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TBJ

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

SEP 13 1992

File Symbol/EPA Reg. No.: 10308-RR

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Thru: Donald Stubbs Acting, Section Head  
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Registration Support Branch  
Registration Division (H7505C)

Applicant: Sumitomo Chemical Co., LTD.

EPA File Symbol/Reg No.: 10308-RR

MRID No. 423432-03,423432-04.

CAS No.: 95737-68-1

Pesticide Chemical Code: 329032-9

Chemical Name: 2-[1-methyl-2-(phenophenoxy)ethoxyl pyridine

Product Name: Sumilarv Technical Grade

Use: Insecticide

Introduction:

Applicant Summitomo Chemical Company Ltd. has responded to the agency's letter dated Sept.15, 1992. as regards to the registration of (MUP) Technical Similarv which contains the active ingredient (AI) Sumilarv. All product chemistry data as described in the 40 CFR 158.120 must be satisfied to achieve full registration. The product chemistry data for Sumilarv was previously reviewed by Harvey Hundley of analytical chemistry section of AnalyticalChemistry Branch. The following deficiencies were found for the TGAI:

61-2: Beginning Materials and Manufacturing Process

A listing of the process equipment and a description of the Quality control process.

61-3: Discussion of the Formation of Impurities

Information on the formation of toxicologically significant impurities such as N-nitrosamines, 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.

63-16: Explodability:

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

RECOMMENDATION:

61-2: Beginning Materials and Manufacturing Process

Applicant must include description of Quality Control measures taken to ensure the quality of the final product, degradation of the product's active ingredient after the production of the product but prior to the its use and the post production reaction must be submitted.

Information on migration of components of packaging materials into the product is required. Information on the contaminants resulting from earlier use of production equipment to produce other products and purification and quality control measures used must be submitted.

For discussion and details on the submitted data for series 61-2 please refer to the Confidential Appendix 'A'

61-3: Discussion of the Formation of Impurities

The registrant has not submitted information regarding the formation of [redacted] impurities as identified in the CSF dated 12/13/91. A detailed explanation regarding each impurity as marketed at a level equal to 0.1% (1000 ppm) based on the composition of each beginning material containing an active such as those present in each unintentionally added inert ingredient of this product must be submitted.

Information on the substance which result from intended (main) reactions and side reactions which occur in the manufacturing and formulation of the product must be provided.

Each impurity as reported in the CSF must be identified, each step of reaction where the impurity was formed in detail must be submitted.

63-14: Oxidation/Reduction Action

Applicant has stated that Sumilarv and the impurities associated with sumilarv do not have the functional groups associated with oxidizing and reducing activity, and Sumilarv has never demonstrated such activity under normal handling, these data should not be required and therefore these conditions have not been met. The registrant must submit experimental evidence of this property, merely this statement is not enough. The above information submitted is not adequate to satisfy data requirement of 40 CFR 148.150. ( Guideline Reference No. 63-14 ).

Since this information is needed this will be considered as a data gap.

63-16: Explodability

Applicant has stated Sumilarv and its impurities do not contain the functional groups that impart explosive properties. Sumilarv has not exhibited explosive characteristics, and based on its structure would not be expected to be explosive under normal conditions. The aforementioned explanation is acceptable, hence the requirement for 40 CFR 158.150 (Guideline Series 63-16 has been satisfied). No further information is needed on this section of the product chemistry section.

Pyriproxyfen

RIN 4445-96

P.C. 129032

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Pages 4 through 7 are not included.

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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.

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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.

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