

RECEIVED
OPPT 0811
August 5, 2005

05 AUG 31 AM 7:23

**American
Chemistry
Council** *Good Chemistry
Makes It Possible*

Document Processing Center (7407M)
Office of Pollution Prevention and Toxic Substances
U.S. Environmental Protection Agency
EPA East
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

8EHQ-0805-16197

Contain NO C

Attention: 8(e) Coordinator



Dear Sir or Madam:

The information below is submitted by the American Chemistry Council's Oxo Process Panel on behalf of the following producers of butyl acetate: Celanese Ltd., The Dow Chemical Company, and Eastman Chemical Company in accordance with EPA's interpretation of Section 8(e) of the Toxic Substances Control Act.

The Oxo Process Panel is sponsoring a two-generation reproductive toxicity study on butyl acetate (CAS #123-86-4). This submission is intended to discharge any Section 8(e) responsibilities relevant to preliminary data generated in the range-finding study on butyl acetate.

A range-finding study is being conducted with n-butyl acetate in order to select inhalation exposure concentrations for a two-generation reproductive toxicity study. Timed-pregnant rats (10/group) were exposed by inhalation from gestation day 3 through 20 and again from lactation day 5 through 21. In addition, the dams received oral gavage doses of n-butyl acetate on lactation days 1 through 4. The oral gavage dosing regimen was selected based on pharmacokinetic modeling predictions. The inhalation exposure concentrations were 0, 500, 1500, 2500, and 3000 ppm.

Two endpoints have produced results that may trigger reporting requirements under Section 8(e) of TSCA. The first was an apparent increase in length of gestation in the three highest exposure concentrations. The gestation lengths in the 0, 500, 1500, 2500 and 3000 ppm groups were 22.3, 22.5, 23.0, 23.1, and 23.2 days, respectively. The values at the three highest exposure concentrations were statistically significant. There is an unusual amount of uncertainty regarding the significance of this endpoint, due to the method of breeding used by the animal supplier. However, the producers are submitting this information so there will be no question regarding the fulfillment of possible Section 8(e) reporting requirements. The second finding was a nonsignificant decrease in postnatal day 1 mean male and female pup body weights. The mean male pup body weights on postnatal day 1 in the 0, 500, 1500, 2500 and 3000 ppm groups were 7.0, 7.0, 7.2, 6.5, and 6.5, respectively. The mean female pup body weights on postnatal day 1 in

RECEIVED
OPPT 0811
2005 SEP 19 AM 9:38



288723

8(e) Coordinator
August 5, 2005
Page 2

the 0, 500, 1500, 2500 and 3000 ppm groups were 6.5, 6.6, 6.9, 6.2, and 6.2, respectively. None of these mean pup weights were statistically significant. The dams in the two highest exposure concentrations had treatment-related reduced feed consumption, body weights, and rate of weight gain during gestation that may have adversely impacted the pup body weights.

As noted, this information should be considered preliminary. The final report will be submitted to the Agency as soon as it is available. If you have any questions regarding the information contained in this letter, please contact me at (703) 741-5609 or by email at Barbara.Francis@americanchemistry.com.

Sincerely yours,

Barbara Francis

Barbara Francis
Managing Director, CHEMSTAR

cc: Oxo Process Panel members