



MR 296368

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June 12, 2006

Via Courier

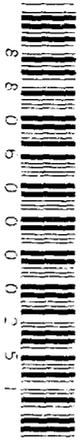
TSCA Confidential Business Information Center (7407 M)
EPA East – Room 6428 – Attn: Section 8(e)
U. S. Environmental Protection Agency
1201 Constitution Avenue NW
Washington, DC 20004-3302

Attn: TSCA 8(e) Notice
Re: CAS Number 2426-08-6; n-Butyl Glycidyl Ether

This submission is made by:
The Society of the Plastics Industry (SPI), Inc.
AGE/BGE Task Force
1667 K Street, NW – Suite 1000
Washington, DC 20006-1620

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Dear TSCA Section 8(e) Coordinator:

On behalf of the members of the Alkyl Glycidyl Ether/Butyl Glycidyl Ether Task Force (AGE/BGE Task Force), SPI is reporting research results pursuant to Section 8(e) of the Toxic Substances Control Act. None of the members of the AGE/BGE Task Force has determined that these results indicate a potential substantial risk of injury to human health or the environment.

This notice does not involve effects in humans. It does not contain confidential business information. It is to report findings contained in a final audited study report.

An oral (gavage) prenatal developmental toxicity study of n-butyl glycidyl ether (CAS No. 2426-08-6) was conducted according to U.S. E.P.A. OPPTS 870.3700 and OECD Guideline 414 to evaluate the potential maternal toxicity and/or prenatal developmental toxicity of the test article when administered to pregnant rats throughout the period of organogenesis, and to determine a no-observed-adverse-effect level (NOAEL) for maternal toxicity and developmental toxicity.

The test article, N-butyl glycidyl ether, in the vehicle, 0.5% methylcellulose (MC) with 0.1% polysorbate 80, was administered orally by gavage to 3 groups of 25 bred



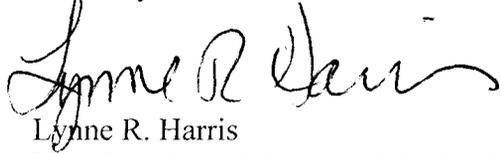
female CrI:CD₁(SD) rats once daily from gestation days 0 through 19. Dosage levels were 40, 100 and 250 mg/kg/day administered at a dosage volume of 5 mL/kg. A concurrent control group composed of 25 bred females received the vehicle on a comparable regimen.

All animals in the control, 40, 100 and 250 mg/kg/day groups survived to the scheduled necropsy. Mean maternal body weights, body weight gains, net body weights, net body weight gains and food consumption in the 40, 100 and 250 mg/kg/day groups were unaffected by test article administration. Mean gravid uterine weight in the 250 mg/kg/day group was lower than the control group value due to the effects noted on embryo/fetal development. No test article-related internal findings were observed at dosage levels of 40, 100 and 250 mg/kg/day.

Based on the results of this study, increased postimplantation loss with corresponding decreased litter viability was observed at the 250 mg/kg/day dosage level. This, in conjunction with decreased fetal weight (primarily due to 7 litters with mean fetal weights less than 2.2 g), resulted in lower mean gravid uterine weight at this dosage level. Developmental delay was also evident at the 250 mg/kg/day dosage level by skeletal developmental variations of unossified and reduced ossification of skeletal elements and unco-ossified vertebral centra in the litters with low fetal weights. Therefore, the no-observed-adverse-effect level (NOAEL) for embryo/fetal development was considered to be 100 mg/kg/day. No maternal toxicity was noted at any dosage level in this study. Therefore, the NOAEL for maternal toxicity was considered to be 250 mg/kg/day.

Please contact me if you have any questions or require additional information. I can be reached by telephone at (202) 974-5217.

Sincerely,



Lynne R. Harris
Vice President, Science and Technology

cc: AGE/BGE Task Force