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Attention: TSCA Section 8(e) Coordinator

RE: Reproductive Toxicity Range-Finding Study of Polyethylbenzene in Rats

Dear Sir or Madam:

On November 19, 2004, the American Chemistry Council Ethylbenzene Panel (Panel) submitted a letter on behalf of the members pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA) to inform EPA of data from a dose range-finding study that is being conducted on Polyethylbenzene Bottoms (CAS No. 68987-42-8) under the HPV Challenge Program. There was an error in the letter regarding sponsoring companies. TOTAL PETROCHEMICALS U.S.A., Inc. (formerly Atofina Petrochemicals, Inc.) is a sponsor of the study that is subject of the letter. Therefore, I am enclosing a corrected copy of the November 19, 2004 report. The only change is the inclusion of TOTAL PETROCHEMCIALS in the sponsor list.

I am sorry for any inconvenience this error may cause.

Yours truly,

Elizabeth J. Moran, Ph.D.
Manager, Ethylbenzene Panel

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Attention: TSCA Section 8(e) Coordinator

RE: Reproductive Toxicity Range-Finding Study of Polyethylbenzene in Rats

Dear Sir or Madam:

The American Chemistry Council Ethylbenzene Panel (Panel) submits this letter on behalf of the members (listed below) pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA) to inform EPA of data from a dose range-finding study that is being conducted on Polyethylbenzene Bottoms (CAS No. 68987-42-8) under the HPV Challenge Program. The sponsors of the Polyethylbenzene in the HPV program are: BP, Chevron Phillips Chemical Company, The Dow Chemical Company, Lyondell Chemical Company, NOVA Chemicals Inc., and TOTAL PETROCHEMICALS U.S.A., Inc. The Panel has not made a determination as to whether a significant risk of injury to health or the environment is presented by these findings.

The Panel conducted a range-finding study at WIL Research Laboratories to develop information to aid in selection of exposure concentrations for a planned OECD 422 study on a Polyethylbenzene Bottoms stream. Both studies are being conducted under the HPV Challenge Program. The range-finding study design called for exposing groups of 5 male and 5 pregnant female Sprague Dawley rats to 3,000, 1,500, 500 or 50 mg/kg/day polyethylbenzene in corn oil for 14 days prior to mating and throughout mating. Male rats were to be dosed for a minimum of 28 days. Female rats were to be treated throughout gestation until one day prior to sacrifice on gestation day 20. Females showing no evidence of mating were to be treated until 7 days following completion of the mating period.

All rats in the 3,000 and 1,500 mg/kg dose groups died or were sacrificed in extremis during the first week of treatment. At the 500 mg/kg/day dose, there were elevations in early resorptions, total resorptions and percent post implantation loss and an increase in the numbers of female fetuses. These effects were not seen in the group of rats receiving daily gavage doses of 50 mg/kg/day. Unaudited draft data tables for these effects are attached.

The study is presently ongoing at the laboratory. The final report will be provided to EPA, once it becomes available.

If you have any questions, please contact me at 301 924 2006 or Elizabeth_Moran@americanchemistry.com.

Yours truly,

Elizabeth J. Moran, Ph.D.
Manager, Ethylbenzene Panel

Attachment: Unaudited Draft Data Tables

SUMMARY OF BODY WEIGHTS [G]

FEMALES

GROUP:		0 MG/KG/DAY	500 MG/KG/DAY	1500 MG/KG/DAY	3000 MG/KG/DAY	50 MG/KG/DAY
DAY 0	MEAN	243.0	242.6	242.8	243.2	251.1
	S.D.	10.98	8.73	9.07	5.93	18.29
	N	5	5	5	5	5
DAY 3	MEAN	245.1	237.2	NA	NA	250.2
	S.D.	12.81	8.30			18.42
	N	5	5			5
DAY 6	MEAN	254.1	239.1	NA	NA	250.4
	S.D.	11.50	9.30			19.74
	N	5	5			5
DAY 10	MEAN	257.7	235.0	NA	NA	252.5
	S.D.	12.99	9.01			18.98
	N	5	5			5
DAY 13	MEAN	259.7	236.1	NA	NA	257.8
	S.D.	15.17	9.76			22.52
	N	5	5			5
DAY 17	MEAN	NA	246.9	NA	NA	NA
	S.D.		20.36			
	N		2			

