

327544

PUBLIC COPY

June 9, 2010

RECEIVED
OFFICE OF POLLUTION PREVENTION AND TOXICS

Via Federal Express

10 JUN 10 PM 12:15

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, DC 20004

8EHQ-0610-17985A
DCN: 88100000314s



8EHQ-10-17985

Dear 8(e) Coordinator:

Mixture containing Hydroxylamine -50% (CAS#7803-49-8) []; Monoethanolamine (CAS#141-43-5) []; Diglycolamine (CAS#929-06-6) []; Gallic acid (CAS#149-91-7) [] and Water (CAS#7732-18-5) []

This letter is to inform you of the results of an acute dermal and an acute oral toxicity study with the above referenced test mixture.

Acute Dermal Toxicity:

The test mixture was applied undiluted at a dose of 2, 1.5, 1.2, or 0.6 g/kg body weight to the shaved backs of groups of five male and five female New Zealand White rabbits. Death occurred in 8/10, 4/10, 7/10, and 1/10 animals dosed at 2, 1.5, 1.2, and 0.6 mg/kg, respectively.

Cyanosis (up to 3 to 6 days) was observed in all animals. Hydroxylamine has been reported to cause cyanosis¹. Hypoactivity was observed in 4 females (all moribund animals) dosed at 2 g/kg and in all animals dosed at 1.2 g/kg. Necrosis was observed on the test site of all animals. Eschar was observed on the test site of 6 rabbits dosed at 1.5 mg/kg, 3 rabbits dosed at 1.2, and all rabbits dosed at 0.6 g/kg. Under the conditions of this study, the dermal LD₅₀ in male and female rabbits is 1.24 g/kg with 95% confidence limits of 0.80 to 1.94 g/kg.

Acute Oral Toxicity:

The test mixture was administered in aqueous formulation by oral gavage to three groups of five fasted male and five fasted female Sprague-Dawley rats at doses of 300, 1000, or 1800 mg/kg of body weight. Rats were observed for 14 days after test substance administration.

Mortality incidences in the 300, 1000, and 1800 mg/kg dose groups were 0/10, 5/10, and 10/10, respectively. All deaths occurred on the day of dosing. All rats exhibited cyanosis¹ up to 3 days after dosing. Five male and four female rats dosed at 1000 mg/kg and 4 male and 4 female rats dosed at 1800 mg/kg were prostrate/hypoactive on the day of dosing. Coma was observed in one female rat dosed at 1000 mg/kg and in two male and one female rat dosed at 1800 mg/kg. Ataxia was observed in one male dosed at 1800 mg/kg, and convulsion was observed in one male and one female dosed at 1800 mg/kg. Under the conditions of this study, the oral LD₅₀ of Experimental EKC 311 in male and female rats is 815 mg/kg with confidence limits of 326 to 2034 mg/kg.

Sincerely,

¹ R.E. Gosselin et al., *Clinical Toxicology of Commercial Products*, Williams & Wilkins, 5th Edition, 1984

Company Sanitized