROVIDES TICK PROTECTION ON HORSES
- PROVIDES MOSQUITO PROTECTION
- PROVIDES FLY PROTECTION
- Protects/Defends Your Horse
- Helps Defend Your Horse from the Discomfort of Fly, Tick, Mosquito & Gnat bites
- Helps Defend Your Horse from the Discomfort caused by listed biting insects
- Defense Against the Discomfort of Fly, Tick, Mosquito, & Gnat bites
- Helps Defend Your Horse's Comfort by Protecting it from listed biting insects

- Protects/Defends the Comfort of Your Horse from listed Biting Insects that may transmit disease that could result in an infection
- Protects/Defends your horse against fly bites that can provide entry points for infection & may transmit diseases, Equine Infectious Anemia Virus
- DEFENSE AGAINST FLIES, TICKS, MOSQUITOES & GNATS

PRODUCT KILL/REPELLENT CLAIMS

- KILLS AND REPELS TICKS (THAT MAY TRANSMIT LYME DISEASE, ANAPLASMOSIS/EQUINE EHRLICHIOSIS OR EQUINE PIROPLASMOSIS)
- KILLS & REPELS HOUSE FLIES, STABLE FLIES, FACE FLIES, HORN FLIES, EYE GNATS, AND TICKS ON HORSES
- KILLS & REPELS GNATS ON HORSES
- KILLS AND REPELS STABLE & FACE FLIES THAT MAY CAUSE SUMMER SORES
- FIGHTS TICKS [ON HORSES]
- FIGHTS MOSQUITOES (ON HORSES)
- FIGHTS FLIES (ON HORSES)
- KILLS TICKS [ON HORSES]

DURATION CLAIMS

- ONE TUBE LASTS 14 DAYS [2 WEEKS]
- EQUINE SPOT-ON PROTECTION [LASTS] FOR UP TO 14 DAYS/2 WEEKS
- PROTECTS/DEFENDS FOR UP TO 14 DAYS/2 WEEKS
- UP TO 14 DAYS /2 WEEKS SPOT-ON PROTECTION/DEFENSE FOR YOUR HORSE

MISCELLANEOUS CLAIMS

- WON'T SWEAT OFF!
- KEEPS ON WORKING EVEN WHEN YOUR HORSE [SWEATS][GETS WET]
- STAYS ON THROUGH SWEAT AND RAIN
- WATER AND SWEAT RESISTANT [FORMULA]
- SWEAT-RESISTANT SPOT-ON [PROTECTION] FOR HORSES
- SWEAT-RESISTANT [WATER-RESISTANT] FORMULA
- FIELD TESTED AND PROVEN EFFECTIVE EVEN WHEN HORSE SWEATS [GETS WET]
- SWEAT AND WEATHER PROOF
- WEATHER RESISTANT
- WEATHER PROOF
- IDEAL FOR PASTURED HORSES
- IDEAL FOR HORSES THAT WORK, PLAY, & LIVE OUT (OF) DOORS

APPLICATOR CLAIMS

- [NO MESS, NO SPILL]
- EASY TO [USE, HOLD]
- FITS COMFORTABLY IN YOUR HAND
- [PROVIDES] PRECISE APPLICATION INSTRUCTIONS [BASED ON YOUR HORSES SIZE, BASED ON YOUR HORSES NEED, UNIQUE TO YOUR HORSE].
- [DEVELOPED TO DELIVER][PROVIDES] THE PRECISE AMOUNT OF PRODUCT YOUR HORSE NEEDS FOR ITS [SIZE, WEIGHT] NOT TOO LITTLE, NOT TOO MUCH.

- APPLICATOR ENSURES YOUR HORSE IS RECEIVING THE CORRECT AMOUNT APPROPRIATE FOR ITS [SIZE, WEIGHT]
- ENSURES YOUR HORSE GETS [ADEQUATE][THE CORRECT AMOUNT OF] PROTECTION [BASED ON SIZE]
- APPLY THE CORRECT AMOUNT [OF PRODUCT] BASED ON HORSES (SIZE, WEIGHT)
- ENSURE [OPTIMAL][MAXIMUM] PROTECTION [FOR YOUR HORSE] BY KNOWING JUST HOW MUCH TO APPLY [BASED ON YOUR HORSE'S SIZE]
- PROVIDES [OPTIMAL] PROTECTION [FOR YOUR HORSE] [BY ENSURING] YOU ARE
 APPLYING THE CORRECT AMOUNT OF PRODUCT FOR YOUR HORSE'S NEEDS
- REDUCES THE RISK OF USING TOO LITTLE OR TOO MUCH [PRODUCT ON HORSES]
- GETS PRODUCT DIRECTLY TO THE SKIN
- APPLY THE CORRECT AMOUNT [AT EACH][ON EACH] (DEFENSE POINT, TARGET AREA)
- APPLY THE CORRECT AMOUNT [WHERE, WHEN] YOU NEED IT

