

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

MEDICAL TOXICOLOGY BRANCH
SUMMARY OF TOXICOLOGY DATA
OXYCARBOXIN

SB950 - 294, TOLERANCE # 50010

Sept. 29, 1987

I. DATA GAP STATUS

Chronic rat : Data gap, inadequate study, possible adverse effect indicated

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

Onco rat : Data gap, no study on file

Onco mouse : Data gap, no study on file

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

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

Terato rabbit : Data gap, no study on file

Gene mutation : Data gap, inadequate study, no adverse effect indicated

Chromosome : Data gap, no study on file

DNA damage : Data gap, no study on file

Neurotox : Not required at this time

Note, Toxicology one-liners are attached

** indicates acceptable study

Bold face indicates possible adverse effect

File name :SB294OXY.CNA

Index and one-liners prepared by D. Shimer.

No EPA one-liners available Sept. 15, 1987.

II. TOXICOLOGY SUMMARY

CHRONIC, RAT

002 27142 "24 Month Dietary Administration - Albino Rats F-461 Technical Final Report." (Hazleton Labs, 4-18-69) F-461 Technical was given to CD derived rats in the feed for 2 years at 0, 300, 1000 or 3000 ppm,

2.

30/sex/experimental group, 60/sex/control. **Possible adverse effect noted**, however of minor scale. NOEL approx. 300 ppm, based on thyroid findings. Thyroids had increased weight in all groups at 6 months (but no dose-relationship at 6 months and no thyroid weight differences at subsequent sacrifices). Hyperplastic alterations were observed in males at 3000 ppm at 6, 12 and 24 months. In addition, there was an apparent treatment-related incidence of "clumped basophilic-staining colloid in the follicles" in 1000 ppm males. **Unacceptable, not upgradeable.** Small number of animals, limited histopathology in terms of tissues and animal numbers. J. Remsen (Gee), 7/26/85.

CHRONIC, DOG

002 27143 "Two Year Dietary Administration - Dogs F-461 Final Report." (Hazleton Labs, 2-5-69) F-461 was administered to beagles in the diet for 2 years at 0, 300, 1000 or 3000 ppm, 4/sex/group. **No adverse effect indicated. Unacceptable, not upgradeable.** dose levels apparently not high enough to elicit chronic toxicity, thus dosing regime not justified; histopathology not done on low and mid dose animals except for selected tissues. J. Remsen (Gee), 7-26-85.

ONCOGENICITY, RAT

No studies on file.

ONCOGENICITY, MOUSE

No studies on file.

REPRODUCTION, RAT

007 36404 "Three Generation Reproduction Study - Rats F-461 Technical Final Report." (Hazleton Laboratories, 8/9/68) F-461 technical was administered to rats in the feed for a 3 generation reproduction study, 2 litters/generation, at 0, 300, 1000 or 3000 ppm, 10 males and 20 females per group. **No adverse reproductive effect indicated:** Apparent parental and developmental NOELs = 300 ppm. Reduced litter sizes and reduced growth rate of pups were observed at 1000-3000 ppm, however these findings were at treatment levels which caused marked growth retardation and clinical signs of toxicity in parents, thus reproductive effects are judged to be secondary to adult toxicity.

Unacceptable, not upgradeable. Summary tables only, test article not fully described, no histopathology, no identification of paternity, no analysis of feed. Initial review by J. Remsen (Gee), 1/21/86, indicated "possible adverse effects". Subsequent review by C. Aldous redesignates study status to **Insufficient information for independent assessment** because of deficiencies in study and report, and because data do not demonstrate unique reproductive toxicity. J. R. Gee, 1/21/86, C. Aldous, 9/29/87.

004 14971 Summary of 007 36404. J. Remsen (Gee), 7-26-85.

TERATOLOGY, RAT

007 36405 "Teratology Study in Rats - Plantvax Technical." (International Research and Development Corp., 6-1-82) Plantvax technical was administered to pregnant COBS CD rats by gavage on days 6 to 19 of gestation at 0, 25, 100

or 200 mg/kg/day as CMC suspension, 25 per group. **No adverse effects indicated.** Maternal NOEL = 100 mg/kg/day, decreased weight gain and increased salivation; Developmental NOEL = 100 mg/kg/day, decreased fetal weight, number of live fetuses and delayed ossification. **Unacceptable, upgradeable.** Analysis of dosing solution is needed (see review). J. Parker, 1-23-86.

004 14970 Summary of 007 36405. J. Remsen (Gee), 7-26-85.

TERATOLOGY, RABBIT

No study on file.

GENE MUTATION

007 36406 "Mutagenicity Evaluation of Plantvax Technical Grade in the Ames Salmonella/ Microsome Plate Test." (Litton Bionetics, 8-80) Plantvax technical was assayed for mutagenicity with Salmonella typhimurium at 0, 0.5, 1.0, 10.0, 100, 500, 1000, 2500 or 5000 ug/plate with and without rat liver activation. **Unacceptable.** (Cannot be upgraded as an independent test). Test article not described for purity, single plate only, no confirming trial. J. Remsen (Gee), 1-21-86.

004 14973 Summary of 007 36406. J. Remsen (Gee), 7-26-85.

CHROMOSOME

No study on file.

DNA DAMAGE

No study on file.

NEUROTOXICITY