

OFFICE OF
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

207DA
CASWELL FILE



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

AUG 12 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: 1-Naphthaleneacetic Acid and Salts - Review of Minor Use Requests from two registrants.
EPA Submission S401099, EPA Barcode D167720, EPA Pesticide Chemical Code: 056002, Caswell No. 207DA, HED Project No. 1-2176.

TO: Larry Schnaubelt/Karen Samek, PM 72
SRRD (H7508C)

FROM: Stephen C. Dapson, Ph.D. *Stephen C. Dapson* 7/16/92
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THRU: Yiannakis M. Ioannou, Ph.D., D.A.B.T.
Section Head, Review Section I

for Marcia van Gemert, Ph.D. *James N. Pave* 7/16/92
Chief, Toxicology Branch II
Health Effects Division (H7509C)

Registrant: AMVAC CHEMICAL CORPORATION
Chas H. Lilly Co.

Action Requested: Review of Minor Use Requests from registrants for 1-Naphthaleneacetic Acid. (**LIST A CHEMICAL**)

Recommendations: TBII reviewed the Minor Use requests for 1-Naphthaleneacetic Acid (1-NAA) and NAA salts from AMVAC CHEMICAL CORP. Since the registrant has agreed to generate the data to satisfy the DCI, no further comment is necessary; however, it must be noted that a metabolism study is still necessary to complete the database. In reference to the data waiver requests from AMVAC for the NAA ester and NAA amides for the S82-1(a) 90-day feeding - rodent, S82-1(b) 90-day feeding - nonrodent and S85-1 general metabolism studies, these requests are denied.

The FIFRA 88 Review Committee has determined that "bridging" studies are necessary to show that data for the acid and the sodium, potassium, or ammonium salts can support the requirements for the ester and amide salts of NAA.

Chas. H. Lilly has asked for data waivers for the NAA-



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Potassium Salt comprising the §82-2 21-day dermal toxicity, §83-1(a) Chronic toxicity - rodent, §83-1(b) Chronic toxicity - non-rodent, §83-2(a) Oncogenicity - rat, and §83-4 2-generation reproduction - rat. These data waiver requests are denied since the other registrant is conducting studies originally requested to be waived; Chas. H. Lilly can consider cost sharing with AMVAC or to generate the data requested under the DCI

Background:

Originally in response to the 9/11/90 and 10/12/90 DCIs for Naphthaleneacetic Acid and It's Salts, Esters, and Amides, the registrants submitted requests for low volume/minor use waivers for:

- § 82-2 21-day dermal toxicity - rabbit/rat
- § 83-1(a) Chronic toxicity - rodent
- § 83-1(b) Chronic toxicity - non-rodent
- § 83-2(a) Oncogenicity - rat
- § 83-4 2-generation reproduction - rat
- § 85-1 General metabolism

Since the initial waiver requests, AMVAC has amended their requests and have stated that they will generate all toxicity data required by the DCIs for the acid and its salts; however they request data waivers for the following studies on the NAA ester and NAA acetamide:

- § 82-1(a) 90-day feeding - rodent
- § 82-1(b) 90-day feeding - nonrodent
- § 85-1 General Metabolism

The registration standard for *Naphthaleneacetic Acid its Salts, Ester, and Acetamide* of August 1981, stated that all the compounds are combined...because they are structurally related and because the Agency has determined that long term toxicity testing should serve for all members of this group of chemicals.

Chas. H. Lilly has submitted requests for low volume/minor use waivers for the potassium salt of Naphthaleneacetic Acid for:

- § 82-2 21-day dermal toxicity - rabbit/rat
- § 83-1(a) Chronic toxicity - rodent
- § 83-1(b) Chronic toxicity - non-rodent
- § 83-2(a) Oncogenicity - rat
- § 83-4 2-generation reproduction - rat

Toxicology Profile for 1-Naphthaleneacetic Acid, It Salts, Ester and/or Acetamide

Chemical#/Case#: 056001 through 8/#0379
Toxicology Chemical No. 589

§ 81-1 Acute oral toxicity - rat
 MRID No.: n/a, Study No.: PH-402-UC-001-82, Study Date: 4/29/82
 Discussion: Study evaluated under Tox document 005377, Core Grade Guideline.