SCENT CLAIMS

- [NOW WITH] CITRUS SCENT
- [NOW WITH] CITRONELLA SCENT

PACKAGE CLAIMS

- [4/6/12] WEEK SUPPLY
- TO LEARN HOW TO APPLY SCAN the QR CODE WATCH the VIDEO (or go to) EQUI-SPOT.com
- Farnam Your Partner in Horse Care™

ICONS for Flies, Ticks, Mosquitoes



ACTIVE INGREDIENT

Permethrin* (CAS #52645-53-1)	45.0%
OTHER INGREDIENTS**	<u>55.0%</u>
TOTAL	100.0%

^{*}cis/trans ratio: Max 55% ($\underline{+}$) cis and min 45% ($\underline{+}$) trans

KEEP OUT OF REACH OF CHILDREN CAUTION

(placed with icon)SEE BACK PANEL FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

^{**} Contains Petroleum Distillates

Net Contents: 1-12 Applicators/Applications of [0.17 fl. oz fl. oz. (20 mL)]	z. (5 mL)] [0.34 fl. oz. (10 mL)] [0.51 fl. oz. (15 mL)] [0.68
EPA Reg. No.: 89459-5	EPA Est. No.:
Manufactured for: Central Garden & Pet 1501 E. Woodfield Rd., Suite 200 West Schaumburg, IL 60173	
(lot number statements as needed)	

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON HORSES OVER 12 WEEKS OF AGE

(Label revision number)

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Hazards to Humans: Harmful if swallowed or 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, or using tobacco. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. Wear protective eyewear.

Hazards to Domestic Animals:

Mfg. & Printed in U.S.A.

DO NOT USE ON CATS. May be toxic and potentially fatal if applied to or ingested by cats.

FOR EXTERNAL USE ON HORSES ONLY

Do not use on foals under 12 weeks of age. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing or horses. Consult a veterinarian before using on or horses with known organ dysfunction. DO NOT USE ON CATS or animals other than horses. Certain medications can interact with pesticides. It is advisable to consult a veterinarian before using this product with any other pesticide or drug.

(Product number)

FIRST AID				
IF SWALLOWED • Immediately call a poison control center or doctor.				
	 Do not induce vomiting unless told to do so by the poison control cer or doctor. 			
	 Do not give any liquid to the person. 			
	 Do not give anything by mouth to an unconscious person. 			
IF IN EYES: • Hold eye open and rinse slowly and gently with water for 15-20 minu				
 Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye. 				
 Call a poison control center or doctor for treatment advice. 				
IF ON SKIN OR	Take off contaminated clothing.			
CLOTHING:	 Rinse skin immediately with plenty of water for 15-20 minutes 			
	 Call a poison control center or doctor for treatment advice. 			

Note to Physician: Contains petroleum distillate. Vomiting may cause aspiration pneumonia.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of medical emergencies or health and safety inquiries, or in case of fire, leaking or damaged container or for product use information, call toll free: (xxx) xxx-xxxx.

Observe the horse following treatment. Sensitivity may occur after using ANY pesticide product on horses. If signs of sensitivity occur bathe your horse with a mild, non-insecticidal shampoo and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

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. As soon as possible, wash thoroughly and change into clean clothes.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. DO NOT USE OR STORE NEAR HEAT OR OPEN FLAMES

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.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are foraging the treatment area.

DIRECTIONS FOR USE

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

HORSES

DO NOT USE ON HORSES INTENDED FOR FOOD USE DO NOT USE ON FOALS UNDER 12 WEEKS (3 MONTHS) OF AGE DO NOT REAPPLY FOR 2 WEEKS (14 DAYS)

<Brand/Product Name> is most effective when applied such that it can spread over the largest portion of the horse's body surface possible. For maximum protection, apply product as described below to the specified target areas in each Application /Defense Zone

Alternate Application Instruction Set 1 - (Applicator A)

[Remove product applicators from package. Fold along perforation between applicators and tear off one application. Return unused applicators to package. Holding applicator with tipped end pointing up and away from face and body, snap off narrow end at fold line. Apply one applicator (5/10/15/20 ml depending on horse's weight, see size chart) of <Brand/Product Name> as follows:

Instructions for applying (product/Product Name) on horse:

Hold the left and right sides of applicator between your thumb and index finger. With the back end of applicator tilted slightly downward, softly place the flat edge of the applicator tip on the location where you want to apply product. Slowly tip back end of applicator upward until a spot of product (approximately the size of a quarter) is expelled from applicator.

Apply one spot to each location pictured in diagram below. Apply to both the right AND left sides of the horse. Use all product in applicator.]

Defense Zone I - Head, Neck & Chest:

- Top of forehead under the forelock
- Poll area
- Side of head at mid jaw line
- Side of neck
- Chest area

Defense Zone II - Body:

- Withers
- Upper hip
- Side of hip
- Lower side of horse

Defense Zone III - Legs:

- On the back of both front legs beginning at knee
- On the back of both hind legs beginning at hock

Do not allow the product to contact horse's eyes or mucous membranes

When finished, wrap tube and put in trash Do not reapply for 14 days (2 weeks)

Alternate Application Instruction Set 2 - (APPLICATOR B)

Remove product applicator(s) from package. Determine how many applicators will be required based on Application by Size Chart. Unscrew cap of applicator prior to applying to horse. Replace cap upon applicator if all product is not required based on size of horse.

