

Pivalolactone

(3,3-dimethyl- β -propiolactone)

Pivalolactone is used in the production of copolymers for sutures and prosthetic devices, to prepare polyoxymethylenes, as a plasticizer for cyanoacrylate adhesive, and to block and graft copolymers with acrylics, isoprene, butadiene, and ethylenemethacrylic acid-vinyl acetate polymer. Occupational exposure may occur during its manufacture and use.

Pivalolactone passed the animal data screen, underwent a preliminary toxicological evaluation, and is being brought to the Carcinogen Identification Committee for consultation. This is a compilation of the relevant studies identified during the preliminary toxicological evaluation.

Epidemiological data

No cancer epidemiology studies were identified.

Animal carcinogenicity data

- Long-term gavage studies
 - 103-week exposure and additional two week observation in male and female Fischer 344 rats: NCI (1978)
 - *Increase in uncommon forestomach squamous cell carcinoma and papilloma (combined) (by pairwise comparison and trend) in males and females*
 - 102-week exposure and additional one week observation in male and female B6C3F₁ mice: NCI (1978)
 - *No treatment-related tumor findings in males or females*

Other relevant data

- Genotoxicity
 - Mutagenicity in *Salmonella typhimurium* (positive): Dunkel *et al.* (1985)
 - Mutagenicity in *Escherichia coli* (positive): Dunkel *et al.* (1985)
- Structure activity considerations
 - Structural similarity to β -propiolactone, a Proposition 65 direct acting carcinogen

References¹

Dunkel VC, Zeiger E, Brusick D, McCoy E, McGregor D, Mortelmans K, Rosenkranz HS, Simmon VF (1985). Reproducibility of microbial mutagenicity assays: II. Testing of carcinogens and non-carcinogens in *Salmonella typhimurium* and *Escherichia coli*. *Environ Mutagen* 7(Suppl. 5):1-248.

National Cancer Institute (NCI, 1978). *Bioassay of pivalolactone for possible carcinogenicity (CAS No. 1955-45-9)*. Technical Report Series No. 140, U.S. Department of Health, Education, and Welfare, Public Health Service, National Institute of Health. National Cancer Institute, DHEW Publication No. (NIH) 78-1395.

¹ Excerpts or the complete publication have been provided to members of the Carcinogen Identification Committee, in the order in which they are discussed in this document.