None significantly different from control group
NA = NOT APPLICABLE

GROUP:	0 MG/KG/DAY	500 MG/KG/DAY	1500 MG/KG/DAY	3000 MG/KG/DAY	50 MG/KG/DAY
CORPORA LUTEA					
MEAN	16.8	11.8*	NA	NA	15.0
S.D.	2.49	3.86			1.41
N	5	4			5
IMPLANTATION SITES					
MEAN	15.6	10.8	NA	NA	14.4
S.D.	0.89	5.85			1.67
N	5	4			5
VIABLE FETUSES (%)					
MEAN	98.7	73.2	NA	NA	95.5
S.D.	3.00	44.58			6.82
N	5	4			5
DEAD FETUSES (%)					
MEAN	0.0	0.0	NA	NA	0.0
S.D.	0.00	0.00			0.00
N	5	4			5
EARLY RESORPTIONS (%)					
MEAN	1.3	26.8	NA	NA	4.5
S.D.	3.00	44.58			6.82
N	5	4			5
LATE RESORPTIONS (%)					
MEAN	0.0	0.0	NA	NA	0.0
S.D.	0.00	0.00			0.00
N	5	4			5

PROPORTIONAL (%) DATA COMPARED USING THE MANN-WHITNEY TEST
CORPORA LUTEA AND IMPLANTATION SITES COMPARED USING DUNNETT'S TEST
* = Significantly different from the control group at 0.05
NA = NO DAMS SURVIVED TO THE SCHEDULED NECROPSY

UNAUDITED DRAFT
A REPRODUCTION/DEV TOXICITY DOSE R-F STUDY OF PEB IN RATS
SUMMARY OF FETAL DATA AT SCHEDULED NECROPSY [% PER LITTER]

GROUP:	0 MG/KG/DAY	500 MG/KG/DAY	1500 MG/KG/DAY	3000 MG/KG/DAY	50 MG/KG/DAY
TOTAL RESORPTIONS (%)					
MEAN	1.3	26.8	NA	NA	4.5
S.D.	3.00	44.58			6.82
N	5	4			5
PRE-IMPLANTATION LOSS (%)					
MEAN	6.2	16.7	NA	NA	4.1
S.D.	7.76	33.35			3.76
N	5	4			5
POST-IMPLANTATION LOSS (%)					
MEAN	1.3	26.8	NA	NA	4.5
S.D.	3.00	44.58			6.82
N	5	4			5
MALES (%)					
MEAN	58.4	18.1+	NA	NA	57.0
S.D.	14.48	21.38			16.60
N	5	4			5
FEMALES (%)					
MEAN	41.6	81.9+	NA	NA	43.0
S.D.	14.48	21.38			16.60
N	5	4			5
MALE FETAL WEIGHTS (g)					
MEAN	3.5	3.2	NA	NA	2.9
S.D.	0.86	0.14			0.45
N	5	2			5

PROPORTIONAL (%) DATA COMPARED USING THE MANN-WHITNEY TEST
FETAL WEIGHTS COMPARED USING DUNNETT'S TEST
+ = Significantly different from the control group at 0.05
NA = NO DAMS SURVIVED TO THE SCHEDULED NECROPSY

GROUP:	0 MG/KG/DAY	500 MG/KG/DAY	1500 MG/KG/DAY	3000 MG/KG/DAY	50 MG/KG/DAY
FEMALE FETAL WEIGHTS (g)					
MEAN	3.3	3.0	NA	NA	2.8
S.D.	0.75	0.65			0.42
N	5	4			5
COMBINED FETAL WEIGHTS (g)					
MEAN	3.4	3.1	NA	NA	2.8
S.D.	0.82	0.57			0.43
N	5	4			5

PROPORTIONAL (%) DATA COMPARED USING THE MANN-WHITNEY TEST
FETAL WEIGHTS COMPARED USING DUNNETT'S TEST
None significantly different from control group
NA = NO DAMS SURVIVED TO THE SCHEDULED NECROPSY

DAMS FROM GROUP 1: 0 MG/KG/DAY

			VIABLE FETUSES			DEAD FETUSES			EARLY RESORPTIONS			LATE RESORPTIONS			IMPLANTATION SITES			CORPORA LUTEA		
	SEX		LEFT	RIGHT		LEFT	RIGHT		LEFT	RIGHT		LEFT	RIGHT		LEFT	RIGHT		LEFT	RIGHT	
DAM#	M	F	HORN	HORN	TOTAL	HORN	HORN	TOTAL	HORN	HORN	TOTAL	HORN	HORN	TOTAL	HORN	HORN	TOTAL	OVARY	OVARY	TOTAL
63799	11	5	5	11	16	0	0	0	0	0	0	0	0	0	5	11	16	5	12	17
63804	10	5	10	5	15	0	0	0	0	0	0	0	0	0	10	5	15	10	5	15
63806	5	10	8	7	15	0	0	0	0	0	0	0	0	0	8	7	15	8	7	15
63811	10	7	10	7	17	0	0	0	0	0	0	0	0	0	10	7	17	10	11	21
63812	9	5	6	8	14	0	0	0	0	1	1	0	0	0	6	9	15	6	10	16
TOTAL	45	32	39	38	77	0	0	0	0	1	1	0	0	0	39	39	78	39	45	84
MEAN	9.0	6.4	7.8	7.6	15.4	0.0	0.0	0.0	0.0	0.2	0.2	0.0	0.0	0.0	7.8	7.8	15.6	7.8	9.0	16.8
S.D.	2.35	2.19	2.28	2.19	1.14	0.00	0.00	0.00	0.00	0.45	0.45	0.00	0.00	0.00	2.28	2.28	0.89	2.28	2.92	2.49
N =	5																			

