UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 25, 2018

Robert Holden
Liskow & Lewis
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701 Poydras Street, Suite 5000
New Orleans, LA 70139

OFFICE OF
RESEARCH AND DEVELOPMENT

Dear Mr. Holden:

This letter is in response to the Request for Correction (RFC) received by the U.S. Environmental Protection Agency (EPA) on June 26, 2017, which was assigned RFC #17002 for tracking purposes. The letter was provided on behalf of Denka Performance Elastomer LLC (DPE). In the RFC letter, DPE states that the *Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information on the Integrated Risk Information System (IRIS)*, disseminated by EPA's Office of Research and Development (ORD) in 2010 (referred to herein as the "IRIS chloroprene assessment"), does not reflect the "best available science" or "sound and objective scientific practices" and requests correction.

Summary of the Request

The DPE RFC requests the IRIS chloroprene assessment be corrected in three ways: 1) the EPA-derived inhalation unit risk (IUR) of 5×10^{-4} per ug/m^3 be replaced with a value derived by Ramboll Environ of 3.2×10^{-6} per ug/m^3, or withdrawn; 2) the EPA cancer classification of chloroprene as a "likely" human carcinogen be classified instead as a "suggestive" human carcinogen; and 3) the EPA derived Reference Concentration (RfC) be withdrawn pending further IRIS review. The RFC letter indicates, as an alternative, that the EPA immediately withdraw the IRIS IUR and RfC values pending further review.

To support the RFC, DPE provided a document "...organized into six sections: Section I demonstrates that the 2010 IRIS Review constitutes "information" "disseminated" to the public; Section II shows that the 2010 IRIS Review is subject to heightened information quality standards because it is influential scientific information; Section III explains how the 2010 IRIS Review fails to comply with the EPA Guidelines; Section IV shows how EPA's correction of the 2010 IRIS Review would benefit DPE, which has been harmed by its errors; Section V provides DPE's contact information; and Section VI sets forth the relief that DPE is seeking."

The EPA Response to DPE Request for Correction

In the Attachments to this response, EPA addresses the assertions and topics raised in Section III of the RFC as this section is relevant to the science evaluation represented in the IRIS chloroprene assessment under EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency (IQG).* The information and assertions in the other sections are either not in dispute or are not pertinent to the evaluation of science issues under the RFC.

Conclusion

The EPA, after careful review of the RFC submitted by DPE, has concluded that the underlying information and conclusions presented in the *Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information on the Integrated Risk Information System (IRIS)* are consistent with the EPA's Information Quality Guidelines.

Your Right to Appeal

If you are dissatisfied with the response, you may submit a Request for Reconsideration (RFR) as described in EPA's Information Quality Guidelines. The EPA requests that any such RFR be submitted within 90 days of the date of the EPA's response. If you choose to submit a RFR, please send a written request to the EPA Information Quality Guidelines Processing Staff via mail (Information Quality Guidelines Processing Staff, Mail Code 2821T, USEPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460); or electronic mail (quality@epa.gov). If you submit a RFR, please reference the case number assigned to this original Request for Correction (RFC #17002). Additional information about how to submit an RFR is listed on the EPA Information Quality Guidelines website at http://epa.gov/quality/informationguidelines/index.html.

Sincerely,

Jennifer Orme-Zavaleta, Ph.D.
Principal Deputy Assistant Administrator for Science

Cc: Tina Bahadori, ScD ORD/NCEA Director
Stephen Fine, PhD, Acting Chief Information Officer
David Gray, EPA Region 6 Director of External Affairs
Vincia Holloman, Director of Enterprise Quality Management Division
Anne Idsal, JD, Region 6 Administrator
Kristina Thayer, ORD/NCEA IRIS Division Director
John Vandenberg, ORD/NCEA RTP Division Director

Attachment 1: U.S. EPA Response to the Denka Performance Elastomers (DPE) Request for Correction of the Toxicological Review of Chloroprene (CAS No. 126-99-8) In Support of Summary Information on the Integrated Risk Information System (IRIS)

Attachment 2: Systematic Review of Chloroprene [CASRN 126-99-80] Studies Published Since 2010 IRIS Assessment to Support Consideration of the Denka Request for Correction (RFC). January 2018. USEPA, ORD, NCEA-IRIS, Washington DC.