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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 2/22/05

Subject: Tau-Fluvalinate RED - Reregistration Eligibility Decision. Product Chemistry Considerations. Case No. 2295

DP Barcode: D311824
PC Code: 109302

From: José J. Morales, Chemist
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This document was originally prepared under contract by Dynamac Corporation (20440 Century Boulevard, Suite 100; Germantown, MD 20874; submitted 08/31/2004). The document has been reviewed by the HED and revised to reflect current OPP policies.

Executive Summary

Tau-fluvalinate [cyano-(3-phenoxyphenyl)methyl N-[2-chloro-4-(trifluoromethyl)phenyl]-D-valinate] is a broad-spectrum contact, stomach insecticide registered for use inside beehives to control a parasitic mite; use on carrots grown for seed has been classified a nonfood use. The Agency has agreed to the use of the name tau-fluvalinate on the label to distinguish between half-resolved fluvalinate, which consists of two isomers and is the active ingredient in the currently registered products, from racemic fluvalinate, which is a mixture of four isomers.

Tau-fluvalinate is a FIFRA List B reregistration chemical. The Fluvalinate Phase 4 Review dated 1/16/91 (C. Olinger) determined that data submitted by Sandoz for GLN 63-10 (OPPTS 830.7370) were acceptable for Phase 5 review; the registrant committed to generate new studies for the remainder of the product chemistry data requirements. Data requirements pertaining to the potential for dioxin formation in fluvalinate were satisfied prior to the Phase 4 Review (CBRS No. 6585, 7/12/90, S. Funk).

Data submitted by Sandoz in response to the Phase 4 Review were reviewed by the Agency in 1992, and numerous deficiencies were identified. The product was subsequently transferred to Wellmark International, and additional product chemistry data have been submitted in support of reregistration of fluvalinate.

All product chemistry data requirements are satisfied for the single registered T/TGAI, the Wellmark 87.2% T/TGAI (EPA Reg. No. 2724-481), except that data are required concerning UV/visible absorption (OPPTS 830.7050). Provided that the registrant submits the data required in the attached data summary table for the tau-fluvalinate T/TGAI, and either certifies that the suppliers of beginning materials and the manufacturing process for the T/TGAI have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, the Agency has no objections to the reregistration of tau-fluvalinate with respect to product chemistry data requirements.

Product Chemistry Deficiencies

Additional data are required for the Wellmark 87.2% T/TGAI (EPA Reg. No. 2724-481) concerning UV/visible absorption of the PAI (OPPTS 830.7050).

Background

Identification of Active Ingredient

The PC code and nomenclature of tau-fluvalinate are listed below in Table 1. The physicochemical properties of tau-fluvalinate are listed in Table 2.

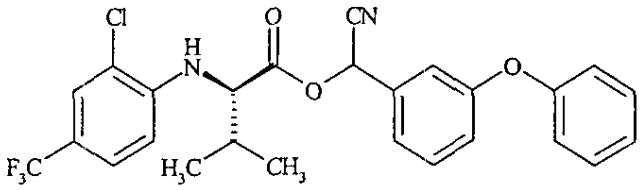
TABLE 1. Tau-Fluvalinate Nomenclature	
Chemical structure	
Common name	Tau-fluvalinate
Molecular Formula	$C_{26}H_{22}ClF_3N_2O_3$
Molecular Weight	502.93
IUPAC name	(*RS*)-α-cyano-3-phenoxybenzyl *N*-(2-chloro-α,α,α-trifluoro-p-tolyl)-D-valinate
CAS name	cyano-(3-phenoxyphenyl)methyl *N*-[2-chloro-4-(trifluoromethyl)phenyl]-D-valinate
CAS registry number	102851-06-9 (tau-fluvalinate) 69409-94-5 (unresolved fluvalinate)
PC Code	109302

