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March 29, 2021

VIA U.S. MAIL & EMAIL
Ms. Katherine Chalfant
Enterprise Quality Management Division
Office of Enterprise Information Programs
United States Environmental Protection Agency
1301 Constitution Ave. NW
Washington, DC 20460
quality@epa.gov
Chalfant.Katherine@epa.gov

Re: Response to March 1, 2021 Letter from Robert Holden to the EPA regarding Denka Performance Elastomer LLC's Withdrawal of its Request for Reconsideration

Dear Ms. Chalfant:

We are in receipt of a letter by Robert E. Holden, Counsel for Denka Performance Elastomer, LLC ("Denka") to you, Ms. Katherine Chalfant, Enterprise Quality Management Division, Office of Enterprise Information Programs, United States Environmental Protection Agency ("EPA"), dated March 1, 2021. In the second to last paragraph of this correspondence appears the following:

> *"... 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 cancer incidence compared with the state average. These epidemiological studies strongly support the PBPK model results."*

Mr. Holden's letter is a gross misrepresentation of the description, significance, and interpretation of any conclusions resulting from a reading or evaluation of the "recent LTR reports". The letter is an attempt to put a positive spin on the withdrawal of the failed 2017 Request For Correction ("RFC") by deeming it unnecessary based on the misuse of the Louisiana Tumor Registry ("LTR") Report in a way specifically prohibited by the report itself.

First, the LTR reports are not, as we are sure you know, epidemiological studies. The LTR is a registry. More importantly the LTR itself has made the following statements:

"The CRISP review and confirmation of cancers in St. John Parish can neither

confirm or refute any links between exposure, to chemicals and cancer or other diseases occurrences."

"3. It is usually very difficult to link cancer incidence directly to a specific exposure. As noted by Goodman, et al, attempts to make these links are confounded by issues such as long latency for cancer development (length of time between the exposure and the diagnosis of cancer), low statistical power of most analyses due to small numbers of cases, uncertain definitions of cluster boundaries and the population of interest, and in- and out- migration in the community. It would be necessary to conduct long-term epidemiological studies to look at individual level-based exposure in persons with and without cancer to see if there is an association between the exposure and disease. ***This is beyond the scope of the LTR data and such claims of association or lack thereof should not be made based solely upon LTR data and such claims of association or lack thereof should not be made based solely upon LTR data."***

"5. This report in ***no way implies that there are no health effects*** *from long-term exposure to chloroprene. While it is difficult without any specific study to determine if there is a connection between chloroprene exposure in St. John and cancer, it is also not possible without these studies to determine that there is no connection. In 2010, the Environmental Protection Agency classified chloroprene as a likely carcinogen after identification as such by the International Agency for Research on Cancer. In addition, this project does not address other health effects that could be related to chloroprene exposure."*

*"**Conclusion***
The LTR is an exceptional resource for learning about types of cancer, their frequency, the rates at which they occur, the distribution of cases, information on cancer stage and pathology, cancer treatment, and cancer survival. It is nationally and internationally recognized for its completeness, accuracy, and timeliness. However, the LTR does not contain information on the causes of cancer. The registry does not collect data on environmental conditions to which persons with cancer may have been exposed. Therefore, ***the CRISP review and confirmation of cancers in St. John parish can neither confirm nor refute any links between exposures to chemicals and cancer occurrence."***

By the clear language in the CRISP review of the LTR, the LTR is not a sufficient basis for yet another reconsideration of the chloroprene inhalation unit risk estimate for which the EPA has already given more than ample consideration.

Historically, the 2016 National Air Toxic Assessment, in a study designed to geographically identify definable areas in our nation with excessive levels of toxic air, determined that the area around the DuPont / Denka Plant had a high incidence of cancer. That assessment was the basis for the EPA ordering the periodic collection of air sampling data focused on chloroprene emissions. The air sampling data, collected over several years, confirmed that concentrations of chloroprene exceeded, by levels of magnitude, the

recommended chronic exposure concentrations of chloroprene of 0.2 $\mu g/m^3$, which recommendation was based on the EPA's 2010 IRIS Assessment. The EPA's efforts to protect the environment and those who live in it occurred before any litigation involvement.

More recently, in 2019, an independent peer-reviewed study initiated by Stanford and finally completed by the University Network for Human Rights ("UNHR") concluded that there was a higher incidence of disease in the community in the proximity of the DuPont / Denka Plant, and that the source of the contaminant chloroprene was likely the DuPont / Denka Plant.

Since the EPA's protective efforts shed light on chloroprene emissions from the DuPont / Denka Plant, DuPont has maneuvered to separate itself legally from the consequences of chloroprene emissions. DuPont, along with Denka, have attempted to influence the EPA and its IRIS program to increase the allowable chronic exposure concentration levels of chloroprene to more than 0.2 $\mu g/m^3$. To date, those efforts have been unsuccessful. Mr. Holden's letter, his efforts in concert with Ramboll (Denka's environmental contractor), and Ramboll's "scientists" are all funded by Denka. Mr. Holden and the litigation group are also exerting pressure and influence on LSU and the Louisiana Tumor Registry in an effort to continue excessive chloroprene contamination from the DuPont / Denka Plant and avoid the consequences of their past and continuing conduct – exposing the surrounding community to this toxin.

In closing, had the LTR shown that St. John the Baptist Parish experienced a greater tumor incidence than the remaining parishes of Louisiana, Denka would strenuously object to any attempt to raise the Inhalation Unit Risk ("IUR") based on such misinterpretation. Epidemiologists understand that this would be a gross misuse of raw data. Likewise, Denka continues to rely on the same sets of prior data (such as Himmelstein 2004) that are being recycled in "new" RFRs. Providing new opinions based on exactly the same data sets does not meet the standard of new scientific data required by law to undertake a revision of accepted IURs. Neither does a "new" parsing, selective quotation or rearrangement of prior data provide sufficient evidence to reject a successfully peer-reviewed IUR.

Sincerely,

Hugh P. Lambert, Esq.

HPL/bjm

cc: Jennifer Orme-Zavaleta – Office of Research and Development (ORD)

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