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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:

83399-8

JAN 3 1 2008

Term of Issuance: Conditional

Name of Pesticide Product:

SVP10

NOTICE OF PESTICIDE:

x Registration ___ Reregistration (under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Summit VetPharm LLC 400 Kelby Street Fort Lee, NJ 07024

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 conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) and (B) 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 the following data:

One year storage stability (830.6317) and corrosion characteristics (830.6320) studies. These studies can be run concurrently. It is recommended that the observation must be made at 0, 3, 6, 9, and 12 months period and the results must be submitted to the Agency on completion. These studies must be submitted within 15 months from today's date.

- 3. Make the following label changes:
- a. Add the phrase "EPA Registration Number 83399-8".

Signature of Approving Official:

Rita Kumar

Date:

JAN 3 1 2008



- b. Revise the Directions for Use as follows: "SVP10 is for use in the manufacture of SVP7, a dog spot-on product. SVP7 will require registration with the U.S. Environmental Protection Agency."
- c. Delete the following statements from Directions for Use: "Please consult technical literature for specific manufacturing suggestions. Mix before dispensing." The Agency has not reviewed the technical literature, and the statement about mixing before dispensing indicates an end-use which cannot be allowed on a manufacturing use product..
- d. Add a Note to Physician below the First Aid statement. Please refer to the acute toxicity review that was mailed to you on January 18 for the types of information that may be included, if applicable for the eye hazard.
- e. In the First Aid statement, move the last sentence starting with "Call a poison control center....." in the *If on skin* box to the box right below it.
- f. Revise the Storage and Disposal statement as indicated below:

Storage and Disposal

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

Pesticide Storage: Keep pesticide in original container. Store in a cool, dry place.

Protect from freezing.

Pesticide Disposal: Wastes resulting from this product may be disposed off at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Do not reuse container. Offer for recycling or reconditioning., or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities.

- g. Move the Environmental Hazard statement out of the Storage and Disposal box.
- 4. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Rita Kumar

Insecticide Rodenticide Branch

Registration Division (7505C)

E-mail: kumar.rita@epa.gov

SVP10: EPA REG. NO. 83399-xxx

PROPOSED LABELING

Date: 1/23/2008

SVP₁₀

For use in the manufacturing of SVP7

ACTIVE INGREDIENTS:

Dinotefuran		4.95%

TOTAL		100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on skin or clothing. Wear protective eyeware (goggles, face shield or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse. Wear long sleeved shirt, long pants, socks, shoes and gloves.

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.)

The product is for use in the manufacture and repack of SVP7. Please consult technical literature for specific manufacturing suggestions. Mix before dispensing.

with COMENTS
in EPA Letter Dated:
JAN 3 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
As amended, for the pesticide
Registered under EPA Reg. No.

SVP10: EPA REG. NO. 83399-xxx

PROPOSED LABELING

Date: 1/23/2008

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, doctor, or 1-800-222-1222 immediately for treatment advice	
If swallowed:		
	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.	
If on skin:	Take off contaminated clothing.	
, ,	Rinse skin immediately with plenty of water for 15 – 20 minutes.	
	Call a poison control center, doctor, or 1-800-222-1222 immediately	
	for treatment advice	
Have the product container or label with you when calling a poison control center or		
doctor or going	doctor or going for treatment.	

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.

ENVIRONMENTAL HAZARD

This pesticide is toxic to shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or ther waters unless in accordance with the requirements of a National Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

Net Contents: xxxx

EPA Reg. No. 83399-xxx EPA Establishment No. xxxxx

Made in the USA (by)
[Summit VetPharm, LLC], Fort Lee, New Jersey 07024
www.summitvetpharm.com

LIMITED WARRANTY AND LIMITATION OF DAMAGES



SVP10: EPA REG. NO. 83395-xxx

PROPOSED LABELING

Date: 1/23/2008

Seller warrants that the material conforms to the chemical parameters of the US EPA registration and the label. Seller makes no warranty to the extent consistent with applicable law, 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.

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