



13544

7-9-1982

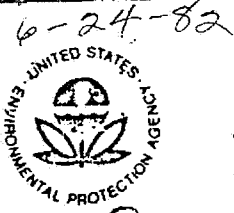
00194991

006124

Chemical:	AMS
PC Code:	005501
HED File Code	13000 Tox Reviews
Memo Date:	07/09/1982
File ID:	00000000
Accession Number:	412-01-0166

HED Records Reference Center
05/23/2001





OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS

CASWELL FILE

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

13000

7-7-82

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Robert Taylor, Product Manager #25
Registration Division (TS-767)

THRU: William L. Burnam, Deputy Branch Chief
Toxicology Branch
Hazard Evaluation Division (TS-769)

THRU: William Butler, Section Head *WMB*
Section III, Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: Ammonium Sulfamate Registration Standard.
EPA #239-2336, CFR 180.188. Review of Data
Requirements and Waiver Request.

WMB
PC-005101

TOX Chem. No. 47

Action Requested:

1. Discussion on whether or not to waive requirement.
2. If decision is not to waive the data requirement, a rationale as to why data are needed should be included.
3. If decision is not to waive the data requirements, alternatives which would allow acceptance of waivers should be included.

For Example:

- a. Label restrictions
- b. Deletion of certain label uses (food uses, home sites, etc.)

Recommendation:

1. The request for a waiver of data (letter from R. F. Holt of DuPont to R. Taylor, Registration Division) can not be supported since the requirements for re-registration have not been met.

2. The data available includes the following:

- a. Data submitted in behalf of registration of the product.
- b. Data acquired by open literature search.
- c. Other publications.

Such data have been previously reviewed and found to be lacking. Upon reviewing the studies suggested in Mr. Holt's letter, I concluded that the previous reviewer's appraisal was correct and I corroborate her findings:

Refer to the following studies:

Acute Toxicity:

- a. "Studies on the Physiological Effects of Sulfamic Acid and Ammonium Sulfamate", Ambrose, 1973.

The report is one step ahead of a summary (publication) and does not meet the requirements as per proposed guidelines.

Only male rats were used. The highest dose level of 1.6 g/kg did not kill any of the 8 rats used. The description of the material used, "in most of the studies, a four percent solution of sulfamic acid or ammonium sulfamate", is not acceptable.

- b. Study: Toxicity Studies, Lehman, 1951. It is a summary of the acute toxicity of various pesticides.


Study is not acceptable

- c. Re-review of the other studies: Subchronic and chronic

1. Subchronic Oral Toxicity, Gupta (1979), supplementary;
2. Acute Dermal Toxicity, Aoyama M. (1975), supplementary;
3. 3-Generation Reproduction, Sherman (1964), a summary;
4. Mutagenicity, Anderson, 1972, supplementary.

Re-reviewing the mentioned studies will not change the conclusion that the studies can not be used on behalf of registration of the product or for a generic standard.

3. Without submission of the required data we can not talk, at this time, of label restriction or deletion of certain label uses.


Alex Arce, Toxicologist
Toxicology Branch
Hazard Evaluation Division (TS-769)

July 9-82

OPP:HED:TOX: A.ARCE:sb 6/24/82 X73710 Rm. 816 #m14

4