

U.S. EPA's Review of the Toxicity Assessment of Chloroprene Monomers (7th Report) – Lawsuit Filed Against EPA for Correction of Toxicity Assessment Based on Latest Science –

Denka Performance Elastomer LLC (DPE), a U.S. subsidiary of Denka Company Limited (Denka), filed a lawsuit for the fair correction of a chloroprene monomer toxicity assessment in United States federal district court in Louisiana in response to the U.S. Environmental Protection Agency (EPA) denying Denka's Request for Correction (RFC) of the toxicity assessment regarding carcinogenic risks on the basis of the latest scientific perspective.

1. Court in which the lawsuit was filed and the date of the filing

- (1) Court: United States federal district court in Louisiana
- (2) Date: January 11, 2023 (local time)

2. Outline of the lawsuit

- (1) Plaintiff: Denka Performance Elastomer LLC
- (2) Defendant: United States Environmental Protection Agency (EPA)
- (3) Purpose: Correction of the chloroprene monomer toxicity assessment regarding carcinogenic risks on the basis of the latest science, the request for which was rejected by the EPA

3. Reasons for the lawsuit

DPE has consistently operated a business manufacturing chloroprene rubber in compliance with the emission standards since it took over the business from DuPont on November 1, 2015. In addition, it regularly measures concentrations in the air around the factories and provides information on environmental actions to local residents and other stakeholders via administrative authorities. Further, it 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. DPE continues working to reduce environmental impact.

On the other hand, since the assessment, in 2010, of the toxicity of chloroprene monomers, which was made based on Integrated Risk Information System (IRIS) was extremely high, DPE has been pursuing for a review

which incorporates the latest scientific technologies, and has consulted EPA for the application of a model of physiologically based pharmacokinetics (PBPK). As a result, EPA has also accepted it, and DPE has been developing a new PBRK model jointly with EPA, for as long as approximately seven years.

However, the EPA rejected this Request for Correction . Its letter published on October 18, 2022¹ states that the reason for the denial was that they were 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. Notwithstanding the above, 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. In addition, toxicity assessments failed to use 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.

In light of the facts mentioned above and the EPA's rejection of the RFC, DPE decided to file a lawsuit for the fair correction of the toxicity assessment on the basis of the latest science.

It is to be noted that this legal action is not directly related to the lawsuit against DPE announced on February 14, 2020, in which the plaintiff claimed that it suffered physical, property and mental damage from the chloroprene monomers emitted by DPE's chloroprene rubber manufacturing plant. In addition, this lawsuit has no impact on DPE's business or production activities.

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 support DPE's activities based on the latest available science for reducing environmental impacts.

Outline of DPE, a subsidiary of Denka

- (1) Company name: Denka Performance Elastomer LLC *Note: Denka has a 70% stake in the company.
- (2) Location: State of Louisiana, USA
- (3) Representative: Mikio Shimizu, President & CEO
- (4) Content of business: Manufacture and sale of synthetic rubber (Neoprene)
- (5) Capital: 62 million USD

(*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 (6th Report)” October 28, 2022

https://www.denka.co.jp/eng/storage/news/pdf/429/20221028_denka_dpe_en.pdf

“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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