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WASHINGTON, D.C. 20460

Analytical Chemistry Section
Building 306, BARC-East
Beltsville, Maryland 20705

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

SEP 2 1992

MEMORANDUM

SUBJECT: Product Chemistry Review on Technical Sumilarv
(EPA ID No. 01308-RR)

FROM: Mark W. Law, Chemist Mark W. Law
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TO: Donald R. Stubbs, Chief
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Applicant: Sumitomo Chemical Co., LTD.

EPA File Symbol/Reg. No.: 010308-RR

MRID No(s).: 41321703, 41654101, 42178301, and 42201401.

CAS No.: 95737-68-1

Pesticide Chemical Code: 329032-9

Chemical Name: 2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy] pyridine

Product Name: Sumilarv Technical Grade

Use: Insecticide

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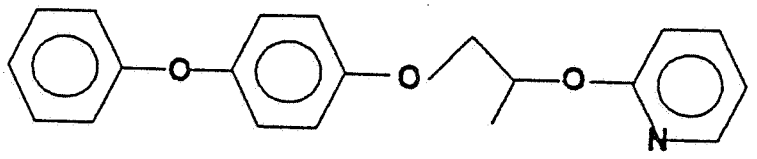
Introduction

Sumitomo Chemical Co. LTD requests the registration of the manufacturing-use product (MUP) Technical Sumilarv which contains the active ingredient (AI) Sumilarv. All product chemistry requirements for the MUP as described in 40 CFR 158.150 must be fulfilled for full registration.

PRODUCT IDENTITY AND COMPOSITION (MRID 40584801)

61-1: Product Identity and Disclosure of Ingredients

Sumilarv is the active ingredient (AI) in the MUP produced by Sumitomo Chemical Co., LTD. The structural formula is:



Empirical Formula: $C_{20}H_{19}NO_3$

Molecular Weight: 321.37

Other Names: Pyriproxyfen (BSI proposed)
4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether

The composition of the MUP is contained in the Confidential Statement of Formula (EPA Form 8570-4) and is discussed in Confidential Appendix B.

The data satisfy the requirements of 40 CFR 158.155. No additional data are needed.

61-2: Beginning Materials and Manufacturing Process

See Confidential Appendix A for a discussion of this requirement. The data do not fully satisfy the requirements of 40 CFR 158.160-162 for the MUP Sumilarv. Additional data are needed to clarify the manufacturing process. The submitted data does not provide a description of the reaction vessel. There is also no information on measures used to ensure the quality of the final product.

61-3: Discussion of the Formation of Impurities

See Confidential Appendix A for a discussion of this requirement. The data do not satisfy the requirements of 40 CFR 158.167 for the MUP Sumilarv. The discussion of the formation of impurities only addresses those impurities listed on the CSF. No discussion of the formation (or lack thereof) of toxicologically significant impurities such as dioxins, nitrosamines, and furans is provided.

62-1 Preliminary Analysis

Samples from five batches of the MUP were examined and reported for the product and impurities.

See Confidential Appendix B for a summary of the results and the analytical methods used. The submitted data satisfy the requirements of 40 CFR 158.170 for the MUP Sumilarv. No additional data are needed.

62-2: Certified Limits

The certified limits are contained in the CSF and are discussed in Confidential Appendix B. The submitted data satisfy the requirements of 40 CFR 158.175 for the MUP Technical Sumilarv. No additional data are needed.

62-3: Enforcement Analytical Methods

An adequate analytical method is submitted for enforcement purposes for the determination of the active ingredient.

The method and validation data are discussed in Confidential Appendix B.

The submitted information satisfies the requirements of 40 CFR 158.180. No additional data are needed.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The physiochemical properties of Sumilarv are summarized below (MRID 41321703 and 41654101).

Guideline Reference Number (GRN)	Property	Description
63-2	Color	White to Yellow
63-3	Physical State	Solid
63-4	Odor	Faint Characteristic Odor
63-5	Melting Point	47.4°C
63-6	Boiling Point	N/A
63-7	Bulk Density	

Guideline Reference Number (GRN)	Property	Description	
63-8	Solubility	Solvent	Quantity
		Water	0.367 mg/L @ 25°C
		Hexane	7.67 g/100ml @
		Ethanol	
		Diethyl-ether	
		Acetone	
63-9	Vapor Pressure	$<1.0 \times 10^{-7}$	
63-10	Dissociation Constant	N/A	
63-11	Octanol/Water Partition Coefficient	5.37 @ 25°C	
63-12	pH in Distilled		
63-13	Heat Stability	Stable at 54°C for 14 days	
63-14	Oxidation/Reduction Action	No Data Provided	
63-15	Flammability	N/A	
63-16	Explodability	No Data Provided	
63-17	Storage Stability	1 Yr. @ Ambient Temp.	
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	
63-20	Corrosion Characteristics	Non-corrosive to steel containers for 1 year	
63-21	Dielectric Breakdown Voltage	N/A	

CONTAINER LABEL

The labels submitted by the registrant meets with requirements of 40 CFR 162.10. No additional data are needed.

SUMMARY OF DEFICIENCIES AND CONCLUSION

The Product Chemistry data requirements for the MUP, Technical Sumilarv have not been satisfied. The following information is needed.

61-2: Beginning Materials and Manufacturing Process

A listing of the process equipment and a description of the quality control process should be submitted. (1)

61-3: Discussion of the Formation of Impurities

Information is needed on the formation (or lack thereof) of toxicologically significant impurities such as N-nitrosamines, (2) dioxins and furans.

63-14: Oxidation/Reduction Action

No data was provided for this requirement. The study (or waiver request, if applicable) should be submitted. ? (3)

63-16: Explodability

No data was provided for this requirement. The study (or waiver request, if applicable) should be submitted. ? (4)

ATTACHMENTS: Confidential Appendices A and B.

Pyriproxyfen

RIN 4445-96 P.C. 129032

Page____ is not included in this copy.

Pages 6 through 9 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

✓ Description of the product manufacturing process.

✓ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
