UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL CENTER FOR ENVIRONMENTAL ASSESSMENT
OFFICE OF
RESEARCH AND DEVELOPMENT

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MEMORANDUM

SUBJECT: EPA's Integrated Risk Information System (IRIS) Assessment of Chloroprene

FROM: John Vandenberg, Director /s/
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TO: Wren Stenger, Division Director
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The purpose of this memo is to provide to you information regarding the EPA's 2010 Integrated Risk Information System's (IRIS) assessment of the air pollutant chloroprene. The information below summarizes key aspects of that assessment. As such, this memo is neither binding on any party nor establishes any obligations.

EPA completed the most recent IRIS assessment of chloroprene in 2010. In that assessment, the agency concluded that chloroprene is "likely to be carcinogenic to humans" through a mutagenic mode of action and that the primary exposure route of concern is the inhalation pathway. Accordingly, the assessment included an inhalation unit risk (IUR), which is an estimate of the increased cancer risk from inhalation exposure to a concentration of 1 µg/m^3 of chloroprene for a lifetime. The IUR is multiplied by a chloroprene exposure concentration (in µg/m^3) to estimate the cancer risk that would be expected in a population exposed to that concentration of chloroprene in the air every day over a lifetime. The composite IUR for chloroprene, which was based on numerous tumors observed in female mice (see some of the tumor types below), is 3 x 10^{-4} per ug/m^3. The adjustment made for a mutagenic mode of action results in a value of 5 x 10^{-4} per ug/m^3. Based on this value, the concentrations associated with the 100-in-1 million and the 1-in-1 million cancer risk-based comparison levels for chloroprene are 0.2 ug/m^3 and 0.002 ug/m^3, respectively.[1]

The conclusion in the 2010 IRIS assessment that chloroprene is "likely to be carcinogenic" to humans was based on a comprehensive review of the available evidence on chloroprene toxicity.

[1] Under EPA's air toxics risk management framework, a cancer risk of 100-in-1 million is generally described as the upper limit of acceptability for purposes of risk-based decisions. Cancer risks at or below 1-in-1 million indicate little potential for cancer risks in the air toxics program.

This included human epidemiological data, animal toxicology data, and evidence that chloroprene is mutagenic. More specifically, in studies of occupational workers, there is evidence that chloroprene causes an increased risk of liver cancer, while other studies in humans show the possibility of an increased lung cancer risk. In animal studies, chloroprene has been shown to cause many different types of tumors, including tumors in the lung, circulatory system, liver, skin, and mammary gland, among others. Additionally, chloroprene's chemical structure is very similar to the known human carcinogens butadiene and vinyl chloride. The IRIS assessment explains that all of this evidence taken together supports the assessment conclusion that chloroprene is "likely to be carcinogenic to humans." The findings of the IRIS assessment are also similar to those of other highly respected, internationally recognized cancer agencies:

- The National Toxicology Program's (NTP) Report on Carcinogens evaluated chloroprene in 2005 and classified it as "reasonably anticipated to be a human carcinogen." This was based on evidence of tumors at multiple tissue sites in multiple species of animals including malignant tumors. The Report on Carcinogens is a congressionally mandated, science-based, public health document. The report identifies agents, substances, mixtures, and exposure circumstances that are known or reasonably anticipated to cause cancer in humans.
- The International Agency for Research on Cancer (IARC) evaluated chloroprene in 1999 and classified it as "possibly carcinogenic to humans." IARC is the specialized cancer agency of the World Health Organization.

The chloroprene IRIS assessment, including the IUR, was also subject to a rigorous review process that included review within EPA, by other Federal agencies and White House offices (e.g., NIEHS, OMB, CEQ, DOD, ATSDR), and the public. The chloroprene IRIS assessment was also reviewed by an independent external peer review panel, which unanimously concluded that chloroprene is a likely human carcinogen that acts via a mutagenic mode of action.

The chloroprene IRIS assessment was developed using a robust, transparent, and public process and represents the Agency's top tier source of toxicity information on chloroprene. We are confident that the chloroprene IRIS assessment and the IUR within are scientifically sound. If you have any questions please do not hesitate to contact me.

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