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<b>Contractor</b>			
<b>Document Title</b>	SUPPORT: LETTER FROM AMER CHEM CNCL OLEFINS PANEL TO USEPA CORRECTING PREV SUBM, REPORT OF PRELIMINARY RESULTS OF MOUSE MICRONUCLEUS TEST WITH C4 CRUDE BUTADIENE, DATED 2/21/2001		
<b>Chemical Category</b>	C4 CRUDE BUTADIENE		

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Room G99, East Tower (Attn: 8(e))  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
401 M Street SW  
Washington, DC 20460-0001

Re: Corrected TSCA Section 8(e) Report

Dear Madam or Sir:

On February 16, 2001, the American Chemistry Council Olefins Panel (Panel) submitted a letter pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA), to inform EPA of positive preliminary results for a mouse micronucleus test of "C4 Crude Butadiene (low 1,3-butadiene content)." Unfortunately, that letter contained a few errors, as follows:

1) The headings for Tables 1 and 2 were inaccurate. The column labeled "%MN" should have been labeled "%MNPCE." The column labeled "%MNPCE" should have been labeled "%PCE."

2) Footnote b to Tables 1 and 2 should have indicated that the units for the dose of CP were mg/kg. (The positive control was dosed orally, whereas the animals treated with the test substance were treated by inhalation.)

3) Table 4 of the letter listed CAS registry numbers used to identify streams in the "Crude Butadiene C4 Category." The sixth paragraph of the letter listed Panel companies that "produce one or more of the streams listed in Table 4." The company identified in that list as "NOVA Chemicals, Inc." should have been given as "NOVA Chemicals Inc." (no comma).

4) NOVA Chemicals Inc. imports, but does not produce, a C4 crude butadiene. In addition, other companies listed in the letter may import as well as produce Crude Butadiene C4 Category streams. The Panel understands that, for purposes of TSCA, importers of chemical substances are considered manufacturers. Nevertheless, for clarity, the sixth paragraph of the letter should read: "The following members of the Panel each produce and/or import one or more of the streams listed in Table 4 . . .".

A revised copy of the letter with these changes is attached.



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February 20, 2001  
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The Panel regrets any inconvenience these errors may have caused. If you have any questions, please call Elizabeth Moran, Manager of the Olefins Panel at 301-924-2006, write her at the address given at the bottom of the first page of this letter, or e-mail her at [Elizabeth\\_Moran@americanchemistry.com](mailto:Elizabeth_Moran@americanchemistry.com).

Sincerely yours,



Courtney M. Price  
Vice-President, CHEMSTAR

Enclosure

cc: Richard H. Hefter (MC 7403)

**REVISED**  
February 16, 2001

Document Control Office (7407)  
Room G99, East Tower (Attn: 8(e))  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
401 M Street SW  
Washington, DC 20460-0001

Re: TSCA Section 8(e)

Dear Madam or Sir:

The American Chemistry Council Olefins Panel, on behalf of certain of its members (listed below), submits this letter pursuant to Section 8(e) of the Toxic Substances Control Act, to inform EPA of positive preliminary results for a mouse micronucleus test of "C4 Crude Butadiene (low 1,3-butadiene content)." The preliminary results for female mice are provided as Table 1, and the preliminary results for the male mice are provided as Table 2. Note that, although the percentages of micronucleated polychromatic erythrocytes were statistically elevated at all doses, there was not a clear dose-response pattern.

The test substance was tested pursuant to the Olefins Panel testing plan under the High Production Volume Chemical Challenge Program.<sup>1</sup> Under that testing plan, several hydrocarbon process streams form Test Group 1, the Crude Butadiene C4 Category. Streams in this category contain 1,3-butadiene (butadiene) at a concentration of 10% or greater, along with a variety of other materials -- primarily hydrocarbons containing 4 carbons. As explained in the test plan, the basis for including these materials in one category was the sponsors' belief that the biological activity of Group 1 streams would be due to the presence of butadiene. The test sponsors believe that the results reported here support the category approach.

C4 Crude Butadiene contains 10 to 82% butadiene. The specific sample tested contained 10% butadiene. Table 3 shows the concentration of butadiene that would have been present at each test dose. Table 4 shows the CAS registry numbers that are used to identify C4 Crude Butadiene, as well as the CAS registry numbers used for the other streams in this category. Table 5 shows the analysis of the specific sample tested.