DAMS FROM GROUP 2: 500 MG/KG/DAY

DAM#	SEX M	SEX F	VIABLE FETUSES LEFT HORN	VIABLE FETUSES RIGHT HORN	VIABLE FETUSES TOTAL	DEAD FETUSES LEFT HORN	DEAD FETUSES RIGHT HORN	DEAD FETUSES TOTAL	EARLY RESORPTIONS LEFT HORN	EARLY RESORPTIONS RIGHT HORN	EARLY RESORPTIONS TOTAL	LATE RESORPTIONS LEFT HORN	LATE RESORPTIONS RIGHT HORN	LATE RESORPTIONS TOTAL	IMPLANTATION SITES LEFT HORN	IMPLANTATION SITES RIGHT HORN	IMPLANTATION SITES TOTAL	CORPORA LUTEA LEFT OVARY	CORPORA LUTEA RIGHT OVARY	CORPORA LUTEA TOTAL
63798	4	9	10	3	13	0	0	0	0	0	0	0	0	0	10	3	13	10	3	13
63803	5	7	5	7	12	0	0	0	2	0	2	0	0	0	7	7	14	7	7	14
63807	0	2	0	2	2	0	0	0	0	0	0	0	0	0	0	2	2	2	4	6
63808	0	1	0	1	1	0	0	0	9	4	13	0	0	0	9	5	14	9	5	14
TOTAL	9	19	15	13	28	0	0	0	11	4	15	0	0	0	26	17	43	28	19	47
MEAN	2.3	4.8	3.8	3.3	7.0	0.0	0.0	0.0	2.8	1.0	3.8	0.0	0.0	0.0	6.5	4.3	10.8	7.0	4.8	11.8
S.D.	2.63	3.86	4.79	2.63	6.38	0.00	0.00	0.00	4.27	2.00	6.24	0.00	0.00	0.00	4.51	2.22	5.85	3.56	1.71	3.86
N =	4																			

DAMS FROM GROUP 5: 50 MG/KG/DAY

DAM#	SEX M	SEX F	VIABLE FETUSES LEFT HORN	VIABLE FETUSES RIGHT HORN	VIABLE FETUSES TOTAL	DEAD FETUSES LEFT HORN	DEAD FETUSES RIGHT HORN	DEAD FETUSES TOTAL	EARLY RESORPTIONS LEFT HORN	EARLY RESORPTIONS RIGHT HORN	EARLY RESORPTIONS TOTAL	LATE RESORPTIONS LEFT HORN	LATE RESORPTIONS RIGHT HORN	LATE RESORPTIONS TOTAL	IMPLANTATION SITES LEFT HORN	IMPLANTATION SITES RIGHT HORN	IMPLANTATION SITES TOTAL	CORPORA LUTEA LEFT OVARY	CORPORA LUTEA RIGHT OVARY	CORPORA LUTEA TOTAL
63791	8	7	8	7	15	0	0	0	0	0	0	0	0	0	8	7	15	8	8	16
63792	8	3	4	7	11	0	0	0	2	0	2	0	0	0	6	7	13	6	8	14
63795	9	4	7	6	13	0	0	0	1	0	1	0	0	0	8	6	14	8	6	14
63810	10	7	9	8	17	0	0	0	0	0	0	0	0	0	9	8	17	9	8	17
63815	4	9	6	7	13	0	0	0	0	0	0	0	0	0	6	7	13	6	8	14
TOTAL	39	30	34	35	69	0	0	0	3	0	3	0	0	0	37	35	72	37	38	75
MEAN	7.8	6.0	6.8	7.0	13.8	0.0	0.0	0.0	0.6	0.0	0.6	0.0	0.0	0.0	7.4	7.0	14.4	7.4	7.6	15.0
S.D.	2.28	2.45	1.92	0.71	2.28	0.00	0.00	0.00	0.89	0.00	0.89	0.00	0.00	0.00	1.34	0.71	1.67	1.34	0.89	1.41
N =	5																			

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