

December 13, 2001

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Christine Todd Whitman, Administrator
U.S. Environmental Protection Agency
P. O. Box 1473
Merrifield, VA 22116

RE: Olefins Panel Robust Summaries on Testing Conducted Under the HPV
Challenge Program: Crude Butadiene C4 Category
HPV Registration No.

Dear Ms. Whitman:

The American Chemistry Council Olefins Panel (Panel) submitted a Test Plan to EPA on May 4, 2000, under the High Production Volume (HPV) chemical Challenge Program pertaining to the Crude Butadiene C4 Category. With this letter, the Panel submits robust summaries of certain studies conducted under the test plan. The Panel also provides an update of other proposed work underway for the category. The Panel has determined that one study originally included in the proposed test plan is no longer necessary.

Enclosed are robust summaries for two studies conducted by the Panel under the HPV Challenge Program for the streams in the Crude Butadiene C4 Category. The tested stream contained approximately 10% butadiene. The two studies covered by these robust summaries are the mouse micronucleus study (OECD 474) and the combined repeat dose/reproduction/developmental screening study (OECD 422). There is a single robust summary for the micronucleus study. The OECD 422 study covers three endpoints, and thus three robust summaries are submitted for this study. These robust summaries are identified as Repeated Dose Toxicity, Toxicity to Reproduction and Developmental Toxicity/Teratogenicity.

The Crude Butadiene C4 streams are mixtures of butadiene and other chemicals, primarily those containing 4 carbons, with butadiene concentrations typically between 10% and 92% butadiene. The rationale for the test category was based on the expectation that butadiene is likely the most biologically active of all the substances present in the process streams included in this category. In addition, it was anticipated that genotoxicity would be the health effect endpoint most likely to show a response at the lowest butadiene concentration for this category, based on the demonstrated genotoxicity of butadiene in laboratory animals. As noted, the tested stream for the studies described in the robust summaries represented the stream in the category containing the lowest level of butadiene, 10%. The Test Plan envisioned conducting both an OECD 471 *in*

vitro bacterial mutagenicity test (Ames test) and an OECD 474 *in vivo* mouse bone marrow micronucleus test, the results of which are reported in the robust summary attached.

The logistics of conducting the work under the test plan were such that the planned *in vivo* OECD 474 Mouse Bone Marrow Micronucleus test was completed before the planned Ames test was initiated. The OECD 474 protocol results demonstrated genotoxicity of the test stream. Based on the genotoxicity observed with the higher-tier, *in vivo* test (OECD 474 protocol), and the known genotoxicity of butadiene (*in vitro* and *in vivo*), performance of the lower tier, *in vitro* Ames test is no longer necessary. Therefore, the Panel no longer intends to conduct the Ames test as part of its work on the Crude Butadiene C4 Category, under the HPV Challenge Program.

The Test Plan for the Crude Butadiene C4 category included technical discussions to address aquatic toxicity, photodegradation, hydrolysis, and biodegradation and the calculation of fugacity. Physicochemical data would also be calculated as described in the EPA document titled, *The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program*. This information will be submitted at a later date.

The Test Plan also envisioned using data from other test programs under the OECD SIDS or HPV Challenge Program to complete characterization of the toxicity of the streams in this category. The Panel plans to submit a report on the category after the data to fully characterize the category are available under these programs.

If you have any questions, please contact Dr. Elizabeth Moran, Manager of the Olefins Panel at 301 924 2006 or Elizabeth_Moran@americanchemistry.com.

Sincerely yours,

Courtney M. Price
Vice President, CHEMSTAR

cc: C. Auer (EPA)
O. Hernandez (EPA)
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