US EPA ARCHIVE DOCUMENT

10-31-96

DATE OUT: OCT 3 [illegible]

DP BARCODE: D222112 **SUBMISSION:** S498997 **REG/FILE SYMBOL No.:** 10308-EU
CHEMICAL NAME: 004006 [2,5-Dioxo-3-(2-propynyl)-1-imidazolidinyl] methyl (1RS)-cis,trans-chrysanthemate, 50.5% AI
COMMON NAME: Imiprothrin **CAS Registry No.:** 72963-72-5

REGISTRATION DIVISION/REGISTRATION SUPPORT BRANCH/PRODUCT CHEMISTRY REVIEW SECTION TRANSMITTAL/PRODUCT CHEMISTRY REVIEW OF A REGISTRATION ACTION FOR A MANUFACTURING-USE PRODUCT ACTION CODE 115 NEW CHEMICAL/NON-FOOD/FEED USES

DATA SUBMITTER: 010308 Sumitomo Chemical Co,Inc. **RCVD DATE:** 01/23/96
MRID's 437507-01 to -12 (twelve volumes)
RD PM#/NAME: 13 George LaRocca **Phone #:** 305-6100
RD CRM NAME: Linda DeLuise **Phone #:** 305-5428

CONCLUSIONS:

1. Product chemistry data requirements for registration of this manufacturing-use product, imiprothrin, Reg. No. 10308-EU, is adequate. Information provided had passed product chemistry screen on 11/14/95 (DP #220593, S. Malak).

2. The submitted label, Reg. No. 10308-EU, EPA received 1/23/96, is unacceptable: (a) delete the term "w/w" following the ingredient statement since the label claim should be expressed in nominal as per PR Notice 91-2. If the desired percentage by weight should be retained at 50.5%, the label claim should be 46.56%; (b) the label should cite the amount of active ingredients in pounds per gallon of product; and (c) the "Physical Chemical Hazard" statement should be cited on the label, indicating the product is "Flammable."

3. The submitted CSF for this manufacturing-use product, imiprothrin, Reg. No. 10308-EU, a basic formulation dated 7/28/95, is unacceptable: (a) The nominal concentration calculated at 46.56% (see conclusion 2 above) can be indicated between parenthesis below the percentage by weight. [redacted] (b) complete box 9 to indicate the Flash Point at 110°C; (c) [redacted] (e) and if the applicant wishes to seek registration of technical imiprothrin, the impurities can be included with the inert ingredient claimed on the label for the manufacturing-use product.

4. Adequate enforcement analytical methods were submitted for the analysis of the active ingredient, imiprothrin, per se, and

INERT INGREDIENT INFORMATION IS NOT INCLUDED
QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED
IMPURITY INFORMATION IS NOT INCLUDED

impurities in both the technical and the manufacturing-use formulations. The methods are discussed in this memorandum. The method for the TGAI is to be found in MRID #437507-06, entitled: "Analytical Methods to Verify Certified Limits of S-41311 Technical Grade". The method was authored by Yoko Okada, dated 6/15/95, 49 pages. The method for the manufacturing-use product is to be found in MRID #437507-07, entitled "Analytical Methods to Verify Certified Limits of S-41311 Manufacturing-Use Product". The method was authored by Yoko Okada, dated 6/21/95, 52 pages.

5. The applicant will need to submit three samples, one for imiprothrin pure active ingredient, a second for the technical grade of active ingredient, and a third for the manufacturing-use product. Samples should be send to EPA's Analytical Chemistry Laboratory in Beltsville, Maryland for validation along with a copy of the procedure as outlined in MRID's 437507-06 & -07. Similar samples must also be submitted to the Pesticide and Industrial Chemical Repository, Research Triangle Park, North Carolina at the following addresses:

   U. S. EPA/OPPTS
   Analytical Chemistry Laboratory
   BARC East - Building 306, ERm. 113
   Beltsville, MD 20705

   U. S. EPA Research Center
   Pesticide and Industrial Chemical Repository
   Research Triangle Park, NC 27711

6. We defer to TOX/HED as to their concern with imiprothrin impurities at their indicated upper limits as shown in product's CSF, Reg. No. 10308-EU, a basic formulation dated 7/28/95.

RECOMMENDATIONS

After resolving Conclusions 2, 3, 5 & 6 above, we can recommend for registration of this manufacturing-use product, imiprothrin, Reg. No. 10308-EU.

NOTES TO CRM: (1) A Status Report of Product Chemistry Data Requirements is Included on Page 3 of this memo; and (2) Information presented on pages 9 to 24 is confidential.

