

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE  
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

BARBAN

SB 950-158, Tolerance # 253

December 10, 1986

I. DATA GAP STATUS

Chronic rat: Data gap, invalid study  
Chronic dog: Data gap, invalid study  
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, no study on file

Chromosome: Data gap, no study on file

DNA damage: Data gap, no study on file

Neurotox: Not required

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**Note, Toxicology one-liners are attached**

\*\* indicates acceptable study

**Bold face** indicates possible adverse effect

File name SB158BAR.JG1

## II. TOXICOLOGY SUMMARY

SB950-158, Tolerance #253

## CHRONIC RAT

003 920016 (IBT, 6-14-61.) JR(Gee), 5-16-85.G) Number of study is not on document so cannot confirm whether valid study but EPA 1-liners identify a study with the same date as #1017, listed as "replaced". Commercial grade Carbyne, no purity stated; fed to 30/sex/group for 2 years at 0, 0.05, 0.15 or 0.50%, w/w; unacceptable (no analysis of diet, inadequate histopathology, no clinical chemistry, inadequate number of animals, others.) Slight decrease in weight gain at 0.5%. EPA 1-liner for IBT #1017: No CORE grade. Systemic NOEL = 135 mg/kg (body weight depression. Oncogenic NOEL > 450 mg/kg (HDT). Levels tested: 0, 45, 135 and 450 mg/kg/day. Invalid: Canadian review.

004 920018 Addendum to 920016 with histopathology.

004 920019 Addendum to 920016, 5-month interim report.

Note: No "replacement" study on file at CDFA.

## CHRONIC DOG

003 920017 (IBT, no number on study, 6/26/61) JR(Gee), 5-16-85. IBT invalid by EPA. Study suggests an effect on the liver at 150 mg/kg but since study is invalid, no use can be made of the data.

004 920020 Addendum to 920017 with pathology report.

ONCOGENICITY, RAT

No study on file.

ONCOGENICITY, MOUSE

No study on file.

## REPRODUCTION, RAT

002 920025 (Cannon Labs, 12-20-79.) JR(Gee), 5-16-85. Technical Barban, 82.8%; fed in diet to 10 males/20 females per group at 0, 174, 957 or 1740 ppm, three generations, two matings; systemic NOEL = 957 ppm (decreased body weight gain), reproductive NOEL  $\geq$  1740 ppm; unacceptable (no identification of the 17.2% remainder of test article, no analysis of diet presented, necropsy of parents not indicated, missing organs for histopathology).

EPA 1-liner: Minimum. Reproductive NOEL > 1740 ppm (HDT), systemic NOEL = 957 ppm (decreased weights of P2 male and female and P3 female).

006 23105 Summary of 920025.

002 920022, 920023 Progress reports for 920025.

007 36144 Exact duplicate of 920025.

## TERATOGENICITY, RAT

002 920021 (Cannon Labs, 2-15-77.) JR(Gee), 5-16-85. Barban, purity not stated; given by oral gavage to 20/group at 0, 8.7, 34.8, 60.9, or 87.0 mg/kg, days 6 - 15 of gestation; no teratogenic effect reported; systemic NOEL > 87.0 mg/kg, terata NOEL > 87.0 mg/kg; unacceptable (incomplete with Appendix missing, no purity of test article, high dose not high enough although stated as 1/10 LD50).

EPA 1-liner: Minimum. Teratogenic NOEL > 87 mg/kg (HDT), Maternal NOEL > 87 mg/kg, Fetotoxic NOEL > 87 mg/kg.

007 36145 Exact duplicate of 920021.

TERATOGENICITY, RABBIT

No study on file.

MUTAGENICITY, GNMU

No study on file.

MUTAGENICITY, CHROMOSOME

No study on file.

MUTAGENICITY, DNA/OTHER

No study on file.

NEUROTOXICITY