

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

FLUCHLORALIN

SB 950-309, Tolerance # 363

NOVEMBER 3, 1986

I. DATA GAP STATUS

Chronic rat: Data gap, inadequate study, no adverse effect indicated

Chronic dog: Data, gap, no study on file

Onco rat: Data gap, no study on file

Onco mouse: Data gap, inadequate study, no adverse effect indicated

Repro rat: Data gap, inadequate study, no adverse effect indicated

Terato rat: Data gap, no study on file

Terato rabbit: Data gap, inadequate study, no adverse effect indicated

Gene mutation: Data gap, no study on file

Chromosome: Datagap, inadequate study, no adverse effect indicated

DNA damage: Data gap, no study on file

Neurotox: Not required

Note, Toxicology one-liners are attached

** indicates acceptable study

Bold face indicates possible adverse effect

File name C7 SB309FLU.JPS

II Toxicology One-Liners and Discussion

CHRONIC

RAT

033 34778; Cannon, 6-74; Apostolou, 7/29/85; Chronic Rat; 0, 125, 375, 1125 ppm, low dose raised to 4400 ppm in food. Brief summary, no effects, unacceptable.

EPA one-liner - Systyemic NOEL= 4400 ppm, oncogenic NOEL greater than 4400 ppm; invalid.

DOG

No study on file

ONCOGENICITY

RAT

No study on file

MOUSE

004 6485 Cannon, 3-75; Apostolou, 7/29/85; Oncogenicity, mouse; 0, 125, 373, 1125 ppm in food. 125 changed to 4400 during study. 50 per sex per group. No adverse effects reported, not acceptable. Not upgradable.

EPA one-liner. Systemic NOEL=4400 ppm (HDT), Oncogenic NOEL greater than 4400 ppm (HDT), invalid.

REPRODUCTION

RAT

004 6484 Cannon, 9/74; Apostolou, 7/85; Reproduction Rat; 0, 2889,10,144 ppm in food. 10 males, 20 females per group. No adverse effects. Not acceptable. Not upgradable.

EPA one-liner - NOEL greater than 10,144 ppm (highest level fed; reproduction and systemic). Invalid.

TERATOLOGY

RAT

No study on file

RABBIT

044 6481 Cannon, 8/73; Apostolou, 7/85; Teratology Rabbit; 0, 800, 1500, 3000 mg/kg by gavage; 12 animals per dose group. No adverse effects. Not acceptable. Not upgradable.

EPA one-liner-NOEL greater than 3,000 mg/kg/day (highest level fed). Invalid.
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GENE MUTATION

No study on file

CHROMOSOMAL ABERRATION

004 6483 Cannon, 7/73; Apostolou, 7/85; Cytogenetics - rat; 0,125,500 mg/kg in food. 6 males per dose group (derived from reproduction study). No adverse effects. Not acceptable. Not upgradable.

EPA one-liner - NOEL=10,144 ppm (highest level fed in reproduction study) for breaks, transformation or interchange figures. Invalid.

004 6482 Cannon, 8/74; Apostolou, 7/85; Schreider, 10/86; Dominant Lethal-Rat; 0, 5, 125, 500 mg/kg. 10 males per dose group mated with 2 females per week per male for seven weeks. No adverse effects. Not acceptable. Not upgradable.

The initial review identified a possible adverse effect based on mitotic index. The index for the first week for the low dose group was incorrectly calculated (too high). There is so much variation that no conclusions can be drawn on the mitotic index. Therefore, a possible adverse effect can not be concluded.

EPA one-liner - NOEL=500 mg/kg/day (highest level fed) invalid.

DNA DAMAGE AND REPAIR