TABLE 2. Physicochemical Properties of Tau-Fluvalinate		
Parameter	Value	Reference
Boiling point	164 °C at 0.07 mm Hg	D165590, 3/4/92, F. Toghrol
pH	Not applicable; fluvalinate is practically insoluble in water	
Density, bulk density, or specific gravity	1.262 g/mL at 25 °C	D165590, 3/4/92, F. Toghrol
Water solubility	2.4 ppb at 25 °C	D272832 and D273228, 3/21/01, K. Dockter
Solvent solubility at 25 °C	55.31 g/100 mL, methanol 24.05 g/100 mL, octanol Miscible at all levels in isooctane, toluene, acetonitrile, 2-propanol, dimethylformamide, and 1-octanol	D272832 and D273228, 3/21/01, K. Dockter D165590, 3/4/92, F. Toghrol
Vapor pressure	$<1.0 \times 10^{-5}$ Pa, 25 °C	D272832 and D273228, 3/21/01, K. Dockter
Dissociation constant, pK_a	Not applicable due to the instability of fluvalinate under acidic and basic conditions, and its extremely low water solubility.	Phase 4 Review, 1/16/91
Octanol/water partition coefficient	$P_{OW} > 10^6$, 25 °C	D272832 and D273228, 3/21/01, K. Dockter
UV/visible absorption spectrum	Not available	

Manufacturing-use Products

A search of the OPPIN product listing conducted 6/04 identified a single manufacturing-use product (MP) registered under PC Code 109302, the Wellmark International 87.2% technical (T; EPA Reg. No. 2724-481). The Wellmark 87.2% T was transferred from Sandoz Agro, Inc. (EPA Reg. No. 55947-104) on 8/5/97. Because fluvalinate is a List B chemical, only the Wellmark 87.2% T/TGAI is subject to a reregistration eligibility decision.

830.1550-7950 Product Chemistry Data Requirements

The current status of the product chemistry data requirements for tau-fluvalinate T/TGAI is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

Case No. 2295
Chemical No. 109302

Case Name: Tau-Fluvalinate
Registrant: Wellmark International
Product(s): 87.2% T (EPA Reg. No. 2724-481)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	Y	41889701, 45598800 [3], CSF 1/28/02 [3]
830.1600	Description of materials used to produce the product	Y	**00076684, 00076685, 00128515**, 41889701, 45598800 [3]
830.1620	Description of production process	Y	**00076684, 00076685, 00128515**, 41889701, 45598800 [3]
830.1670	Discussion of formation of impurities	Y	**00076684, 00076685, 00128515**, 41889701, 41889702, 44701401 [4], Letter 11/2/00 [5], 45598800 [3]
830.1700	Preliminary analysis	Y	**00076684, 00076685, 00128515**, 41889702, 44701401 [4], 45598801 [6]
830.1750	Certified limits	Y	41889701, 41889702, 45598800 [3], CSF 1/28/02 [3]
830.1800	Enforcement analytical method	Y	41889702, 45598801 [6]
830.6302	Color	Y	41889703
830.6303	Physical state	Y	41889704
830.6304	Odor	Y	41889705
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	41889713, 44694101 [5]
830.7000	pH	N/A [7]	41889712 [3]
830.7050	UV/Visible absorption	N	
830.7200	Melting point/melting range	N/A [8]	
830.7220	Boiling point/boiling range	Y	41889706
830.7300	Density/relative density/bulk density	Y	41889707
830.7370	Dissociation constants in water	N/A [9]	41597201 [10]
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	41889711, 44694101 [5]
830.7840	Water solubility: column elution method; shake flask method	Y	41889708, 44694101 [5]
830.xxxx	Solvent solubility	Y	41889709, 44694101 [5]
830.7950	Vapor pressure	Y	41889710, 44694101 [5]

[1] Y = Yes; N = No; N/A = Not Applicable. The 87.2% T was transferred to Wellmark International from Sandoz Agro, Inc., and some of the data summarized above include data submitted by Sandoz. The current registrant, Wellmark, has submitted adequate information confirming the product composition and manufacturing process subsequent to the product transfer.

[2] **Bolded** references were reviewed under CBRS No. 6585 dated 7/12/90 by S. Funk; underlined references were reviewed under D165590, dated 3/4/92 by F. Toghrol; and the remaining references were reviewed as noted.

[3] D287902.

[4] D245217, 7/19/00, K. Dockter.

[5] D272832 and D273228, 3/21/01, K. Dockter.

[6] D281113, 2/25/03, K. Dockter.

