

U.S. EPA's Review of the Toxicity Assessment of Chloroprene Monomers (4th Report)

Denka Performance Elastomer LLC (DPE), a U.S. subsidiary of Denka Company Limited (Denka), submitted a Request for Correction (RfC) of a toxicity assessment of chloroprene monomers regarding carcinogenic risks to the U.S. Environmental Protection Agency (EPA) on July 15, 2021.

In response, the EPA announced its dismissal of the RfC on March 14, 2022. It argued that the toxicity assessment value would not be immediately revised even following the update of scientific information on the grounds that the conclusion stated in the carcinogenic risk assessment under the Integrated Risk Information System (IRIS) and its supplementary materials created by the EPA in 2010 was consistent with the EPA's Information Quality Guidelines created in 2002.

the RfC rejected by the EPA presented a toxicity assessment model known as the physiologically based pharmacokinetic (PBPK) model. It conforms to the recommendations by the EPA and the U.S. National Academy of Sciences regarding human health risk assessments. The PBPK model was designed to estimate human health risks by a method that is scientifically more accurate than the method employed by the EPA in its toxicity assessment of carcinogenic risks in 2010. A study on the assessment results was published in the leading peer-reviewed major scientific journal, *Inhalation Toxicology*. While the EPA recommends a 70-year average exposure concentration of 0.2 $\mu\text{g}/\text{m}^3$ on the basis of its 2010 IRIS toxicity evaluation, according to the toxicity assessment model in the RfC, the EPA's recommendation value could overstate by as much as 130 times.

The EPA's IRIS toxicity evaluation was based solely on the impact on a single lineage of female mice. Meanwhile, the new model produced results that were consistent with a decades-long study updated by researchers from the University of Pittsburgh on chloroprene manufacturing plant workers, statistical data on the incidence of cancer by the Louisiana Tumor Registry, and other existing epidemiological studies on chloroprene monomers. All of them suggest that chloroprene monomers emitted from DPE's plant in the Saint John the Baptist Parish did not increase the carcinogenic risks among workers of the plant or neighboring inhabitants.

To swiftly determine response measures, DPE is considering submitting a Request for Reconsideration (RfR) following the close examination of the recent EPA's decision. This matter has no impact on DPE's business or its production activities.

Denka sees the EPA's decision as regrettable, and will continue to support for DPE's activities of approaching the EPA for toxicity evaluation of chemicals based on the best available science.

The results of the assessment using the PBPK model published in January 2020 in the scientific journal *Inhalation Toxicology*, are available at:

<https://www.tandfonline.com/doi/full/10.1080/08958378.2020.1715513>

The RfC submitted by the DPE, which discussed the PBPK model and the epidemiological study on chloroprene monomers, is available on the EPA website at:

<https://www.epa.gov/quality/rfc-21005-chloroprene>

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 (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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