Sami Malak **Reviewer: Sami Malak, Ph.D., Chemist**	10/31/96 **Date**
Sami Malak for **Section Head: Harold Podall, Ph.D., Chemist**	10/31/96 **Date**

7505W:RD:RSB:PCRS:S.Malak:CS-1:Rm650:s.m.:11/04/96:703-308-8392:<10308-EU>

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STATUS REPORT OF PRODUCT CHEMISTRY DATA REQUIREMENTS FOR REREGISTRATION OF A TECHNICAL GRADE ACTIVE INGREDIENT
REVIEWER: Sami Malak **DATE REVIEW WAS COMPLETED:** 10/31/96

GRN #	TITLES	Ac	NA	UP	Dg	MRID No.
	Series 61-Product Identity and Composition (40CFR§158.155, 160, 162, 165 & 167)					
61-1	Product Identity & Disclosure of Ingredients	X				437507-01
61-2	Description of Starting Materials & Manufacturing Process	X				437507-02
61-3	Discussion of Formation of Impurities	X				437507-02
	Series 62-Analysis and Certification of Product Ingredients (40CFR§158.170, 175 & 180)					
62-1	Preliminary Analysis of Product Samples	X				437507-03,04
62-2	Certification of Ingredient Limits	X				437507-05
62-3	Analytical Methods to Verify Certified Limits	X				437507-06,07
	Series 63-Physical and Chemical Characteristics (40CFR§158.190)					
63-2	Color	X				437507-08
63-3	Physical State	X				437507-08
63-4	Odor	X				437507-08
63-5	Melting Point		X			
63-6	Boiling Point	X				437507-08
63-7	Density, Bulk Density, or Specific Gravity	X				437507-08
63-8	Solubility	X				437507-08
63-9	Vapor Pressure	X				437507-08
63-10	Dissociation Constant	X				437507-08,09
63-11	Octanol/Water Partition Coefficient	X				437507-08
63-12	pH	X				437507-08
63-13	Stability	X				437507-10
63-14	Oxidizing or Reducing Action	X				437507-08
63-15	Flammability	X				437507-08
63-16	Explodability	X				437507-08
63-17	Storage Stability	X				437507-08,11
63-18	Viscosity	X				437507-08
63-19	Miscibility	X				437507-08
63-20	Corrosion Characteristics	X				437507-08,12
64-1	Submittal of Samples				X	

EXPLANATIONS::
AC = Acceptable.
NA = Not Applicable/Waiver Acceptable.

Up = Needs upgrading.
Dg = Data Gap. GLR# = Guideline Reference Number.

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Detailed Considerations

PRODUCT CHEMISTRY DATA REVIEW

1. A statement of data confidentiality dated 7/25/95 was included with this submission claiming confidentiality of some of the data requirements on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI information is to be found in Confidential Appendix A.

2. A GLP statement dated 7/25/95 was included with this submission to the effect that some of the submitted studies were conducted in full compliance with GLP requirements of 40CFR§160.

NOTE: To support the registration of this manufacturing-use product, the applicant included some data generated, where applicable, using the technical grade of active ingredient. These were: GRNs 62-1, 62-3, 63-10 & 63-13. The remaining data requirements as well as GRNs 62-1 & 62-3 were conducted using the MUP as the test substance.

Series 61 Product Identity and Composition

MRID #437507-01 The submitted study entitled "Product Identity and Disclosure of Ingredients for Imiprothrin Manufacturing-Use Product", was adhered by Y. Yamada, dated 6/2/95, 5 pages.

61-1 Product Identity & Disclosure of Ingredients

Chemical Name: 004006 [2,5-Dioxo-3-(2-propynyl)-1-imidazolidinyl] methyl (1RS)-cis,trans-chrysanthemate.

Common Name: Imiprothrin

Trade Name: Pralle

EPA Reg. No.: 10308-EU

CAS Registry No.: 172963-72-5

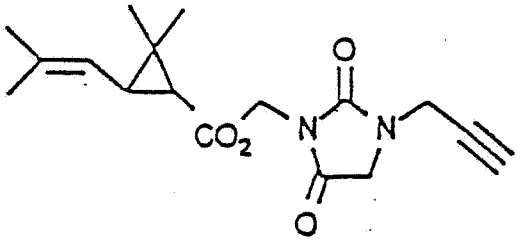
Type: Insecticide

Uses: For the manufacturing of products to control insects.

Empirical Formula: $C_{17}H_{22}N_2O_4$

Molecular Weight: 318-38

Structural Formula:



Nominal Concentration.... 50.5%
Upper Limit..... 52.0%
Lower Limit..... 49.0%

61-2 Description of Starting Materials and Manufacturing Process
See Confidential Appendix A.

61-3 Discussion of Formation of Impurities
See Confidential Appendix A.

Series 62 Analysis and Certification of Product Ingredients

62-1 Preliminary Analysis of Product Samples
See Confidential Appendix A.

62-2 Certification of Ingredient Limits
See Confidential Appendix A.

62-3 Analytical Methods to Verify Certified Limits

Methods for the Active Ingredient:

MRID #437507-06 The submitted study entitled "Analytical Methods to Verify Certified Limits of S-41311 Technical Grade", was adhered by Yoko Okada, dated 6/15/95, 49 pages.

A gas chromatographic method (GC) was employed to determine S-41311 content and trans isomer ratio as well as some impurities. A high-performance liquid chromatography (HPLC) method was used to determine 1R isomer ratio.

Determination of S-41311 content: The test substance and standard samples, each was dissolved in an internal standard (di-2-ethylhexyl phthalate in acetone) and 1 μl samples were injected into a GC column packed with 3% thermon 3000 on shimalite using FID detector. Operating oven temperature was 215°C using nitrogen as a carrier gas at a flow rate of 30 ml/min.

