

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

CAS 7783-30-2

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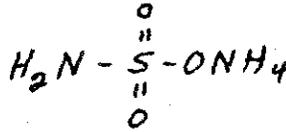
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RDCoberly:deg  
October 5, 1967

PC005501

Chemical Name : Ammonium Sulfamate

Chemical Structure :



Empirical Formula : H<sub>6</sub>O<sub>3</sub>N<sub>2</sub>S

Molecular Weight : 114.13

Physical State : Crystalline Solid

Melting Point : 131°C-132°C

Stability : Stable under conventional condition.  
Decomposes upon heating to 160°C

Solubility : Soluble in water, glycerol, glycols  
and formamide.

Reason : First review by PHS

Company : E. I. du Pont de Nemours & Co.

Washington, D. C.  
September 29, 1967

Mr. Kenneth Nash  
Pesticide Regulation Division  
Agricultural Research Service  
U. S. Department of Agriculture  
Washington, D. C. 20250

Dear Mr. Nash:

The toxicological data on Ammonium Sulfamate, received from you on June 17, 1966, in connection with two recently received products, Reg. Nos. 829-G and 1022-L, has been reviewed.

These data indicate that an undue human hazard should not be created under normal circumstances by the routes of contact presented in the aforementioned data. No data was received on the effects of the chemical by the inhalation route. The report does indicate that a threshold value of 15 mg/M<sup>3</sup> has been established as the safe atmospheric concentration to humans. The basis being low rodent oral toxicity and human experience. But that does not answer the question, "What is the unsafe level?"

As indicated above, the presented data does appear strong enough to justify registration. We also feel an acute inhalation study should be made available for review.

Sincerely,

Robert D. Coberly  
Biologist  
Registration Section  
Pesticides Program

RDCoberly:mw

Acute Rat S.C. : 2 ml of 4% solution caused no irritation or necrosis.

Acute Rat Oral : LD<sub>50</sub> = 3.9 gm/Kg

Acute Rat IP : MLD = 0.8 gm/Kg

Acute Sheep Oral : 14 or 28 grams/animal gave no ill effects. 100 grams/animal caused enteritis and death.

Acute Dog IV : 0.1 gm/Kg was well tolerated.

Acute Rabbit Eye : 0.5 ml of 4% solution caused no irritation.

Subacute Rat Oral : Nine to 15 treatments of 0.5 gm/animal on alternate days produced no effect.

Subacute Dog Oral : One gram/animal for six days produced no systemic effects.

Subacute Deer Feeding : Amount consumed was not obtained. Neither of two does showed ill effects.

The value of this study is very limited.

Subacute Calf Feeding

Study No. 1 : Calves force-fed 28 or 56 grams/animal for 10 days showed no effect.

Study No. 2 : Two calves with free choice for one week showed no effect. Amount consumed was not specified.

Subacute Yearling Wether Feeding : Ingestion of 227 grams during five days caused no ill effects.

- Pregnant Ewe : Was fed 112 grams. Delivered two normal lambs.
- Subacute Rat Feeding (105 days) : 1.0% in the diet had no effect.  
2.0% in the diet caused reduced growth rates and a slight cathartic action. No gross or histological changes were noted.
- Subacute Rat Dermal
- Study No. 1 : Sixteen applications of a 20% solution produced no irritation or systemic toxicity.
- Study No. 2 : Eleven applications of a 50% solution produced no irritation, systemic toxicity or histological changes.
- Subacute Human Dermal : Produced no irritation as a 4% solution.
- Human Patch Test : A 10% solution caused no irritation.
- Pharmacodynamic and Metabolic Studies : 80% and 84% was excreted in the dog urine as sulfamic acid.
- Three-generation Rat Reproduction : Levels tested were 0.035% and 0.05% (350 ppm and 500 ppm). No evidence of toxicity was noted.

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October 5, 1967

Sulfamic Acid

Acute Rat Oral

Results are based on the work of Lehman during 1951. Protocol was not listed.

Results

LD<sub>50</sub> = 3.9 gm/Kg. At the very high doses, tremors were noted and death occurred within 10 minutes. Animals that survived for 24 hours usually recovered. Ambrose (1943) noted that an oral dose of 1.6 gm/Kg was tolerated by white mice without toxic signs.

Acute Rat IP

These findings are based on the work of Ambrose (1943).

Results

He found the minimum fatal dose for rats to be 0.8 gm/Kg. Fatal doses produced stimulation of respiration and prostration; death occurred within 45 minutes following administration of the compound.

