

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

Nomination: Diethanolamine

Review Committee: RG1

Date: 12/10/01

Major Issues Discussed

Basis of Nomination:

- Exposure: consumer exposure associated with the use of diethanolamide surfactants in consumer products; occupational exposure associated use in gas purification, textile processing, and metal working fluids.
- An NTP 2-year dermal study was judged to show clear evidence of carcinogenicity in male and female mice based on increased incidences of liver neoplasms in male and female mice and increased incidences of renal tubule neoplasms in male mice.

Scientific Concerns:

- Human epidemiological studies indicate small excesses of cancer associated with exposure to metal working fluids.
- NTP dermal studies of DEA condensates conducted concurrently with the DEA study indicate a strong association between the concentration of free DEA in the condensates and the incidences of hepatocellular neoplasms in male and female mice.
- Neither DEA or DEA condensates were carcinogenic in rats.
- The increased incidence of renal tubule neoplasms in male mice was due to a significant increase of renal tubule adenomas; renal tubule carcinomas were not significantly increased.
- The majority of the RG1 members felt that the carcinogenicity data was a single tumor type (liver) in one species (mice) and thus did not meet the criteria for listing in the Report on Carcinogens. However, a couple of RG1 members felt the renal tumors represented a second tumor site.

Recommendation:

Recommended that Diethanolamine not be listed in the Report on Carcinogens.

Votes: 7/yes 2/no