

BASIC ACRYLIC MONOMER MANUFACTURERS, INC.

NTP Delisted Ethyl Acrylate as a Carcinogen in 2000

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NTP listed ethyl acrylate as “reasonably anticipated to cause cancer in humans” in its Fifth Annual Report on Carcinogens (ROC) in 1989. The listing was based on forestomach tumors observed in oral gavage studies in rats and mice reported by NTP in 1986. Tumor increases had not been reported in cancer studies conducted by inhalation, dermal, or in drinking water. In 1997, Bamm petitioned NTP to reconsider its listing decision based on studies performed by NTP scientists and others that cast doubt on the relevance of the oral gavage studies to humans. In response, the NTP initiated a formal reevaluation that included three scientific committee reviews, the last from the NTP Board of Scientific Counselors, and a report that was reviewed by both the Director of NTP and the Secretary of Health and Human Services before being transmitted to Congress. Key to the NTP evaluation were mechanistic data demonstrating that ethyl acrylate causes tumors only in rodent forestomachs, and only after gavage dosing at extremely high levels for long periods has overwhelmed the forestomach tissue’s detoxification mechanisms. NTP also considered evidence supporting the conclusion that EA should be considered non-genotoxic. (NTP, 1998, p. 14)

Following its review, the NTP determined that the forestomach tumors reported in its 1986 gavage studies were not relevant to humans and delisted ethyl acrylate as a carcinogen in its Ninth Report on Carcinogens (ROC) in 2000. The NTP Executive Committee’s Interagency Working Group for the Ninth ROC included representatives of eleven federal agencies. In the Ninth ROC, NTP explained that the delisting was:

based on the fact that the forestomach tumors induced in animal studies were seen only when the chemical was administered by gavage at high concentrations of ethyl acrylate that induced marked local irritation and cellular proliferation, and because significant chronic human exposure to high concentrations of ethyl acrylate monomer is unlikely. (*See* Ninth ROC, App. B, p. B-2).

Thus, NTP formally reversed itself and found the forestomach tumors following gavage dosing not relevant to human carcinogenicity. The NTP delisting decision was based on data that was not available when NTP made its original listing (and also was not available when IARC made its listing decision in the late 1980’s).

References:

1. National Toxicology Program (1998). Report on Carcinogens: Background document for ethyl acrylate. Meeting of the NTP Board of Scientific Counselors Report on Carcinogens Subcommittee. Research Triangle Park, N.C.
2. National Toxicology Program (2000). Report on Carcinogens, 9th ed., Carcinogen Profiles. U.S. Department of Health and Human Services, Public Health Service, National Institute of Environmental Health Sciences. Research Triangle Park, N.C.
3. National Toxicology Program (2000). Appendix B: Agents, Substances, Mixtures, or Exposure Circumstances Delisted from Report on Carcinogens.

Disclaimer

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