§ 81-2 Acute dermal toxicity - rabbit/rat
 MRID No.: n/a, Study No.: PH-402-UC-001-81, Study Date: 5/11/82
 MRID No.: n/a, Study No.: 11480, Study Date: 2/24/83
 Discussion: First study evaluated under Tox document 005377, Core Grade Guideline, second study under 005067, Core Grade Guideline.

§ 81-3 Acute inhalation toxicity - rat
 MRID No.: n/a, Study No.: MD75-849, Study Date: 8/13/75
 Discussion: Study evaluated under Tox document 005377, Core Grade Supplementary Data.

§ 81-4 Primary eye irritation - rabbit
 MRID No.: n/a, Study No.: 45-51, Study Date: 4/17/82
 MRID No.: n/a, Study No.: 11480, Study Date: 1/10/83
 Discussion: First study evaluated under Tox document 005377, Core Grade Guideline, second study under 005067, Core Grade Guideline.

§ 81-5 Primary dermal irritation
 MRID No.: n/a, Study No.: 45-51, Study Date: 4/27/82
 MRID No.: n/a, Study No.: 11480, Study Date: 1/10/83
 Discussion: First study evaluated under Tox document 005377, Core Grade Guideline, second study under 005067, Core Grade Guideline.

§ 81-6 Dermal sensitization
 MRID No.: n/a, Study No.: 47-80, Study Date: 7/11/84
 Discussion: Study evaluated under Tox document 006166, Core Grade Guideline.

§ 82-1(a) 90-day feeding - rodent
 MRID No.: n/a, Study No.: n/a, Study Date: 3/10/79
 Discussion: Study evaluated under Tox document 004110, Core Grade Minimum Data.

§ 82-1(b) 90-day feeding - nonrodent
 MRID No.: n/a, Study No.: 1395, Study Date: 5/3/79
 Discussion: Study evaluated under Tox document 004110, Core Grade Minimum Data.

§ 82-2 21-day dermal toxicity - rabbit/rat
 Discussion: No study is available.

§ 82-3 90-day dermal toxicity - rodent
Discussion: No study is available.

§ 83-1(a) Chronic toxicity - rodent
Discussion: No study is available.

§ 83-1(b) Chronic toxicity - non-rodent
Discussion: No study is available.

§ 83-2(a) Oncogenicity - rat
Discussion: No study is available.

§ 83-2(b) Oncogenicity - mouse
MRID No.: 00061900, Study No. NCI, Study Date: 4/29/69
Discussion: Study evaluated under Tox document 004110, Core Grade Minimum Data.

§ 83-3(a) Teratogenicity - rat
MRID No.: n/a, Study No.: 46K-350, Study Date: 1/14/77
Discussion: Study evaluated under Tox document 004110, Core Grade Minimum Data.

§ 83-3(b) Teratogenicity - rabbit
MRID No.: n/a, Study No.: 369-105, Study Date: 11/28/83
Discussion: Study evaluated under Tox document 003864, Core Grade Minimum Data.

§ 83-4 2-generation reproduction - rat
Discussion: No study is available.

§ 84-2(a) Gene mutation-ames
MRID No.: n/a , Study No.: n/a, Study Date: 5/11/78
MRID No.: n/a , Study No.: n/a, Study Date: 7/25/78
Discussion: Both studies evaluated under Tox document 004110, Acceptable.

§ 84-2(b) Structural chromosomal aberrations
MRID No.: n/a, Study No.: n/a, Study Date: 2/28/79
MRID No.: n/a, Study No.: n/a, Study Date: 1/30/79
Discussion: Both studies evaluated under Tox document 004110, Acceptable.

§ 84-4 Other genotoxic effects
MRID No.: n/a, Study No.: n/a, Study Date: 7/17/78
Discussion: Study evaluated under Tox document 004110, Acceptable.

§ 85-1 General metabolism
Discussion: No study is available.