



U S ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505C)
Ariel Rios Building
1200 Pennsylvania Ave , NW
Washington, D C 20460

EPA Reg Number

Date of Issuance

83399-11

OCT 16 2012

Term of Issuance Unconditional

NOTICE OF PESTICIDE

[x] Registration

[] Reregistration

(under FIFRA as amended)

Name of Pesticide Product

SVP 11

Name and Address of Registrant (include ZIP Code)

Ceva Animal Health
301, Route 17 North
Rutherford, NJ 07070

Note Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce In any correspondence on this product always refer to the above EPA registration number

On the basis of information furnished by the registrant the above named pesticide is hereby registered/reregistered under the Federal Insecticide Fungicide and Rodenticide Act Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency In order to protect health and the environment the Administrator on his motion may at any time suspend or cancel the registration of a pesticide in accordance with the Act The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others

This product is unconditionally registered in accordance with FIFRA sec 3(c)(5) provided that you

1 Submit and/or cite all data required for registration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under FIFRA section 4

2 Submit one year storage stability (830 6317) and corrosion characteristics (830 6320) studies These studies can be run concurrently Observation must be made at 0, 3, 6, 9, and 12 months period and the results must be submitted to the Agency upon completion These studies must be submitted within 15 months from today's date

3 Make the following label change

Add the phrase "EPA Registration Number 83399-11" to the front panel

Signature of Approving Official

[Handwritten signature]

Date

OCT 16 2012

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If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec 6(e) Submit one copy of the revised final printed label before you release the product for shipment Your release for shipment of the product constitutes acceptance of these conditions

A stamped copy of the label is enclosed for your records A copy of product chemistry review is enclosed The efficacy and acute toxicity reviews were sent to you by e-mail If you have any questions, contact Rita Kumar at (703) 308-8291, or kumar.rita@epa.gov

Sincerely,

John Hebert
Product Manager 1
Insecticide Rodenticide Branch
Registration Division (7505P)

Enclosures (2)

SVP11
October 2 2012

"Master Label"
FRONT PANEL OF OUTER BOX

SVP 11

Alternate Brand names Vectra EQ

For use on Horses, Ponies, Donkeys, Mules, (Colts, Fillies, Geldings)

Repels Stable Flies

(Optional marketing claims—front or back or side panels/see on pages 5-6)

ACTIVE INGREDIENTS

Dinotefuran	4.95%
Pyriproxyfen	0.44%
Permethrin	36.08%

OTHER

INGREDIENTS	58.53%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

XXX Doses Net Contents xxx doses each xxx mls

Front, back, side and/or insert language
See package insert for directions for use, precautionary statements and first aid

Cat/Dog Icons DO NOT USE ON CATS or Dogs

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON Horses, Ponies, Donkeys and Mules

PRECAUTIONARY STATEMENTS

1

ACCEPTED
With COMMENTS
In EPA Letter Dated
OCT 16 2012

Under the Federal Insecticide, Fungicide
and Rodenticide Act As amended, for the
pesticide Registered under EPA Reg No

83399-11

Hazards to Humans WARNING Causes substantial but temporary eye injury Harmful if swallowed Do not get in eyes or on clothing Wear protective eyewear (goggles or safety glasses) Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum using tobacco or using toilet Remove and wash contaminated clothing before reuse Wear long sleeved shirt, long pants, socks, shoes and gloves for application

Hazards to Domestic Animals For external use on horses, ponies, donkeys and mules only Do not use this product on cats or dogs

Do not use on cats, may be fatal Do not use this product on debilitated, aged, medicated, pregnant or nursing animals or animals known to be sensitive to pesticide products without first consulting a veterinarian Individual sensitivity, such as slight transitory redness erythema or pruritus at the site of application, may occur after using ANY pesticide product for equines If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water If signs of individual animal sensitivity occur and persist, contact your veterinarian Have the product container or label with you when calling your veterinarian for advice

Cat icon DO NOT USE ON CATS Due to their unique physiology and inability to metabolize certain compounds this product must not be used on cats If applied to a cat, or ingested by a cat, this product may have serious harmful effects If this occurs, contact your veterinarian immediately

FIRST AID	
If in eyes	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 Call a poison control center or doctor, for treatment advice
If swallowed	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 to an unconscious person

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If on skin	Take off contaminated clothing Rinse skin immediately with plenty of water for 15 – 20 minutes if skin appears irritated after rinsing call a poison control center Call 1-800-999-0297 between 8am and 6pm EST weekdays, during evening and weekends call poison control center, doctor, or 1-888-426-4435 immediately for treatment advice
Have the product container or label with you when calling a poison control center or doctor or going for treatment You may contact 1-800-999-0297 between 8am and 6pm EST weekdays or 1-888-426-4435 for emergency medical treatment information evenings and weekends Note to Physician Vectra EQ contains permethrin, a synthetic pyrethroid Sensitive individuals may experience mild, temporary tingling or paresthesia following contact with skin Treatment is symptomatic and should include washing the affected area with soap and water	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling [Precaucion al consumidor si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente (To the User If you cannot speak English, do not use this product until the label has been fully explained to you)]

HOW TO APPLY

- 1 **Use Restrictions USE ONLY ON Horses Do not use on cats or other animals Do not have contact or allow children to have contact with treated areas until treatment is completely dry**
- 2 Remove applicator from package
- 3 For easy application the horse should be standing – secured if necessary-
- 4 Holding the applicator upright, place your thumb and index finger firmly around the disk While maintaining applicator in an upright position, pointed away from face, push down firmly on the top of the applicator tip, piercing the seal (see illustration)
OR
(Remove the tube [applicator] from the package Unscrew the cap and replace with applicator tip) Holding the tube (applicator) upright, place thumb and index finger around the applicator tip under the large disk With other hand, grasp the stem of applicator tip above smaller disk Press down firmly on small disk until both disks meet, piercing the seal (See illustration)

