Denka

February 14, 2020
Denka Company Limited

Review of Chloroprene Monomer Toxicity Assessment Performed by the U.S. Environmental Protection Agency

The U.S. Environmental Protection Agency (EPA) is reviewing the chloroprene monomer toxicity assessment (Integrated Risk Information System: IRIS) implemented in 2010. In the National Air Toxics Assessment, which was released by the EPA in December 2015 based on this toxicity assessment, it specifies the area surrounding the factory that produces chloroprene rubber in LaPlace, Louisiana, as having a high carcinogen risk in the United States. The factory was run by DuPont from 1969 until its acquisition by Denka Performance Elastomer LLC (DPE), a subsidiary of Denka, in November 2015.

According to the letter regarding this toxicity assessment that was sent by the EPA to the Louisiana Department of Environmental Quality (LDEQ) on September 23, 2019, it is expected that the EPA will accept and review the assessment method submitted by DPE, which is based on cutting-edge physiologically based pharmacokinetic (PBPK) modeling. According to this PBPK model, the original toxics assessment value of chloroprene monomer is remarkably low. The Inhalation Unit Risk (IUR) value in the toxicity assessment may be used to calculate "tolerable" average exposure concentrations over a 70-year exposure period. It is estimated that the concentration based on this PBPK value is about 130 times larger compared to 0.2 μg/m3 or less, which was calculated based on the 2010 IUR and suggested as the recommended value by the EPA in May 2016. Further, as discussed below, EPA's September 2019 letter to LDEQ shows that the 0.2 μg/m3 does not reflect EPA policy.

A paper regarding the assessment results using the PBPK model was published in "Inhalation Toxicology," a U.K. science journal, in January 2020. The results of this study are also consistent with the results of epidemiological research by experts and the neighboring health data assembled by the state government, which suggest that chloroprene monomer has no influence on the health risks of workers at the factory that has been operating for many years and neighborhood residents.

In addition, according to the letter sent by the EPA to the LDEQ in September 2019, EPA confirmed that the guidance that annual average exposure to chloroprene monomer over a 70-year lifespan should not exceed 0.2 $\mu g/m^3$ would not be set as the regulatory value of chloroprene in the air. It was clearly stated that IRIS was not an assessment performed based on actual exposure and

was not to be directly used as an environmental concentration standard for regulatory purposes.

The PBPK model is considered to be more accurate in terms of prediction of the influence of chemicals on the human body when compared with the IRIS assessment implemented in 2010, which equates the influence on a highly sensitive species of mice with the potential influence on humans. The PBPK model is also in accordance with the recommended methods regarding risk calculation models of the National Academy of Sciences and the World Health Organization (WHO).

As soon as the assessment using the PBPK model that is currently being validated by the EPA is finished, a peer review process by external experts will begin. Therefore, we anticipate that more time is required to finish the toxicity assessment by the EPA.

DPE has also voluntarily invested more than US$35 million in technologies to decrease emissions in the air and reduced chloroprene monomer emitted from the factory into the air by approximately 85% in 2018, compared with 2014. DPE will continue to pursue the best scientific solutions for chemicals in cooperation with state and federal regulatory authorities and will strive to reduce the environmental burden.

For background information, refer to “Statement regarding NATA’s Toxicity Assessments on the Areas Surrounding Denka’s U.S. Subsidiary and Initiatives Being Undertaken to Reduce Environmental Burden” posted on our website on June 19, 2019.
(https://www.denka.co.jp/storage/news/pdf/621/20190619_statement_jp.pdf)

About Denka: Denka is a chemical manufacturer headquartered in Chuo-ku, Tokyo. The company specializes in developing business activities on a global scale across a wide range of fields, from inorganic and organic chemicals, to electronic materials and pharmaceuticals. Founded in 1915, Denka has steadily continued to develop and manufacture products that contribute to the development of society by fully utilizing its unique concepts and technological capabilities. Upholding its corporate slogan, “Possibility of Chemistry,” the company and its president, Manabu Yamamoto, are committed to contributing to the sound development of society while sincerely tackling the challenges that society is now confronting.