

U.S. EPA's Review of the Toxicity Assessment of Chloroprene Monomers (6th Report)

Denka Performance Elastomer LLC (DPE), a U.S. subsidiary of Denka Company Limited (Denka), submitted a Request for Reconsideration (RfR) to the U.S. Environmental Protection Agency (EPA) on June 10, 2022 in response to the EPA denying the Request for Correction (RfC) of a toxicity assessment of chloroprene monomers regarding carcinogenic risks that DPE had submitted to the EPA. However, the EPA published a letter denying our Request for Reconsideration on October 19 on its official website. *¹

According to the letter published by the EPA, the reason for the denial was that they are not obligated to bring newer science into the assessment because the toxicity assessment of chloroprene monomers conducted based on Integrated Risk Information System (IRIS) in 2010 was systematized through peer review by a strict third party at that time using the best science of the time which complied with the EPA Information Quality Guidelines.

As a result of DPE's consultation with the EPA regarding the application of a physiologically based pharmacokinetics (PBPK) model, with the goal of reviewing the results of the toxicity assessment in 2010 by introducing the latest science technologies, the EPA accepted this concept and we jointly developed a new PBPK model.

The result of the toxicity assessment using the new PBPK model was posted in the science magazine *Inhalation Toxicology*, and according to the toxicity assessment model, the EPA recommendation value which is a 70-year average exposure concentration of 0.2 µg/m³ or below on the basis of its 2010 IRIS toxicity evaluation could overstate higher than it should be.

Denka regrets EPA's denial of the review of the toxicity assessment regarding the carcinogenic risks of chloroprene monomers based on the new PBPK model and new statistic data. Also, Denka is concerned about that the latest objective scientific research and statistical data, such as the results of the epidemiological research that followed approximately 7,000 employees who worked in the facilities handling chloroprene monomers for nearly 70 years in the U.S., which was updated by researchers at University of Pittsburgh, and the statistical data regarding the cancer rate in Louisiana summarized by the Louisiana Tumor Registry will not be used for toxicity assessments. DPE is currently considering specific actions to address this denial and continue to appeal the correctness of this decision.

This matter has no impact on DPE's business or its production activities.

DPE has been continually operating its business in compliance with emission standards. In addition, DPE regularly measures concentrations in the air around the factories and provides environmental information to local communities and other stakeholders via administrative authorities. Further, DPE has voluntarily invested a total of more than 35 million dollars in the environment and introduced emissions reduction equipment, which has reduced the amount of chloroprene the facility emits by 85 percent compared with 2014. The Louisiana Department of Environmental Quality (LDEQ) and the EPA have approved these initiatives.

Under the Denka Group ESG Basic Policies, the Denka Group conducts its activities while respecting the human rights of all people, striving to protect the environment, and observing laws and regulations and culture in each region.

Denka will continue to provide support for DPE's activities by approaching the EPA for toxicity evaluation of chemicals based on the latest available science.

(*1) EPA Official Homepage “EPA response to Request for Reconsideration 21005A” (October 19, 2022)

https://www.epa.gov/system/files/documents/2022-10/RFR%2021005A_Final_Response_10192022_VWN.pdf

Regarding DPE's environmental initiatives, please refer to the following information posted on Denka's official website. <https://www.denka.co.jp/eng/>

“U.S. EPA's Review of the Toxicity Assessment of Chloroprene Monomers (5th Report)” June 18, 2022

https://www.denka.co.jp/eng/storage/news/pdf/407/20220617_denka_dpe_en.pdf

“U.S. EPA's Review of the Toxicity Assessment of Chloroprene Monomers (4th Report)” April 28, 2022

https://www.denka.co.jp/eng/storage/news/pdf/406/20220428_denka_dpe_en.pdf

“U.S. EPA's Review of the Toxicity Assessment of Chloroprene Monomers (Updated)” March 2, 2021

https://www.denka.co.jp/eng/storage/news/pdf/332/20210302_denka_dpe_en.pdf

” Latest epidemiological study of chloroprene monomer workers in the US” December 17, 2020

https://www.denka.co.jp/eng/storage/news/pdf/317/20201217_denka_dpe_en.pdf

“Transition to Review Process in Toxicity Assessments Reconsideration of Chloroprene Monomer by the United States Environmental Protection Agency” August 7, 2020

https://www.denka.co.jp/eng/storage/news/pdf/311/20200807_denka_dpe_en.pdf

“LDEQ confirms 85% emissions reduction achieved, DPE's completion of voluntary program” June 8, 2020

https://www.denka.co.jp/eng/storage/news/pdf/314/20200608_denka_dpe_en.pdf

“Notice Regarding Litigation Against US Subsidiary” February 14, 2020

https://www.denka.co.jp/eng/storage/news/pdf/265/20200214_denka_dpe_litigation_en.pdf

“U.S. EPA's Review of the Toxicity Assessment of Chloroprene Monomers” February 14, 2020

https://www.denka.co.jp/eng/storage/news/pdf/266/20200214_denka_statement_en.pdf

“Notice Regarding Initiatives to Reduce Environmental Burden Being Undertaken by Denka's Subsidiary in the United States” June 19, 2019

https://www.denka.co.jp/eng/storage/news/pdf/238/20190619_statement_en.pdf

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