

CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION  
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA  
ETHYLENE

Chemical Code # 000270, Tolerance # 01016  
SB 950 # 673

December 21, 2001

I. DATA GAP STATUS

Combined, rat: (chronic/oncogenicity)	Data gap, inadequate study, no adverse effect indicated.
Chronic toxicity, rat:	Data gap; see combined, rat
Chronic toxicity, dog:	Data gap, no study on file
Oncogenicity, rat:	Data gap: see combined, rat
Oncogenicity, mouse:	Data gap, no study on file
Reproduction, rat:	Data gap, no study on file
Teratology, rat:	Data gap, no study on file
Teratology, rabbit:	Data gap, no study on file
Gene mutation:	Data gap, no study on file
Chromosome effects:	Data gap, no study on file
DNA damage:	Data gap, no study on file
Neurotoxicity:	Data gap, no study on file

---

Toxicology one-liners are attached.

All record numbers through 092055; volume 001 and 002 were examined.

\*\* indicates an acceptable study.

**Bold face** indicates a possible adverse effect.

File name: T20011221

Kishiyama and Gee, 12/21/01

Ethylene has been classified as a biorational chemical by US EPA, R.E.D. FACTS, 9/92. It is a plant growth regulator and is naturally occurring. US EPA has exempted it from tolerance requirements. Information from the literature was used by US EPA in evaluating the toxicity of ethylene.

On January 10, 1995, the Office of Environmental Health Hazard Assessment agreed with the Department of Pesticide Regulation that no further studies were needed for ethylene at that time. Therefore, although no adequate studies have been submitted under SB 950, none are required at this time. (Gee, 12/21/01)

## II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

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

### COMBINED, RAT

001, 002 092053, 092054, 092055 Errico, P. H. and J. G. Keller, A Tracor Jitco audit report on an IBT study. "24-Month Chronic Inhalation Toxicity and Carcinogenicity Study with Ethylene in Albino Rats" (Industrial Bio-Test Laboratories, Inc., IBT study No. 8562-08808, 1/15/82.) [This study was not included in the validation report on IBT studies.] Ethylene gas was introduced into inhalation chambers at nominal concentrations of 0, 300, 1000 or 3000 ppm. There were 120 Fischer 344 rats/sex/group with exposure for 6 hours/day, 5 days/week for 24 months. There were interim sacrifices of 5/sex at 6 and 12 months and 20/sex at 18 months. The pathology evaluation was conducted at EPL and an audit of the study was performed by Tracor Jitco. The conclusion of both pathology reviews was that there were no treatment-related effects. Most of the other data collected by IBT were not included in the audit report. The original IBT study was not included. The study is UNACCEPTABLE (insufficient information/data) and not upgradeable (major deficiencies, no MTD) as submitted. (Kishiyama and Gee, 12/21/01).

### CHRONIC TOXICITY, RAT

See combined, rat study.

### CHRONIC TOXICITY, DOG

No study on file.

### ONCOGENICITY, RAT

See combined, rat study.

### ONCOGENICITY, MOUSE

No study on file.

REPRODUCTION, RAT

No study on file.

TERATOLOGY, RAT

No Study on file.

TERATOLOGY, RABBIT

No study on file.

GENE MUTATION

No study on file.

CHROMOSOME EFFECTS

No study on file.

DNA DAMAGE

No study on file.

NEUROTOXICITY

No study on file.