JONES WALKER

Robert E. Holden
D: 504.582.8139
F: 504.589.8139
bholden@joneswalker.com

March 1, 2021

Ms. Katherine Chalfant
Enterprise Quality Management Division
Office of Enterprise Information Programs
United States Environmental Protection Agency
1301 Constitution Ave NW
Washington, D.C. 20460

Re: Request for Reconsideration (RFR #17002A)
Chloroprene Toxicological Review

Dear Ms. Chalfant:

We are in receipt of the letter from Mr. Vaughn Noga, Chief Information Officer and Deputy Assistant Administrator for Environmental Information, United States Environmental Protection Agency (EPA), to Mr. Patrick A. Walsh, CIH, Safety, Health, and Environmental Manager, Denka Performance Elastomer LLC (DPE), dated February 5, 2021, regarding DPE's Request for Reconsideration (RFR #17002A, Chloroprene Toxicological Review), filed on July 23, 2018. As suggested in Mr. Noga's letter, the purpose of this letter is to withdraw DPE's pending RFR in order to allow DPE to submit new information to support a new Request for Correction for consideration by the Office of Research and Development (ORD).

DPE originally filed its Request for Correction (RFC #17002) of the Toxicological Review of Chloroprene on June 26, 2017. On January 25, 2018, EPA denied the RFC, and on July 23, 2018, DPE filed its timely Request for Reconsideration seeking review of the denial. As stated in Mr. Noga's letter, on July 19, 2019, EPA paused the review of the RFR to allow time for the development and peer review of a new physiologically based pharmacokinetic (PBPK) model for chloroprene. During this pause, DPE's scientific consultant, Ramboll US Consulting, Inc. ("Ramboll"), has developed the PBPK model with EPA's input. The model is necessary to help EPA's Office of Research and Development's Integrated Risk Information System (IRIS) to better understand how response data from laboratory mice should be used under a best available science approach to evaluate the potential human toxicological response to chloroprene. As you know, on October 5 and 6, 2020, an EPA sponsored peer review panel met to review Ramboll's PBPK model and report, entitled "Incorporation of In Vitro Metabolism Data in a Physiologically Based

Pharmacokinetic (PBPK) Model for Chloroprene." Ramboll is currently updating the 2020 model and report to address the comments of the peer review panel.

DPE believes that the revised PBPK model and PBPK report provide a better basis for updating the 2010 Toxicological Review of Chloroprene than was provided in DPE's 2017 RFC and better aligns with EPA processes than the current RFR. Similarly, new epidemiological studies have become available since the filing of the 2017 RFC, including a major update by researchers at the University of Pittsburgh, as well as objective health data collected by the state-run Louisiana Tumor Registry (LTR). Recent LTR reports continue to show that St. John the Baptist Parish regularly exhibits average or below-average rates of the cancer incidence compared with the state average. These epidemiological studies strongly support the PBPK model results.

Mr. Noga's letter stated that DPE could withdraw its RFR by notifying EPA by March 1 of the withdrawal. Accordingly, DPE hereby withdraws RFR #17002A. We hope to meet with ORD soon to discuss the next steps in the review of the 2010 Toxicological Review of Chloroprene. We anticipate filing a new RFC as soon as the revised PBPK model and report can be finalized; subject to our discussions with ORD, we hope this will occur within approximately 60 days. DPE will be in communication with your office shortly about this. We appreciate and thank EPA for its cooperation.

Sincerely yours,

Robert E. Holden
Counsel for Denka Performance Elastomer LLC

REH/kb
cc: Jennifer Orme-Zavaleta – Office of Research and Development (ORD)
Vaughn Noga – Office of Environmental Information
Kris Thayer – ORD
John Vandenberg – ORD
Louis D'Amico - ORD
David Gray – EPA Region 6
Erika Sasser – Office of Air and Radiation
Providence Spina – Office of Enforcement and Compliance Assurance
Tracy Sheppard – Office of General Counsel
Dr. Chuck Carr Brown – Louisiana Department of Environmental Quality
Kelly Rimer – Office of Air and Radiation
Jaclyn Hotard Gaudet, St John the Baptist Parish President

ED_006848_00000040-00002