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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: New Chemical Product Chemistry Screen for Sumilarv

FROM: Kerry B. Leifer, Chemist *K Leifer*
Registration Support Branch
Registration Division (H7505C)

TO: Richard Mountfort (PM-10)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

THRU: Bipin Gandhi, Head *B Gandhi*
Registration Support Branch
Registration Division (H7505C)

A new chemical product chemistry screen has been conducted on sumilarv technical {2-[1-Methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine; CAS Reg. No. 95737-68-1; Pyriproxyfen (BSI proposed)} [Sumilarv Technical Grade; Sumitomo Chemical Co., Ltd.; EPA File Symbol 10308-RR]. The results of this screen are discussed below.

The applicant has submitted the following product chemistry data in support of EPA File Symbol 10308-RR:

Pesticide Assessment Guideline Series No.	MRID No.
61-1	42178301
61-2	42178301
61-3	42178301
62-1	42201401
62-2	42201401
62-3	42201401
63-2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 13, 17, 20	41320703
63-17 and 63-20	41654101

The information provided in support of Guideline No. 61-2 (Description of Beginning Materials and Manufacturing Process) and Guideline No. 61-3 (Discussion of the Formation of Impurities), while meeting the product chemistry screen criteria, may be determined to be deficient upon definitive product chemistry review.

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6/12/92*

More specifically, the description of the manufacturing process does not include full description of the reaction conditions (e.g., time lengths for reactions steps, equipment used to produce the product) or a statement as to whether the production is conducted in a batch or continuous process. No information is provided describing measures used to ensure the quality of the final product. 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 (e.g., dioxins/furans) is provided.

The submission does not include data/waiver requests for Guideline Nos. 63-14 (Oxidizing or Reducing Action) and 63-16 (Explosibility); these requirements are applicable to all manufacturing-use products.

Guideline Nos. 63-6 (Boiling Point), 63-15 (Flammability), 63-18 (Viscosity) 63-19 (Miscibility) and 63-21 (Dielectric Breakdown Voltage) are not required for liquid products.

SUMMARY

This submission is determined to have passed the new chemical product chemistry screen, however the following items must be addressed before this submission will be considered acceptable for definitive product chemistry review

1. Guideline No. 61-2 (Description of Beginning Materials and Manufacturing Process)

a) A full description of the reaction conditions (e.g., time lengths for reactions steps, equipment used to produce the product) and a statement as to whether the production is conducted in a batch or continuous process should be provided.

b) Information describing measures used to ensure the quality of the final product should be provided

2. Guideline No. 61-3 (Discussion of the Formation of Impurities)

A discussion of the formation (or lack thereof) of toxicologically significant impurities (e.g., dioxins/furans) should be provided.

3. Guideline No. 63-14 (Oxidizing or Reducing Action)

The study (or waiver request, if applicable) should be submitted.

4. Guideline No. 63-16 (Explodability)

The study (or waiver request, if applicable) should be submitted.

cc: R. Kearns/EFED

March 25, 1992

Bipin --

The new chemical product chemistry screen has been completed for Sumilarv (see attached memo) and it has conditionally passed.

Based on the memo I received from EFED (see attached), Sumilarv has passed the OPP initial screen and will be put into full review, I assume a new bean sheet with a February 2, 1993 (250 days) due date will be sent to PCRS. Since I haven't sent the screen memo to the PM (although I did send cc: copy to EFED), I would suggest that Joe log out the screen action and return the memo only to the PM. Meanwhile we will hold the data in our review queue and await submission of the new bean.

If you have any questions about this, please let me know.

Kerry

Dick,
attached are the comments from Kerry. There are deficiencies in product chemistry and are considered the data gaps. Anyway, I will put this review for Tech review but I can't complete the review unless deficient data are submitted. We, therefore, may not be able to complete our reviews in the time frame

BG

3/26/92