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Contractor					
Document Title		SUPPORT: LTR FRM DBE TO USEPA RE ADDTNL RESLTS FRM A 90-DAY STDY OF DIMETHYL ESTERS OF BUTANEDIOIC ACID, PENTANEDIOIC ACID, & HEXANEDIOIC ACID IN RATS, DATED 111300			
Chemical Category		BUTANEDIOIC ACID, DIMETHYL ESTER			

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DBE

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Via Messenger/RETURN RECEIPT

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Attention: 8(e) Coordinator

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The Dibasic Esters (DBE) Group is submitting the following information based upon EPA guidance regarding the reportability of toxicity data under TSCA Section 8 (e). The DBE Group, comprised of Aceto Corporation, E.I. duPont de Nemours & Company, and Solutia, Inc. The DBE Group is informing you of additional results from a 90-day inhalation study conducted in male and female rats and previously reported to the Agency in a letter of September 28, 2000 with butanedioic acid, dimethyl ester (DMS, CAS # 106-65-0); pentanedioic acid, dimethyl ester (DMG, CAS # 1119-40-0); and hexanedioic acid, dimethyl ester (DMA, CAS # 627-93-0). The DBE Group is conducting the study under a TSCA Section 4(a) Consent Agreement (Docket No. OPPTS-42190) and is copying this letter to our ECA Coordinator George Semeniuk.

A 90-day inhalation toxicity study in rats was conducted with DMG, DMS, and DMA to evaluate the subchronic toxicity of the test substances. Groups of male and female rats were exposed via inhalation to 0, 10, 50, or 400 mg/m³ DMG, 400 mg/m³ DMS, or 400 mg/m³ DMA. Following 90 days of exposure the epididymides were collected and a combined weight was recorded. The right cauda epididymis was weighed separately. The left epididymis and testis were frozen in liquid nitrogen and stored between -65°C and -85°C for counting of sperm and homogenization-resistant spermatids, respectively. All male rats designated for the 90-day sacrifice were evaluated for epididymal sperm counts. The control and 400 mg/m³ DMG, DMS, and DMA male rats designated for the 90-day sacrifice were examined for testicular sperm counts.

There were no compound-related effects on testicular spermatid counts (per testis and per gram testis) following inhalation exposure to DMG, DMS or DMA.

There was an increase in epididymal sperm counts following exposure to DMG. The number of sperm per cauda and per gram cauda epididymis was significantly increased at 50 and 400 mg/m³ (131% and 124%; 127% and 124% of control, respectively). Epididymal sperm counts were similar to control at 10 mg/m³ DMG. In male rats exposed to DMS, epididymal sperm counts (per cauda epididymis and per gram cauda epididymis) were significantly increased (153% and 141% of control, respectively). Although not statistically significant there was a compound-related effect on epididymal sperm counts following exposure to DMA.



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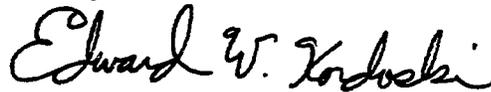
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Inhalation exposure to DMG, DMS, or DMA caused an increase in epididymal sperm counts that occurred in the presence of normal spermatogenesis as determined by testis histopathology, organ weights, and testicular spermatid counts. Thus, sperm output from the testis appeared normal but DMG, DMS, and DMA exposure increased epididymal sperm counts. In the absence of histopathological changes in the epididymis, the biological significance of these findings, is unclear.

Under these experimental conditions, the findings described above appear to be reportable, based upon EPA guidance regarding the reportability of such data under TSCA Section 8(e) criteria.

Sincerely,



Edward W. Kordoski, MBA, Ph.D.
Executive Director

cc: TSCA Section 4 (Dr. Semeniuk)
R. Opatick, DBE Group
DBE Group

CERTIFICATE OF AUTHENTICITY

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