Determination of trans-isomer ratio: The test substance was dissolved in an acetone and 1 µl samples were injected into a GC column packed with 5% silicone using FID detector. Operating oven temperature was 200°C using nitrogen as a carrier gas at a flow rate of 40 to 50 ml/min.

Determination of (1R)-isomer ratio: The test substance was dissolved in a mobile phase consisting of hexane/dichloromethane/ acetonitrile (70:29:1). A 10 µl samples were injected into a HPLC stainless steel column packed with sumichiral using an ultraviolet absorption photometer detector at a wave length = 230 nm. Operating column temperature was ambient at a flow rate of 1.05 or 1.3 ml/min.

No validation data was included because of the high purity of technical imiprothrin, determined at 97.3 to 98.3%. No chromatographic interferences were observed.

Sample calculations and sample chromtograms were included in this submission.

Methods for the Manufacturing-Use Product:

MRID #437507-07 The submitted study entitled "Analytical Methods to Verify Certified Limits of S-41311 Manufacturing-Use Product", was adhered by Yoko Okada, dated 6/21/95, 52 pages.

This report describes the analytical methods for the determination of the active ingredient, isomers,a nd impurities of S-41311 MUP.

The enforcement method for the active ingredient in the MUP is a gas chromatography with a hydrogen flame-ionization detector on a column of 3% thermon 3000 using di-2-ethylhexyl phthalate as an internal standard. Operating oven temperature was 220°C using nitrogen as a carrier gas at a flow rate adjusted to give a retention time of 12 minutes.

The trans-isomer ratio is determined by a gas chromatography with on a column 5% silicone. (1R)-isomer ratio is determined by normal phase high performance liquid chromatography on a column of Sumichiral OA-2000. The contents of isopropyl myristate, 2,6-di-tert-butyl-4-methylphenol, 4-methyl-2-pentanone and the other impurities are determined by gas chromatography on a column of 20 SE-30, 10% PEG 20M, chromosorb 101, 3% thermon 3000, and fused silica capillary column cross-linked and surface-banded with DB-1.

The methods were validated and the recoveries were satisfactory, about 78 to 80%. Accuracy and precessions of the methods were also reported. Sample calculations and chromatograms were included in this submission.

Series 63 Physical and Chemical Characteristics

The submitted studies entitled "Physical and chemical characteristics of S-41311, Technical Grade Active Ingredient and the Manufacturing-Use Product." The studies were conducted by several authors, during 1993: MRID 437507-08, 554 pages; MRID 437507-09, 10 pages; MRID 437507-10, 20 pages; MRID 437507-11, 21 pages; and MRID 437507-12, 8 pages. The following properties are for the MUP. Properties reported for the TGAI are cited between parenthesis or otherwise indicated:

63-2	Color:	Golden yellow (Amber).
63-3	Physical State:	Liquid (Liquid).
63-4	Odor:	Sweet (Slightly sweet).
63-5	Melting Point:	NA
63-6	Boiling point:	---- (128°C)
63-7	Density, Bulk Density, Specific Gravity:	0.979 g/ml (1.122 g/ml)
63-8	Solubility at 25°C: (For TGAI Only)	Water..... 93.5 ppm Hexane..... 0.62 g/100 ml Soluble in all proportions in n-octanol, methanol, acetonitrile, & octane.
63-9	Vapor Pressure: (For TGAI Only)	1.39 mm Hg at 25°C 8.64 mm Hg at 35°C
63-10	Dissociation Constant: (For TGAI Only)	Could not be measured.
63-11	Octanol/Water Partition Coefficient: (For TGAI Only)	$P = 7.92 \times 10^2$ at 25°C Log K_{ow} = 2.9
63-12	pH:	5.22 (5.95)

63-13	Stability: (For TGAI Only)	Stable to metals, metal ions, sunlight & elevated temperature.
63-14	Oxidizing of Reducing Action: (For the TGAI & EUP)	Product does not contain oxidizing or reducing agents.
63-15	Flammability	Flash Point = 110°C
63-16	Explodability	Product does not contain explosive materials.
63-17	Storage Stability (For the TGAI & EUP)	Stable when stored in commercial package (steel cans) for one year.
63-18	Viscosity	60 centipoise
63-19	Miscibility	Miscible in myristic acid & isopropyl ester.
63-20	Corrosion Characteristics	Non corrosive to its commercial packaging, steel cans.
63-21	Dielectric Breakdown Voltage:	N/A. Product is not recommended for use around electrical equipment.

Attachment: Confidential Appendix A (pages 9 to 24).

cc: Sami Malak and Central File (Reg. No. 10308-EU).
7505W:RD:RSB:PCRS:S.Malak:CS-1:Rm650:s.m.:10/31/96:703-308-8392:<10308-EU>

PAGES 9-24 ARE NOT INCLUDED - INFORMATION CONCERNING BEGINNING MATERIALS, MANUFACTURING PROCESS, AND ANALYSIS OF IMPURITIES AND INERT INGREDIENTS