

June 24, 1992

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Office of Toxic Substances
Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

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8EHQ-0692-5141 Init

Attention: Section 8(e) Coordinator (CAP Agreement) 889200037875

The following information is provided under Section 8(e) of TSCA and pursuant to the Compliance Audit Program (CAP) Agreement

[redacted] is a distributor, in commerce, of a product containing 2-butoxyethanol, CAS # 111-76-2. [redacted] is also a participant in EPA's Compliance Audit Program.

In the continuing review of our files and other chemical information for the purposes of assuring our compliance with applicable environmental requirements, we have discovered information concerning 2-butoxyethanol not included in our CAP Report [redacted].

In response to a phone call by one of our Product Safety Staff to Central Data Management at the National Toxicology Program (NTP), we were sent some preliminary data tables from a Short Term Toxicity Study prior to the release of the final report. While we do not know the exact date on which we received the information, we believe it was within the CAP period. Since a final report has not been issued, and we have not seen the raw data, [redacted] cannot comment on the accuracy or validity of the data tables. Enclosed are copies of the data for your review.

Data Summary:

2-butoxyethanol was administered to 10 male and 10 female F344/N rats in drinking water at 0, 750, 1500, 3000, 4500, and 6000 ppm for 90 days. No 2-butoxyethanol related mortality occurred at any dose level in either sex.

In male rats, a statistically significant decrease (t test, p<0.05) in epididymal sperm density was noted at the 3000, 4500, and 6000 ppm dose levels. Decreased left epididymal weight was noted at 4500 and 6000 ppm. To date, we have not identified a previous description of the reported effects in the toxicological literature.

In female rats, a dose related decrease in uterine weight was described between 3000 and 6000 ppm of 2-butoxyethanol in drinking water. Significant changes in the relative frequency of estrous stages were also reported. Based on our literature review, altered relative frequency of estrous stages has not been previously described. Also, the significant decrease in uterine weight has not been reported in non-pregnant animals.

Previously Published Data:

Decreased uterine weight has been reported in pregnant rats in Status Report # 8EHQ-0483-0475 submitted by Eastman Kodak on March 2, 1983. In this study, 4 groups of 30 mated female F344 rats were exposed via inhalation to vapor concentrations of 0, 100, 200, and 300 ppm 2-butoxyethanol for 6 hours per day on gestation days 6 through 15. Decreased uterine weight was reported for the 300 ppm dose group and was attributed to "the high degree of embryo and fetal lethality present at this exposure level." Significantly decreased uterine weights were also noted in pregnant F344 rats and in New Zealand White rabbits exposed to 200 ppm 2-butoxyethanol via inhalation (Environmental Health Perspectives, Vol. 57, pp. 47-68, 1984).

Discussion:

In the absence of the raw data, it is difficult to interpret the significance of the "effects" reported by NTP. This is especially true for the altered estrus cycle frequency since data are not reported on the data sheets. The approximately 12% non-dose related decrease in epididymal sperm density is also difficult to interpret in the absence of fertility data. Also, none of these effects were reported in a companion study in mice conducted under the auspices of NTP. Thus, these effects may be limited only to the rat which is a species known to be sensitive to the effects of glycol ethers such as 2-butoxyethanol.

This information is supplied as an amendment to our Report¹. We have assumed EPA was aware of these studies by virtue of EPA's

¹Allowing an amendment of our Report is consistent with extensions of the submittal date granted, by EPA, to many CAP participants who requested such extensions (as well as with the extension to submit certain Final Reports until July 31, 1992, announced by Michael Wood on April 10, 1992). Before our CAP report was submitted, [REDACTED] had considered seeking an extension of the date to file its final CAP Report, but decided not to do so since, notwithstanding EPA's liberal extension policy, we had no compelling need for such an extension at that time.

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EPA's position on the Executive Committee of NTP and because its staff specifically tracks toxicological developments concerning this chemical. For this, and other reasons, we are uncertain whether [REDACTED] had an obligation to report this information under Section 8(e). However, we have for purposes of the CAP, adopted an extremely broad interpretation of Section 8(e) requirements and are, therefore, submitting a Report.

In filing this Report, [REDACTED] does not waive any defenses it may have, outside of CAP, with respect to this information and its obligations with respect thereto. If you have any questions about this Report or our CAP agreement, please call me at [REDACTED].

Very truly yours,

[REDACTED]

attachments