Acute Sheep Oral

Oral doses of 14 or 28 grams were given to yearling wethers. One hundred grams and less was given to adult goats.

Results

The yearlings showed no signs of ill effects. The adult goats showed severe enteritis and death at 100 grams/animal. Lesser doses were tolerated by the adult goats.

Acute Dog IV

Protocol was not listed.

Results

A dose of 0.1 gm/Kg was well tolerated (Ambrose, 1943).

Subacute Rat Oral

Intubation of 0.5 gram/animal was done on alternate days for nine or fifteen treatments.

Results

These treatments produced no signs of toxicity in rats except for a decrease in growth rates at the beginning of the experiment. The animals overcame this weight loss during the latter part of the treatment. No significant gross or micropathology was found.

Subacute Dog Oral

One gram of the test material was fed daily for six days.

Results

This administration of the test material produced no systemic effects.

Subacute Deer Feeding (34 Days)

The crystalline product was made available to two yearling does on a free choice basis for 34 days.

Results

The amount consumed was not obtained due to the hygroscopic nature of the chemical. Neither of the animals involved showed any signs of illness or loss of condition.

The value of this study with regard to extrapolation to human toxicity appears to be very limited.

#### Subacute Calf Feeding

##### Study No. 1

Two calves (5-7 months of age) were forced-fed 28 grams and 56 grams, respectively, each day for ten days.

##### Study No. 2

The chemical was also made available to two calves on a free choice basis for seven days.

#### Results

##### Study No. 1

These calves showed no effect.

##### Study No. 2

These calves showed no effects. Amount of the test material consumed was not specified.

#### Subacute Yearling Wether Feeding

The yearling wether was allowed to consume 227 grams of the test material over a five day period.

#### Results

No ill effects were noted.

### Pregnant Ewe Study

The ewe was fed 112 grams (number of doses or time required to consume was not specified in this report).

The ewe delivered two normal lambs.

### Subacute Rat Feeding (105 Days)

In this study the rats were provided with 1% and 2% of the test material in the diet of female rats.

### Results

The 1% dietary level was without effect. The 2% inhibited growth weights and induced a slight cathartic action. No gross or histological changes were noted.

The 1% and 2% dietary levels are equivalent to 10,000 ppm and 20,000 ppm respectively.

### Subacute Rat Dermal

#### Study No. 1

Sixteen applications of a 20% aqueous solution was applied to the skin of ten white rats over a period of twenty-seven days.

#### Study No. 2

Eleven applications of a 50% aqueous solution was applied to the shaved skin of five rats over a period of nineteen days.

Results

The test material in both studies did not produce irritation, systemic toxicity or histological changes.

Subacute Human Dermal

Topical application of a 40% solution was made to the anterior surface of one arm of each of five human subjects several times a day for five days.

Results

The test material did not produce irritation in any of the subjects.

Acute Rabbit Eye

Approximately 0.5 ml of a 4% solution was placed into the conjunctival sac of five rabbits.

Results

No irritation was observed.

Acute Rat Subcutaneous

Treatment consisted of the injection of two ml of a 4% solution.

Results

There were no signs of irritation, inflammation or necrosis.

Pharmacodynamic and Metabolic Study

Studies conducted by Haskell Laboratories in which sulphur distribution in the urine of dogs was determined, showed that the compound is largely

excreted in the form of sulfamic acid. In two studies each receiving one gram per day for five days, 80% and 84% of the amount was recovered. Tests were made for various constituents of the urine and blood serum which would indicate effects on liver function; no adverse effects were noted.

According to Ambrose 20 ml/Kg intravenously to dogs had no effect on blood pressure and respiration. At 100 mg/Kg slight transient effects were noted but neither system was seriously influenced.

As reported by Haugen, the blood pressure in calves was unchanged after the animals were force-fed 28 or 56 grams/day for 10 days.

#### Three-generation Rat Reproduction Study

Forty-eight males and forty-eight females were divided into three groups of sixteen males and sixteen females and offered the dosage levels of 0.0, 0.035% and 0.05 (equivalent to 350 ppm and 500 ppm respectively). At three months, a three-generation reproduction study was initiated within each group. After the original generation had been on test for approximately 19 months, six males and six female rats were selected at random from the control group and the group receiving the 0.05% and was subjected to a hematological evaluation, a urinalysis and a test to measure liver function (plasma, alkaline phosphatase activity) and a test to measure kidney function (urine glutamic-oxaloacetic transaminase activity).

Results

No evidence of toxicity as measured by histopathologic appraisal, growth curves, and reproduction lactation indices was noted.