

00/45269 180.162

Tox. Chem. No. 47 - Ammonium Sulfamate

Acceptable Daily Intake -  
EPA/ OPP / HED / Tox.

Material :

Doc. No. for Updated ADI

PLD  
ADI or PADI 0.025 mg/kg

004611

Safety Factor = 1000

O.K. 9/20/85

Dated : 5/13/83

*[Handwritten signatures: D. B. ...]*  
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Updated : 8/14/85

Study : 3 - Generation Rat Reproduction Stere Scenten

NOEL : 25 mg/kg or 500 ppm

Lab. :

Section Head N/A

Study No. :

Study Date :

Doc. No. : 004028

Comments:

Data Gap :

107 b

## 47 - Ammonium Sulphate

### Data Considered

- \* 1. 3-Generation Reproduction - rat (NOEL = 500 ppm; no core grade)
2. 30-Day Feeding - rat (0.5g only dose; no core grade)
3. 6-Day Feeding - dog (1g only dose; no core grade)

### Data Gaps

1. Chronic Feeding - dog
2. Chronic Feeding - rat
3. Teratology - rat
4. Teratology - rabbit

### Other Considerations

No oncogenic study was listed.

\* used

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2/11/83

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Ammonium sulfate : PADI from a 3-Generation  
Red Paperhoney study

In an effort to support the published  
toxicology data on ammonium sulfate, a PADI  
was established from the available toxicity  
data conducted by the Toxicology Branch.  
Studies considered are available in establishing  
a PADI from a 3-generation rat reproduction,  
30-day rat feeding and 6-day dog feeding.  
The 30-day rat feeding and 6-day dog feeding  
studies were sufficient to determine only one dose  
was used and no NOEL was established.  
The PADI from the 3-generation rat study  
(NOEL = 25mg/kg or 500 ppm) was 0.25mg/kg/day.

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Study/Lab/Study #/Date	Material	EPA	Results: LD50, LC50, PIS, NOEL, LE
		Accession No.	
3 Generation reproduction - rat	Technical		Reproduction NOEL = 500 ppm Levels tested - 350 and 500 ppm
6 Day feeding - dog	Technical		Fed 1 g of test material for 6 no systemic effects observed
30 Day feeding - rat	Technical		0.5 g was administered on alter days for 15 treatments; weight loss occurred but animals over weights loss during the latter part of treatment
105 Day feeding - rat	Technical (1% and 2%)		NOEL = 10,000 ppm (1%) LEL = 20,000 ppm (2%) Inhibited growth weights and induced a slight cathartic act Levels tested - 1% (10,000 ppm) and 2% (20,000 ppm)
Dermal - human	Technical (40% soln.)		Topical application to the ante surface of one arm several tir day for five days produced no irritation
Primary dermal irrita- tion - rat	Technical (20% and 50% aq. soln.)		No irritation to shaved and uns skin
Primary eye irritation - rabbit	Technical (4% soln.)		No irritation
Primary dermal irrita- tion - rat	Technical (4% soln.)		No signs of irritation, inflam or necrosis
Acute oral LD50 - rat	Technical		LD50 = 3.9 g/kg

File last updated 10/18/85

ACCEPTABLE DAILY INTAKE DATA

PAT, Older NOEL	S.F.	PLD		
		<del>ADI</del>	M PLD	
ug/kg	ug	ug/kg/day	ug/day/60kg	
25,000	500.00	1000	0.0250	1.5000

Published tolerances

GROUP	tolerance	Food Factor	ug/day/1.5kg
Apples( 1)	5.000	0.53	0.16975
pears(116)	5.000	0.26	0.01916

ADI	GROUP	PLD
1.5000 ug/day/60kg	0.2005 ug/day/1.5kg	15.93

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