The results of this test of C4 Crude Butadiene (low 1,3-butadiene content) are consistent with previous studies of butadiene. For example, Autio et al. (1994) evaluated micronucleus formation in 1,3-butadiene-exposed CB6F1 female mice at concentrations of 0, 50, 200, 500 or 1300 ppm for 6 hours per day for 5 days.<sup>2</sup> A clear increase in micronucleus formation was observed at all concentrations, along

<sup>1</sup> The plan is available at <http://www.epa.gov/chemrtk/olefins/olefintp.pdf>.

<sup>2</sup> Autio, K., Renzi, L., Catalan, J., Albrecht, O., and Sorsa, M. (1994). Induction of micronuclei in peripheral blood and bone marrow erythrocytes of rats and mice exposed to 1,3-butadiene by inhalation. *Mutat. Res.* 309:315-320.



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with a clear dose response pattern.<sup>3</sup> As shown in Table 3, the dose levels in the current study fall in approximately the same range as the Autio et al. study. However, as noted above, unlike the Autio et al. study, there was not a clear dose response pattern in this study. Also, the mean incidence of micronucleus formation was not as high in this study at dose levels comparable to the Autio et al. study. The test sponsors believe these differences may be because other constituents in the stream are competing for the same metabolic pathway as butadiene.

Because the test substance contained the lowest butadiene concentration of the streams included in Test Group 1, and because the test sponsors believe the positive results were due to the presence of butadiene in the stream, it is likely that all substances in Test Group 1 would be positive for the mouse micronucleus test. Table 4 lists the substances included in Test Group 1.

The following members of the Panel each produce and/or import one or more of the streams listed in Table 4 and are sponsors of the Group 1 testing: Chevron Phillips Chemical Company LP, CONDEA Vista Company, The Dow Chemical Company, E.I. du Pont de Nemours and Company, Eastman Chemical Company, Equistar Chemicals, LP, ExxonMobil Chemical Company, Formosa Plastics Corporation, U.S.A., Huntsman Corporation, NOVA Chemicals Inc., Shell Chemical Company, Texas Petrochemicals Corporation, Union Carbide Corporation, Westlake Chemical Corporation, and Williams Olefins LLC.

The Panel notes that all streams included in Test Group 1 are covered by an Occupational Health and Safety Standard, 29 C.F.R. 1910.1051, and therefore that these streams are manufactured and processed pursuant to stringent worker protection standards.

If you have any questions, please call Elizabeth Moran, Manager of the Olefins Panel at 301 924 2006, write her at the address given at the bottom of the first page of this letter, or e-mail her at [Elizabeth\\_Moran@americanchemistry.com](mailto:Elizabeth_Moran@americanchemistry.com).

Sincerely yours,



Courtney M. Price  
Vice President, CHEMCTAR

cc: Richard H. Hefter (MC 7403)

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<sup>3</sup> In the same study, increased micronuclei formation was not observed in rats.

Table 1

**Summary Micronucleated Polychromatic Erythrocytes (MNPCE) Frequencies and % Polychromatic Erythrocytes (%PCE) – Females**

**TEST MATERIAL: C4 Crude Butadiene, Low 1,3-Butadiene Content**

Dose, mg/L	N <sup>a</sup>	%MNPCE		%PCE	
		Mean	Std. Dev.	Mean	Std. Dev.
0	6	2.8	1.0	62.3	5.9
0.5	6	5.6 <sup>c</sup>	2.6	63.6	4.3
10	6	5.8 <sup>c</sup>	2.2	61.8	11.4
20	6	6.5 <sup>c</sup>	1.4	66.2	9.6
120 CP <sup>b</sup>	6	36.8 <sup>c</sup>	5.1	48.0 <sup>c</sup>	9.4

<sup>a</sup>N is the number of animals per dose group at the time of scheduled sacrifice. 2000 PCE were examined/animal for MN incidence, and expressed as MN/1000 PCE (%MNPCE).

<sup>b</sup>CP = Cyclophosphamide monohydrate (positive control). The dose is in mg/kg.

<sup>c</sup>The values are significantly different from the negative control (alpha=0.05).

