004526 180.184

Tox. Chem. No. 47- Ammonium Sulfamate

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

Material :

Doc. No. for Updated ADI
004611

ADI or ~~PADI~~ PLD 0.025 mg/kg

O.K. 9/20/85

Safety Factor = 1000

Dated : 5/13/83

Updated : 8/14/85

Study : 3 - Generation Rat Reproduction

NOEL : 25 mg/kg or 500 ppm

Lab. :

Section Head N/A

Study No. :

Study Date :

Doc. No. : 004068

Comments:

Data Gap.

185

47 - Ammonium Sulfamate

Data Considered

x 1. 3-Generation Reproduction - rat (NOEL = 5000 ppm; no core grade)

2. 30-Day Feeding - rat (0.5% only dose; no core grade

3. 6-Day Feeding - dog (1% only dose; no core grade)

Data Gap

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

Other Considerations

No oncogenic study was listed.

2

* Used

8/11/83

004611

Ammonium Sulfamate: PADI from a 3-Generation Rat Reproduction Study

In an effort to support the published tolerance for ammonium sulfamate, a PADI was established from the available toxicity data as conducted by the Toxicology Branch. Studies considered as available in establishing a PADI were 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 eliminated because only one dose was used and no NOEL was established. The *PADI from the 3-generation rat study (NOEL = 25 mg/kg or 500 ppm) was 0.25 mg/kg/day.

BEST AVAILABLE COPY

3

Tox Chem No. 47 Ammonium Sulfamate

File Last Updated 12/10/84

Study/Lab/Study #/Date	Material	EPA Accession No.	Results: LD_{50}, LC_{50}, PIS, NOEL, LE
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 alte days for 15 treatments; weight loss occured but animals overc weights loss during the latte 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 irritation - 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 irritation - rat	Technical (4% soln.)		No signs of irritation, inflam or necrosis
Acute oral LD_{50} - rat	Technical		LD_{50} = 3.9 g/kg

File last updated 10/16/85

ACCEPTABLE DAILY INTAKE DATA

RAT,Older NOEL		S.F.	~~ADI~~ PLD	MPLD PPI
mg/kg	ppm		mg/kg/day	mg/day/60kg
25.000	500.00	1000	0.0250	1.5000

Published Tolerances

CROP	tolerance	Food Factor	mg/day/1.5kg
Apples(1)	5.000	.53	0.13975
Pears(116)	5.000	0.26	0.01916

ADI	TMRC	% ~~ADI~~ PLD
1.5000 mg/day/60kg	0.2057 mg/day/1.5kg	13.73

****