[7] Data are not required because the TGAI is practically insoluble in water.

[8] Data are not required because the TGAI is a liquid at room temperature.

[9] Data are not required due to the instability of fluvalinate under acidic and basic conditions and extremely low water solubility.

[10] Fluvalinate Phase 4 Review, 1/16/91, C. Olinger.

BIBLIOGRAPHY

Study Citations

00076684 Reuter, S. (1979) Purity Determination of Technical Fluvalinate. Method no. 146-1179-OAR dated Sep 1, 1979. (Unpublished study received May 13, 1981 under 20954-EX-18; submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070093-C)

00076685 Reuter, S. (1980) Purity Determination of Technical Fluvalinate by HPLC Internal Standard. Method no. 149-0380-OAR dated Mar 13, 1980. (Unpublished study received May 13, 1981 under 20954-EX- 1; submitted by Zoecon Corp., Palo Alto, Calif.; CDL:070093-D)

00128515 Zoecon Corp. (1983) Product Chemistry: [Fluvalinate Technical]. (Compilation; unpublished study received May 16, 1983 under 20954-126; CDL:250303-A)

41597201 Apodaca, C. (1990) Determination of the Dissociation Constant of Fluvalinate: Lab Project Number: 480603: Report No: 1. Unpublished study prepared by Sandoz Crop Protection Corp. 27 p.

41889701 Sandoz Crop Protection Corp. (1991) Fluvalinate Technical Product Identity and Composition: Lab Project Number: 05-91-61. Unpublished study. 107 p.

41889702 Sandoz Crop Protection Corp. (1991) Fluvalinate Technical Analysis and Certification of Product Ingredients: Lab Project Number: 05-91-62. Unpublished study. 346 p.

41889703 Widlak, A. (1991) Fluvalinate: Color Determination: Lab Project Number: DP 300216: 480603. Unpublished study prepared by Sandoz Protection Corp. 10 p.

41889704 Pal, A. (1991) Fluvalinate: Physical State Determination: Lab Project Number: DP 300215: 480603. Unpublished study prepared by Sandoz Crop Protection Corp. 10 p.

41889705 Buck, B. (1991) Fluvalinate: Determination of Odor: Lab Project Number: PD300193: 480606. Unpublished study prepared by Sandoz Protection Corp. 18 p.

41889706 Chen, H. (1991) Fluvalinate: Boiling Point Determination: Lab Project Number: DP 300277: 480603. Unpublished study prepared by Sandoz Crop Protection Corp. 13 p.

41889707 Pal, A. (1991) Fluvalinate: Determination of Density: Lab Project Number: DP 300214: 480603. Unpublished study prepared by Sandoz Crop Protection Corp. 12 p.

41889708 Yu, C. (1991) Fluvalinate: Water Solubility: Lab Project Number: 480605-4. Unpublished study prepared by Sandoz Crop Protection p. 11 p.

41889709 Yodual, L. (1991) Solubility of Technical Fluvalinate in Polar and Non-Polar Organic Solvents: Lab Project Number: 480603: DP300294. Unpublished study prepared by Sandoz

Crop Protection Corp. 30 p.

41889710 Srnak, Z. (1987) Vapor Pressure of Fluvalinate Using Thermal Evolution Analyzer: Lab Project Number: 480600-2. Unpublished study prepared by Sandoz Crop Protection Corp. 48 p.

41889711 Yu, C.; Guirquis, A. (1987) Determination of N-Octanol/Water Partition Coefficient for Fluvalinate: Lab Project Number: 480605. Unpublished study prepared by Sandoz Crop Protection Corp. 19 p.

41889712 Widlak, A. (1991) PH Determination of Technical Fluvalinate: Lab Project Number: DP 300245: 480603. Unpublished study prepared by Sandoz Crop Protection Corp. 15 p.

41889713 Yodual, L. (1991) Stability of Technical Fluvalinate: Lab Project Number: 480603: DP300293. Unpublished study prepared by Sandoz Crop Protection Corp. 114 p.

44694101 Seymour, D.; Clark, A. (1998) Physical and Chemical Properties Test for tau-Fluvalinate: Final Report: Lab Project Number: 2516: 4851-01. Unpublished study prepared by Midwest Research Institute. 39 p.