OR
(Remove the tube [applicator] from the package Unscrew the cap,
(pierce safety seal) and replace with applicator tip)

GRAPHICS DEPICTING HOW TO OPEN PACKAGE/APPLICATOR

5 Apply approximately 1/3 of contents (8ml) as a continuous uniform stripe from the base of each ear to the base of the tail approximately 6-8 inches off the mid line Repeat on the other side again using about 1/3 of contents Apply a small stripe approximately 6 inches long below the forelock, then apply uniform stripe from the caudal aspect of the hock to the pastern and caudal aspect of knee to pastern

[GRAPHICS DEPICTING TREATMENT OF ANIMAL]

Do not get the product in your horse's eyes or mouth

6 Discard empty applicator (tube) as outlined in the Storage and Disposal section

7 Repeat every month, or as recommended by your veterinarian

8 For treatment control and prevention of flies, ticks, mosquitoes, biting and sucking lice, fleas and their immature stages year-round treatment is recommended

STORAGE AND DISPOSAL

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

Storage Store in a cool, dry place Protect from freezing

Disposal **If empty**, do not reuse the container Place in trash or offer for recycling if available **If partially filled**, call your local solid waste agency for disposal instructions Never place unused products down any indoor or outdoor drain

NET CONTENTS X applications (applicators), each 0.9 fl oz (24.0 mL)
Example 3 single dose (applicators)(package) 72.0 ml (0.9 fl oz total 2.7 fl oz)
Product will be packaged in 1,2,3,4,6 12,18, 24 and 36 dose cartons)

EPA Reg No 83399-xxx

EPA Est No

[Made in the USA (by)] [Sold by]
Ceva Animal Health
301 Route 17 North
Rutherford, NJ 07070

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Seller warrants that the material conforms to the chemical parameters of the US EPA registration and the label. To the extent consistent with applicable law, seller makes no warranty, express or implied, other than indicated on the label. Buyer and user assume all risk of use and handling of this material when such use and handling are contrary to the label instructions. To the extent consistent with applicable law, any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profit or values.

PACKAGE INSERT (full label text plus additional copy)

ALTERNATE MARKETING TEXT (for use on front or side or back panels)

- Protects for one month
- Satisfaction guaranteed or Ceva Animal Health will supply replacement product
- Picture(s) of Horse (pony)(donkey) (mule)
- Using the (patented) (Trademark) applicator SVP11 is specially designed to spread over the horse's body providing effective control of flies
- Formula for (your) horse(s)
- Remains effective after bathing
- Easy spot on (topical) application
- (Patented) applicator tip (Trademark) for easy application directly to the skin
- Guaranteed effective for one month or your money back
- Satisfaction guaranteed or your money back (Ceva ICON) (Please call (contact) our professional staff at xxx-xxx-xxxx if you have any questions or comments about SVP11)
- SVP11 contains the insecticide dinotefuran a neonicotinoid with knockdown effect and permethrin an effective insecticide/acaricide that works with dinotefuran and pyriproxyfen to repel flies
- Quick onset of activity
- Prevents re-infestation
- Monthly (year round) treatment is recommended for control and prevention of stable flies
- Once monthly application
- X applicators
- X monthly doses (applications) (treatments)
- Quick-drying non greasy and water-resistant (waterproof)
- Easy to apply topical application



SVP11
October 2 2012

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- Convenient easy to apply
- Convenient to use
- Water resistant (Waterproof)
- Quick drying
- Non-greasy
- Convenient (easy to apply) topical treatment
- Convenient (easy to apply) topical treatment [with (patented) applicator tip] that allows application down to the skin

- Remains effective even after exposure to rain (or sunlight)
- Remains effective even after (shampooing) (bathing)
- Convenient topical treatment for horses (ponies) (donkeys) (mules)
- Formulated for horses (ponies) (donkeys) (mules)
- Available from licensed veterinarians
- Sold by (your equine) veterinarian(s)
- After application SVP11 spreads over the horse s body to provide (full body) (all-over) protection against flies
- SVP11 (also) contains permethrin an effective insecticide/acaricide that combines with dinotefuran to provide repellency against stable flies
- Questions or comments—please call (tel no)
- For more information call (tel no)
- For emergencies call (tel no)

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- Controls aggressive feeding by stable flies
- Proven treatment technology for the control of stable flies
- Pony pack
- Horse pack
- Veterinary pack (Ceva pack) (Stable pack)
- Effective monthly treatment of flies
- Repels stable flies
- Monthly (year round) treatment is recommended for control
- Long lasting repellency control for your horse
- SVP11 repels stable flies before they bite
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- Maintains residual repellency after bathing (and rain)
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- Repellency against stable flies
- Contains the proven effective topical repellent permethrin (for control of flies)
- Repels flies which may inflict irritating bites
- Repels (annoying) (bothersome) (nuisance) stable flies
- Repels stable flies in the pet s (horse s) environment
- Repels [(annoying) (bothersome) (nuisance) flies
- SVP11 repels stable flies and controls infestation that may lead to painful skin irritation and bacterial infection
- Illustration of stable fly life cycle
- Illustration of stable fly

APPLICATOR LABELING

SVP 11

KEEP OUT OF REACH OF CHILDREN

WARNING
READ ENTIRE LABEL BEFORE USE

Dinotefuran	4.95%
Pyriproxyfen	0.44%
Permethrin	36.08%

X fl oz (X mL)

DO NOT USE ON COMPANION ANIMALS
USE ONLY ON Horses, Ponies, Donkeys and Mules

EPA Reg No 83399-XXX
EPA Est No TBD

Lot # (*designation will identify producing establishment*)