

Review Summary of the National Institute of Environmental Health Sciences (NIEHS/NTP) RoC Review Committee (RG1)

Nomination: Nitromethane

Review committee: RG1

Date: 2/6/2002

Major Issues Discussed

◆ Application of Criteria:

Exposure: Evidence of exposure is primarily occupational during the production of nitromethane and nitromethane derivatives. To a lesser extent exposure occurs when nitromethane is used as a fuel or fuel additive.

Sufficient evidence in experimental animals: Multiple species – mice (male and female) and rats (female)

▪ Inhalation studies

Male Mice: Significant increase in incidence of benign and benign and malignant combined harderian gland tumors. Increased incidences of malignant and benign and malignant combined lung tumors (alveolar bronchiolar) were considered exposure related. – *clear evidence of carcinogenicity.*

Female Mice: Significant increase in incidence of benign and benign and malignant combined harderian gland tumors. Significant increase in benign and benign and malignant combined liver tumors (hepatocellular). Increased incidences of benign, malignant, and combined lung tumors (alveolar bronchiolar) were considered exposure related. – *clear evidence of carcinogenicity.*

Female Rat: Significant increase in incidence of benign and malignant mammary tumors. – *clear evidence of carcinogenicity.*

◆ Other Scientific Concerns

- Genotoxicity and Mechanistic concerns
 - Negative evidence of genotoxicity with nitromethane.
 - Although the mechanism of carcinogenicity in rodents is not known there is no evidence to suggest mechanisms unique to rodent.
- Human Studies
 - No human studies available.

Recommendation:

◆ Motion

Recommend Nitromethane to be listed as *reasonably anticipated to be a human carcinogen* based on sufficient evidence in animals.

Votes: 8/yes 0/no