UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
National Center for Environmental Assessment
Washington, DC 20460

OFFICE OF
RESEARCH AND DEVELOPMENT

May 30, 2018

Robert Holden
Jones Walker LLP
201 St. Charles Ave, Ste 5100
New Orleans, LA 70170

Re: Response to DPE 05/17/2018 letter referencing Chloroprene Request for Correction #17002; Status Report on PBPK Model Development for Chloroprene

Dear Mr. Holden:

You sent a letter to EPA on April 6, 2018, on behalf of Denka Performance Elastomers (DPE), that included a document titled "Workplan to provide a physiologically-based pharmacokinetic (PBPK) model to support the inhalation unit risk for chloroprene" (workplan dated March 23, 2018). The April 6 letter indicated DPE would be in contact regarding the workplan and on May 17, 2018 your letter on behalf of DPE was received by the U.S. Environmental Protection Agency (EPA) regarding "Chloroprene Request for Correction #17002 Status Report on PBPK model development for chloroprene, our file 165671-00". In the May 17 letter, you indicated the PBPK model development was proceeding and being performed by Dr. Harvey Clewell and others at Ramboll. You indicated you would like to schedule a meeting or telephone conference to discuss the EPA review of the updated PBPK model and a path forward, and that you would be in touch about this request.

I am writing to let you know that our chloroprene assessment team is willing to meet and discuss the development, evaluation, peer review, and potential application of the PBPK model developed under the DPE workplan. We encourage scheduling this meeting soon to ensure any work done as part of the DPE workplan is approached efficiently. To support this discussion, we have provided a "An Umbrella Quality Assurance Project Plan (QAPP) for PBPK Models." This attachment provides information helpful to understand how EPA approaches the evaluation of PBPK models.

To arrange a meeting to discuss the model, please contact Dr. John Vandenberg, NCEA RTP Division Director at vandenberg.john@epa.gov. He and Dr. Kris Thayer, NCEA IRIS Division

Director, will coordinate this meeting and facilitate the discussion.

Again, thank you for your letter. Should you have any questions, you may also contact me by phone (202-564-7903) or email (bahadori.tina@epa.gov).

Sincerely,

Tina Bahadori, Sc.D.
Director, National Center for Environmental Assessment
National Program Director, Human Health Risk Assessment
U.S. EPA, Office of Research and Development

Cc: Jennifer Orme-Zavaleta, EPA/ORD/IOAA
Richard Yamada, EPA/ORD/IOAA
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David Gray, EPA Region VI
Anne Idsal, EPA Region VI
Kristina Thayer, EPA/ORD/NCEA
John Vandenberg, EPA/ORD/NCEA
Jorge Lavastida, DPE
Elise Henry, Jones Walker

Attachment 1: An Umbrella Quality Assurance Process Plan (QAPP) for PBPK Models