Instructions for applying (product/Product Name) on horse:

Place tip of applicator on horse's coat at location where spot of product is desired. Gently press downward until one spot of product approximately the size of a quarter is deposited on horse's coat (Approximately 2-3 seconds). Squeeze applicator slowly and gently until product is observed on horse's coat.

Apply amount of product specified in the Application by Size Chart. Follow instructions in the Application by Size Chart regarding where and how much product to be applied to the horse. Apply to both the right AND left sides of the horse. One ML is approximately 4 product spots approximately the diameter of a quarter. Refer to guide on side of applicator for approximate amount of product remaining in applicator.

Replace cap on applicator if all product was not used based on Product Quantity by Size Chart.

Alternate Application Instruction Set 3 - (APPLICATOR C)

Remove product applicator(s) from package. Determine how many applicators will be required based on Application by Size Chart(s). [Open] [Unscrew] [Remove] cap of applicator prior to applying to horse. Replace cap upon applicator if all product is not required based on size of horse. Instructions for applying (product/Product Name) on horse:

Place tip of applicator on horse's coat where spot of product is desired. Gently depress the button on [top/back] of applicator to dispense [measured amount of product] on horse. No pressure to horse's skin is required.

Apply amount of product specified in the Application by Size Chart(s). Follow instructions in the Application by Size Chart(s) regarding where and how much product to be applied to the horse. Apply to both the right AND left sides of the horse. The applicator has been preset to deliver 0.25 ml with each press of the button. One ML is equal to 4 product spots approximately the diameter of a quarter. Refer to guide on side of applicator for approximate amount of product remaining in applicator.

Replace cap on applicator if all product was not used based on Dose by Size Chart(s) and store for later use.

Directions for Small and Medium Horses: (optional chart for DFU)

Based on Application By Size Chart, apply one spot, approximately the size of a quarter, at each red dot shown in diagram for small horses. Apply one spot at each red dot and blue dot shown in diagram for medium horses.

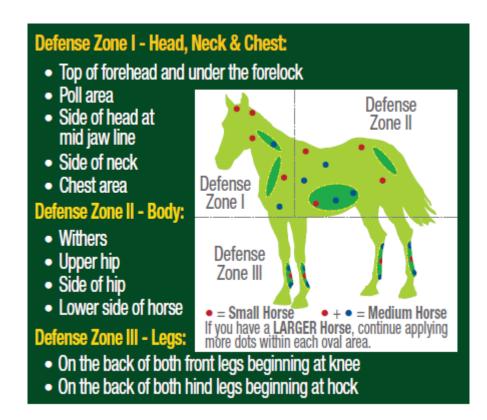
Apply to BOTH the left and right sides of horse's body. Add spots on legs as shown.

Application by Size Chart			
	Small	Medium	
Horse's Weight	Less than 600 lbs	600-1100 lbs	
Dose Size	5 ML	10 ML	
# of spots to apply/side	8	14	
(excluding legs)			

Directions for Large and Extra Large Horses: (optional chart for DFU)

Based on Application By Size Chart, apply one spot, approximately the size of a quarter, at each red dot and blue dot in diagram and then add remaining product uniformly [as spots in blue oval target areas] in each Defense Zone as shown in below diagram for large and X-Large horse until desired amount is dispensed. Apply to BOTH the left and right sides of horse's body. Add spots on legs as shown. Use all product in applicator for X-Large Horse.

	Application by Size Chart		
	Large	X-Large	
Horse's Weight	1100 -1800 lbs	Over 1800 lbs.	
Dose Size	15 ML	20 ML	
# of spots to apply/side	22	30	
(excluding legs)			



	Application Points Based on Size of			
	Horse			
	Small	Medium	Large	X-Large
Defense Zone I	2 ML	3 ML	5 ML	6 ML
Defense Zone II	2ML	4 ML	6ML	9ML
Defense Zone III	1ML	3ML	4ML	5ML

STORAGE AND DISPOSAL

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

Pesticide Storage: Store only in original container in a cool, dry place inaccessible to children and pets. Protect from freezing.

Pesticide Disposal and Container Handling: Non-refillable container. Do not reuse or refill this container. If empty: 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, CENTRAL GARDEN & PET 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 MADE ON THIS LABEL.

Text for Tube Label

PRODUCT NAME
For Use Only on Horses Over 12 Weeks of Age
PERMETHRIN 45% W/W

KEEP OUT OF REACH OF CHILDREN CAUTION
{DO NOT USE ON CATS}
READ DIRECTIONS AND
PRECAUTIONS BEFORE USING
NET CONTENTS
BATCH/LOT NO.

EPA Reg. No. 89459-5

{USE THIS STATEMENT AND/OR CAT ICON IN CIRCLE WITH SLASH}

