

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

1-(2-HYDROXYETHYL)-2-ALKYL-2-IMIDAZOLINE
(Derived from Tall Oil Fatty Acids)

Chemical Code # 001664, Tolerance # 51635
SB 950 # 452

Original date: May 6, 2003

I. DATA GAP STATUS

Chronic toxicity, rat:	Data gap, no study submitted
Chronic toxicity, dog:	Data gap, no study submitted
Oncogenicity, rat:	Data gap, no study submitted
Oncogenicity, mouse:	Data gap, no study submitted
Reproduction, rat:	Data gap, no study submitted
Teratology, rat:	No data gap, no adverse effect.
Teratology, rabbit:	Data gap, no study submitted
Gene mutation:	No data gap, no adverse effects.
Chromosome effects:	Data gap, study inadequate, no adverse effect.
DNA damage:	Data gap, study inadequate, no adverse effect.
Neurotoxicity:	Not required at this time

Toxicology one-liners are attached.

All record numbers through 129438 were examined.

** indicates an acceptable study.

Bold face indicates a possible adverse effect.

File name: T030506

Original by: J. Kishiyama and Gee, 5/6/03.

In August, 1995, US EPA issued a "Reregistration Eligibility Decision" regarding alkyl imidazoline.

The conclusion was that no further studies were required based on the use pattern and corrosivity. The Department apparently has on file those studies reviewed by US EPA in reaching this decision. There are two products currently registered in California, both as fuel additives with a signal word of "Danger" on both labels.

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may contain additional effects.

COMBINED, RAT

No study submitted

CHRONIC TOXICITY, RAT

No study submitted

CHRONIC TOXICITY, DOG

No study submitted

ONCOGENICITY, RAT

No study submitted

ONCOGENICITY, MOUSE

No study submitted

REPRODUCTION, RAT

No study submitted

TERATOLOGY, RAT

** 003 116017 Schroeder, R. E. "Teratogenicity Study in Rats with EH&S 592."
(Bio/dynamics, Inc., Project No. 90-3613, January 14, 1992.) EH&S 592, purity 85 ± 3%, was administered by oral gavage at doses of 0 (Mazola® oil), 15, 65 or 100 mg/kg/day to 24 mated female CD® rats/group on gestation days 6 through 15. Mid and high dose groups had lower food consumption, lower body weights, increased incidence of excessive salivation, stained skin/fur of ano-genital region, snout and extremities, labored breathing and rales. The low dose group had a slight increase in the incidence of excessive salivation, stained skin/fur of ano-genital, snout and extremities. Maternal NOEL < 15 mg/kg (clinical signs but of minor incidence). There was no evidence of teratogenicity or developmental toxicity. Developmental NOEL = 100 mg/kg. ACCEPTABLE. (Kishiyama and Gee, 5/5/03)

TERATOLOGY, RABBIT

No study submitted

GENE MUTATION

** 002 116015 San, R. H. C. and V. O. Wagner. "Salmonella/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test)." (Microbiological Associates, Inc., Laboratory Study Number T9412.501, November 12, 1990.) EH&S 593, purity 100%, was evaluated for mutagenic potential at concentrations of 1.0, 3.3, 10, 33 and 100 : g/plate with and without microsomal enzymes (Aroclor 1254-induced male rat liver) with *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA 1538. A 2.0-2.2- fold increase in the number of revertants with TA1537 with S-9 Mix was not repeated in a second trial with S9 with concentrations of 10, 33, 100, 333 and 1000 ug/plate. Evaluated as negative for mutagenicity. ACCEPTABLE. (Kishiyama and Gee, 4/21/03).

CHROMOSOME EFFECTS

004 129438 Putman, D. L. and M. J. Morris. "Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells." (Microbiological Associates, Inc., Rockville, MD., Laboratory Study No. T9412.337, 12/17/90.) EH&S 593 (purity and lot number not stated, viscous liquid) was assayed at concentrations of 0.0013, 0.0025, 0.005, 0.01, and 0.02 : l/ml without S9 Mix and at 0.0065, 0.013, 0.025, 0.05, and 0.1 : l/ml with rat liver metabolic activation (S9 Mix) for chromosome aberrations using Chinese Hamster Ovary cells. Treatment periods were 2 and 18 hours with and without S9, respectively. The total incubation time was approximately 20 hours. A preliminary toxicity test indicated the test material caused cell cycle delay. No increase in chromosome aberrations was noted. UNACCEPTABLE. Upgradeable with test article stability and purity. (Kishiyama and Gee, 4/21/03).

DNA DAMAGE

002 116016 Curren, R. D. "Unscheduled DNA Synthesis in Rat Primary Hepatocytes." (Microbiological Associates, Laboratory Project ID T9412.380, December 21, 1990.) EH&S 593, purity not stated, amber viscous liquid, was evaluated at concentrations of 0.001, 0.003, 0.006, 0.01 and 0.03 : l/ml for the ability to induce unscheduled DNA synthesis in rat primary hepatocytes. EH&S 593 treatment under study conditions did not increase the net nuclear grain count. At 0.03 : g/ml, cell survival was reduced to 23% of controls by release of lactic acid dehydrogenase. DMBA (positive control) caused a significant increase in net nuclear grains. UNACCEPTABLE. Upgradeable (characterization of the test article). (Kishiyama and Gee, 4/21/03).

NEUROTOXICITY

Not required at this time