44701401 Fathulla, R. (1998) Determination of Polar and Non-Polar Nitrosamines in Tau-Fluvalinate: Lab Project Number: COVANCE 6882-100: 2529: CMS 21760A. Unpublished study prepared by Covance Labs., Inc. 74 p.

45598800 Wellmark International (2002) Submission of Residue Data in Support of the Reregistration of Tau-Fluvalinate. Transmittal of 1 Study.

45598801 Ko, J.; Burleson, J. (2002) Analysis and Validation of Some tau-Fluvalinate Impurities in Technical tau-Fluvalinate: Amended Final Report: Lab Project Number: 2758. Unpublished study prepared by Wellmark International. 30 p.

Agency Memoranda Citations

CBRS No(s).:	6585
Subject:	Product Chemistry Data for Fluvalinate to Determine the Potential for Halogenated Dibenzo-p-Dioxin/Dibenzofuran Formation. I.D. No. 55947-98. Record No. 262799.
From:	S. Funk
To:	E. Feris
Dated:	7/12/90
MRID(s):	00076684, 00076685, 00128515

DP Barcode(s):	D165590
Subject:	Fluvalinate (ID#: 109302-055947). Phase 5 Reregistration Review of Product Chemistry. Sandoz Response to CBRS Fluvalinate Phase 4 Data Requirements, Regarding Product Chemistry.
From:	F. Toghrol
To:	J. Ellenberger
Dated:	3/4/92
MRID(s):	41889701 through 41889713

DP Barcode(s):	D209046
Subject:	Fluvalinate Technical, EPA Reg. No. 55947-104. Proposed Change in Nomenclature. Sandoz Agro Letter Dated 10/19/94.
From:	M. Flood
To:	G. LaRocca/A. Heyward
Dated:	11/22/94
MRID(s):	None

DP Barcode(s):	None
Subject:	Review of Product Chemistry Data for Fluvalinate
From:	J. Kearns, SRRD
To:	M. Johnston, Sandoz Agro, Inc.
Dated:	10/11/95
MRID(s):	None

DP Barcode(s):	D245217
Subject:	Fluvalinate; EPA Reg. No. 2724-481. PC Code 109302. List B Reregistration Case 2295. Product Chemistry Response to 11/8/95, 5/7/99, and 6/8/2000 Rebuttals
From:	K. Dockter
To:	B. Shackleford
Dated:	7/19/00
MRID(s):	44701401

DP Barcode(s):	D269017
Subject:	Fluvalinate; EPA Reg. No. 2724-481. PC Code 109302. List B Reregistration Case 2295. Updated 8/30/00 Confidential Statement of Formula [CSF] in Response to Agency Request.
From:	K. Dockter
To:	B. Shackleford/K. Rothwell
Dated:	2/6/01
MRID(s):	None

DP Barcode(s):	D272832 and D273228
Subject:	Fluvalinate; EPA Reg. No. 2724-481. PC Code 109302. List B Reregistration Case 2295. Product Chemistry Response to K. Dockter 7-19-2000 Review; D245217.
From:	K. Dockter
To:	B. Shackleford
Dated:	3/21/01
MRID(s):	44694101

DP Barcode(s):	D281113
Subject:	Fluvalinate; EPA Reg. No. 2724-481. PC Code 109302. List B Reregistration Case 2295. Analysis and Validation of Impurities; OPPTS 830.1800 in Response to Agency Request.
From:	K. Dockter
To:	B. Shackleford/T. Lane
Dated:	2/25/03
MRID(s):	45598801

DP Barcode(s):	D287902
Subject:	Registrant's Response to Product Chemistry Requirements for the Wellmark Tau-Fluvalinate 87.2% T/TGAI (EPA Reg. No. 2724-481); OPPTS 830.1550, 1600, 1620, 1670, and 1750.

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Chemical:	**Fluvalinate**
PC Code:	**109302**
HED File Code	**11000 Chemistry Reviews**
Memo Date:	**02/22/2005**
File ID:	**DPD311824**
Accession Number:	**412-05-0093**

HED Records Reference Center
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