



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 7, 2007

MEMORANDUM

Subject: Name of Pesticide Product: SVP 7
EPA Reg. No. /File Symbol: 83399-6
DP Barcode: D343071
Decision No.: 381993
Action Code: 360
PC Codes: 044312 (Dinotefuran: 4.95%)
109701 (Permethrin: 36.08%)
129032 (Pyriproxyfen: 0.44%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
12-7-2007
R. Whitley 12-7-2007

To: Rita Kumar/Venus Eagle, RM 01
Insecticide-Rodenticide Branch
Registration Division (7505P)

Registrant: SUMMIT VETPHARM, LLC

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
044312 Dinotefuran	4.95%
129032 Pyriproxyfen	0.44%
109701 Permethrin	36.08%
<u>Other Ingredient(s):</u>	<u>58.53%</u>
TOTAL	100.00%

ACTION REQUESTED: The Risk Manager requests:

“...Please review these four acute tox studies to support this registration. The registrant submitted these studies in response to your review of 7/30/2007. ...these data are currently in review for SVP10 (DP 342800). The two reviews should be bundled...”

BACKGROUND:

The material received for review includes 4 acute toxicity studies (MRIDs 47197001 through 47197004) submitted under DP 342800. There was a previous TRB review for this product (dated 22 June 2007).

COMMENTS AND RECOMMENDATIONS:

1. An Agency contractor, Oak Ridge National Laboratory, conducted the primary review of the 4 acute toxicity studies which were submitted under DP 342800. TRB performed the secondary review and made changes as necessary.

2. The four submitted acute toxicity studies (MRIDs 47197001 through 47197004) have been reviewed (see the review of December 6, 2007 for 83399-I) and have been classified as acceptable.

3. An eye irritation study (MRID 47027102) for this formulation was previously reviewed (TRB memorandum for 83399-A dated 22 June 2007). Based on this eye irritation study, this formulation is in EPA Toxicity Category II for eye exposure hazard.

3. Based on the results of the submitted acute toxicity studies, and waiver of the inhalation data requirement, the following is the acute toxicity profile for EPA Reg. No. 83399-6 [SVP 7]. There are some minor changes (oral LD50: from III to IV; dermal irritation: from IV to III) from the acute toxicity profile given in the memorandum dated 22 June 2007 for 83399-A. However, the indicated signal word remains WARNING:

Acute oral toxicity	IV	Cited	MRID 47197001
Acute dermal toxicity	IV	Cited	MRID 47197002
Acute inhalation toxicity	[IV]	Waived	
Primary eye irritation	II	Cited	MRID 47027102
Primary dermal irritation	III	Cited	MRID 47197003
Dermal sensitization	Negative	Cited	MRID 47197004

4. From the acute toxicity profile for 83399-6 [SVP 7] given above, as well as information from the CSF and proposed labeling, the following would be its precautionary and first aid labeling, as obtained from the label review system:

PRODUCT ID #: 083399-00006

PRODUCT NAME: SVP7

PRECAUTIONARY STATEMENTS

SIGNAL WORD: WARNING

Hazards to Humans and Domestic Animals:

Causes substantial but temporary eye injury. Avoid contact with skin or clothing. Do not get in eyes or on clothing. Wear protective eyewear (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 and long pants, socks, shoes, and gloves.

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 on skin:

- Take off contaminated 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: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.