

US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD

FIPRONIL
CYPHENOTHHRIN
(Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs)

STUDY TYPES: **Product Identity and Composition (OPPTS 830.1550)**
Description of Materials Used to Produce the Product (OPPTS 830.1600)
Description of Production Process (830.1620)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)
MRIDs 481296-01 and 481296-02

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
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Prepared by
Toxicology and Hazard Assessment Group
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Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 1-38

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Date: DEC 01 2010
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Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

DATE OUT:01/04/11

SUBJECT: End Use Product Chemistry Review
Product Name: Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs

FROM: (2) 01/04/11
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TO: Bonaventure Akinlosotu / Richard Gebken PM10
Branch / Registration Division (7505P)

Company Name: Sergeant's Pet Care Products, Inc.

Formulation Type: Insecticide

A. INTRODUCTION:

The applicant submitted an application for registration of a new non-food use end use product. In support of the application, the applicant submitted product chemistry data corresponding to guideline 830 series, group A & group B (MRIDs 481296-01 and 481296-02). A CSF for a basic formulation (dated 6/18/2010) was submitted along with the product label. TRB has been asked to determine the acceptability of the product chemistry data and the proposed CSF.

The primary review for Sergeant's Fipronil + Cyphenothrin Squeeze-On for Dogs was done by Oak Ridge National Laboratory Oak Ridge, TN 37831

B. SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fipronil (9.8%), Cyphenothrin (5.0%)
2. All the source materials for the active ingredients are derived from registered sources:
[X] Yes; [] No
3. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses [X] Yes; [] No.
4. Confidential Statement of Formula(s):

[X] Basic - Dated: June 18, 2010 resubmitted (email) – Dated: 01/03/11

[] Alternate # 1 - Dated: 01/03/11

5. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2)

Yes, if not, explain below:

Metallic equivalent: Yes NA;

Soluble arsenic: Yes NA

Isomeric ratios: Yes NA

Acid equivalent: Yes NA; {name} acid equivalent = xx %

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: Yes No NA

Methanol at > 4%: Yes No NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

Yes No

Is the sub statement in compliance with PR Notice 97-6? Yes, if not, explain below:

d. Label requires an additional Storage and Disposal statement: Yes No; if yes explain below:

6. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	481296-01
830.1600	Description of materials used to produce the product		X		A	481296-01
830.1650	Description of formulation process		X		A	481296-01
830.1670	Discussion on the formation of impurities		X		A	481296-01
830.1700	Preliminary analysis			X	NA	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	481296-01
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method			X	NA	MRID # pending

A = Acceptance, N = Not Acceptable, G = Data Gap,
 W = Waiver Request, I = In Progress, NA = Not Applicable

7. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid	A	481296-02
830.6315	Flammability	Flashpoint >90°C	A	481296-02
830.6316	Explosibility	Does not contain explosive ingredients	NA	481296-02
830.7000	pH	Not soluble/dispersible in water	NA	481296-02
830.7300	Density (units)	1.00 – 1.05 g/cc	A	481296-02

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
 NA = Not applicable, I = In progress

C. CONCLUSIONS:

The TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. The proposed CSF (dated 6/18/2010) resubmitted by e-mail and alternate CSF #1 both dated 01/03/11 are acceptable.
2. The data submitted corresponding to guidelines 830.1600 (description of materials used to produce the product), 830.1650 (description of the formulation process), 830.1670 (discussion of the formation of impurities), and 830.1750 (certified limits) are acceptable. Applicant has stated that Enforcement analytical method was submitted and MRID # is pending
3. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6315, 830.7100 (viscosity), and 830.7300 (density) are acceptable.
4. No data were submitted for guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics). The registrant states that these data will be submitted when the studies are completed. It is recommended that the observations should be made at 0, 3, 6, 9, and 12 month intervals.
5. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the RM team.