780A

CASWELL FILE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

JAN 24 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Naptalam - Review of response to screening of data for List A in-depth review.
EPA ID No.: 030703, Barcode D164908, MRID # 418600-01, 418600-02, 418600-03, & 418600-04, HED Project No.1-1394, EPA Pesticide Chemical Code 030703, Caswell No. 780A.

TO: Walter Waldrop/Susanne Cerrelli (PM 71)
SRRD (H7508W)

FROM: Stephen C. Dapson, Ph.D. Stephen C. Dapson 1/17/92
Senior Pharmacologist, Review Section I
Toxicology Branch II/HED (H7509C)

THRU: Yiannakis M. Ioannou, Ph.D., D.A.B.T. Y.M. Ioannou 1/17/92
Section Head, Review Section I
and
Marcia van Gemert, Ph.D. Management 1/21/92
Chief, Toxicology Branch II
Health Effects Division (H7509C)

Action Requested : Review of response to screening of data for List A in-depth review - Naptalam.

Recommendations : Toxicology Branch II reviewed the additional information submitted in response to screening of data for List A in-depth review - Naptalam. Attached is the report.

Pesticide: Sodium N-1-naphthylphthalamate
Transmitted to HED on: 6/6/91 **Chemical#/Case#:** 030703/0183
Tox. Chem #: 780A
Sponsor: Uniroyal Chemical
CRM: Susanne Cerrelli **Phone#:** 703-308-8077

Response, by Guideline #

Guideline #: 81-2 Acute dermal/rabbit

EPA SCREENING POSITION:

MRID # - , Study # 5294, Study Date: 12/10/76
Recommendation: Based on preliminary assessment of the study, a recommendation is reserved. The study is not acceptable at this time in it's present form, it is only a summary page. The study must be reformatted before a review can be conducted.

COMPANY RESPONSE:

The registrant is conducting a new study with a proposed submittal date of March 15, 1993.

EPA RESPONSE:

This is acceptable to the Agency.

Guideline #: 81-3 Acute inhalation/rat

EPA SCREENING POSITION:

MRID # 000605153, Study # IBT No. 8562-09884, Study Date: 1/26/77
Recommendation: Based on preliminary assessment of the study, a recommendation is reserved. The study is not acceptable at this time in it's present form, it is only a few summary pages. The study was conducted by IBT and validation must be determined.

COMPANY RESPONSE:

Uniroyal Chemical respectfully requests that the Agency reconsider its rejection of this study on the stated grounds that it was conducted by IBT. Uniroyal wishes to point out that this study was properly audited and validated in 1980, so that the conducting lab should not be an issue for its acceptability.

Background: Although the study in point was indeed conducted by IBT (Peters and Goode, 1977. Lab Project No. 8562-09884. MRID No. 00060153), this study was audited and validated in 1980 by the Bureau of Chemical Safety, Health Protection Branch, Health and Welfare Canada, which reported to Uniroyal on June 19, 1980 that "this study has been deemed to be acceptable to both EPA and HPB" (see Volume 4, page 10). The above-cited validation document was previously submitted to the Agency in Uniroyal's 90-Day Response to the Reg. Standard Document (dated 10/8/85), which was assigned Accession No. 260019 and at a later date assigned MRID No. 00060153. Since the Agency letter of 3/8/91 does not acknowledge the existence of this validation, Uniroyal requests that the Agency reconsider the point and place the study into review. To facilitate review at this time, Uniroyal has reformatted this study, and appended the IBT validation document, as Volume 4 of this package.

In summary, in response to the Agency's request for additional information indicated in a preliminary screen of Naptalam to studies (3/8/91), Uniroyal Chemical herein submits three volumes of supplemental data (Volumes 1, 2 and 3) for Guideline 83-1a, 83-2b, 83-4 and 85-1 studies previously submitted. Uniroyal has committed to conduct a new Acute Dermal Tox. - Rabbit study) with a proposed submittal date of 3/15/93. Finally, Uniroyal has resubmitted IBT validation documentation in a reformatted Acute Inhalation - Rat study (Volume 4), for which Uniroyal requests the Agency to reconsider its rejection and instead to place the study into review.

EPA RESPONSE:

A brief review of the submitted study indicates that the particle size was greater than 25 microns; the Agency requires that the test compound be ground up to a point approaching 1 micron for testing. This study would be classified as supplementary data. A repeat study is necessary.

Guideline #: 83-1a Chronic toxicity/rodent
Guideline #: 83-2a Oncogenicity/rat

EPA SCREENING POSITION:

CHRONIC:
MRID # 00077053, Study # 798-177, Study Date: 5/20/81
Recommendation: Based on preliminary assessment of the study, a recommendation is reserved. The study is not acceptable at this time but may be upgraded by submission of the following data: percent active ingredient of the test compound, and diet analyses.

ONCOGENICITY:
MRID # 00077053, Study # 798-177, Study Date: 5/20/81
Recommendation: Based on preliminary assessment of the study, a recommendation is reserved. The study is not acceptable at this time but may be upgraded by submission of the following data: percent active ingredient of the test compound, and diet analyses. Consideration of the MTD will be made upon review.

COMPANY RESPONSE:

The registrant submitted supplemental data concerning the percent active ingredient of the test compound used in the study and the analysis of the diet for the study (MRID 00077053).

EPA RESPONSE:

The additional information is acceptable to the Agency. Study MRID # 00077053 is acceptable for review. MTD considerations will be made upon review of the study.

Guideline #: 83-4 Two-generation reproduction/rat

EPA SCREENING POSITION:

MRID # 00031684, Study # 5847, Study Date: 1/11/80
Recommendation: Based on preliminary assessment of the study, a recommendation is reserved. The study is not acceptable at this time but may be upgraded by submission of the following data: percent active ingredient of the test compound, diet analyses, and age of animals at start of study.

COMPANY RESPONSE:

The registrant submitted supplemental data concerning the percent active ingredient of the test compound used in the study, the analysis of the test diet and the age and weight of the animals at the start of the study (MRID 00031684).

EPA RESPONSE:

The additional information is acceptable to the Agency. Study MRID # 00031684 is acceptable for review.

Guideline #: 85-1 General Metabolism - rat

EPA SCREENING POSITION:

MRID # 402745-02, Study # 8660, Study Date: 7/7/87
Recommendation: This study is unacceptable since the registrant has not stated whether the analytically pure grade of the active ingredient was used. The registrant should be requested to submit this information.

COMPANY RESPONSE:

The registrant submitted supplemental data concerning the percent active ingredient of the test compound used in the study.

EPA RESPONSE:

The study (MRID # 402745-02) is acceptable for review.

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Chemical:	**Benzoic acid, 2-((1-naphthalenylamino)ca**
PC Code:	**030703**
HED File Code	**13000 Tox Reviews**
Memo Date:	**01/24/92**
File ID:	**DPD164908**
Accession Number:	**412-02-0280**

HED Records Reference Center
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