**Table 2**  
**Summary Micronucleated Polychromatic Erythrocytes (MNPCE) Frequencies and % Polychromatic Erythrocytes (%PCE) – Males**

**TEST MATERIAL: C4 Crude Butadiene, Low 1,3-Butadiene Content**

Dose, mg/L	N <sup>a</sup>	%MNPCE		%PCE	
		Mean	Std. Dev.	Mean	Std. Dev.
0	6	2.1	1.4	65.6	6.0
0.5	6	4.7 <sup>c</sup>	1.2	62.3	5.6
10	6	9.3 <sup>c</sup>	1.9	60.8	8.6
20	6	6.1 <sup>c</sup>	2.7	61.3	4.0
120 CP <sup>b</sup>	6	34.4 <sup>c</sup>	7.5	37.9 <sup>c</sup>	8.0

<sup>a</sup>N is the number of animals per dose group at the time of scheduled sacrifice. 2000 PCE were examined/animal for MN incidence, and expressed as MN/1000 PCE (%MNPCE).

<sup>b</sup>CP = Cyclophosphamide monohydrate (positive control). The dose is in mg/kg.

<sup>c</sup>The values are significantly different from the negative control (alpha=0.05).

**Table 3****Mean Butadiene Concentration at Each Dose of Test Substance**

<b>Dose level of C4 Crude Butadiene (mg/L)</b>	<b>Mean Butadiene Concentration</b>	
	<b>mg/L</b>	<b>ppm</b>
0.5	0.054	24.5
10	1.054	468
20	1.90	861

**Table 4**

**Chemical Substances in Test Group 1  
 (Crude Butadiene C4 Category)  
 Olefins Panel HPV Testing Program**

<b>CASRN</b>	<b>Industry Product Description</b>
25167-67-3	C4 crude butadiene (coproduct of ethylene manufacturing unit)
64742-83-2	C4 crude butadiene (coproduct of ethylene manufacturing unit)
68187-60-0	C4 crude butadiene (coproduct of ethylene manufacturing unit)
68476-44-8	C4 crude butadiene (coproduct of ethylene manufacturing unit)
68476-52-8	C4 crude butadiene (coproduct of ethylene manufacturing unit)
68955-28-2	C4 crude butadiene (coproduct of ethylene manufacturing unit)
68956-54-7	C4 crude butadiene (coproduct of ethylene manufacturing unit)
64742-83-2	Pyrolysis C4+ (coproduct of ethylene manufacturing unit)
68477-41-8	C4 crude butadiene (from oxydehydrogenation unit)
68512-91-4	Butadiene unit heavy ends – high 1,3 BD content
69103-05-5	Butadiene unit heavy ends – high 1,3 BD content
68513-68-8	Pyrolysis C3+ (coproduct of ethylene manufacturing unit)
106-99-0	1,3-butadiene (high purity)

Substances in this group contain butadiene at concentrations of 10 percent or more. Note, however, that the definitions found in the TSCA Chemical Substance Inventory for the CAS registry numbers included in this group are vague with respect to composition. Therefore, it is not uncommon to find that the same CASRN is correctly used to describe different streams (compositions) or that two or more different CASRNs are used to describe the same stream (composition or process). In particular, CASRNs 25167-67-3 and 69103-05-5 describe both streams in this group and streams that contain less than 5% butadiene.

Table 5

**Approximate Composition of Sample Tested  
C4 Crude Butadiene (low 1,3-butadiene content)**

Component	CASRN	Wt%
1,3-Butadiene	106-99-0	10.3
C2 & C3 hydrocarbons		0.01
IsoButane	75-28-5	4.9
n-Butane	106-97-8	4.3
CycloButane	287-23-0	0.05
trans-butene-2	624-64-6	28.8
Butene-1	106-98-9	29.6
isoButylene	115-11-7	11.3
cis-Butene-2	590-18-1	10.6
isoPentane	78-78-4	0.01
1,2-Butadiene	590-19-2	0.01
C5 and higher hydrocarbons		0.07
Total		99.95

Note: The test substance and all of the other streams in Test Group 1, except the product 1,3-butadiene (high purity), are complex substances with variable composition. The analysis above is representative of C4 Crude Butadiene with low 1,3-butadiene content.