

15 December 2004

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Great Lakes Chemical Corporation
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www.greatlakes.com

Document Control Office (7407M)
U.S. Environmental Protection Agency
Attention: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, NW
Washington, DC 20460 - 0001

8EHQ-1204-15587

RE: Internal ID #: 04-02 Submission of Maternal and Developmental Fetal Body
Weight Effects in the Rat of Tricresyl Phosphate; (CAS No.: 1330-78-5) on 09 June
2004. **8EHQ-04-15587**.
(When responding, please refer to JAB-04-071).

Dear Sir:

Great Lakes Chemical Corporation (GLCC) is submitting the enclosed letter of
substantial risk notification as a revision of the original letter dated 09 June 2004. Upon doing
our internal end of the year review of TSCA 8(e)s submitted, we noted an information error in
the RE: part of the original submission letter. It referenced the study as having been done in
accordance with OECD Guideline 421, when in fact it was completed using OPPTS Guideline
870.3700.

We apologize for any inconvenience this may have caused.

Sincerely,

John A. Biesemeier
Manager, Regulatory Toxicology
Regulatory Affairs

JAB/jab
Enclosure:



CONTAINS NO CBI

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RE: Submission of Maternal and Developmental Fetal Body Weight Effects in the Rat via an OPPTS 870.3700 Guideline Study of Tricresyl Phosphate; (CAS No.: 1330-78-5).
(When responding, please refer to JAB-04-045R).

Dear Sir:

Great Lakes Chemical Corporation (GLCC) submits this letter of substantial risk notification in accordance with Section 8(e) of the Toxic Substances Control Act, 15 USC 2607(e), and the Environmental Protection Agency's "Statement of Interpretation and Enforcement Policy" thereof 43 FR 1110, 35 seq., March 16, 1978. The notification is in regards to un-audited draft Summary Data Tables received from the laboratory that is performing an OPPTS 870.3700 Guideline Study entitled, "An Oral Prenatal Developmental Toxicity Study of Tricresyl Phosphate in Rats".

The test material was administered via oral gavage using corn oil as the carrier vehicle to groups of 25 female Sprague-Dawley CrI:CD*(SD)IGS BR strain of rat. The test material was given once daily at dose levels of 20, 100, 400 or 750 mg/kg. The 40 males used strictly for mating were not dosed. Females were dosed beginning Day 0 of gestation and continued daily through gestation Day 19. A concurrent control group of identical design received the carrier vehicle corn oil on a comparable regimen.

The study design included recording cage side and detailed clinical observations, body weights and food consumption, which corresponded to the days that body weights were recorded, moribund and premature delivery observations. On gestation Day 20, the females were euthanized and immediately subjected to a macroscopic uterine and ovarian examination prior to the uterus being excised. The gravid uterine weight was recorded and then the fetuses were removed. Uterine information recorded was total implantations, total corpora lutea, viability, and resorptions (late and early). Maternal gross lesions were collected and saved in preservative for possible microscopic examination. Fetuses were tagged before being examined macroscopically for external malformations and variations, and individually weighed and sexed. Approximately half of the fetuses of each litter were processed and examined for soft tissue anomalies. The remainder were processed and examined for skeletal malformation and variations.

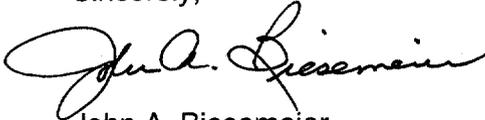
The mean gravid uterine weight and mean weight change from Day 0 of the 400 and 750 mg/kg/day dose groups were statistically lower in comparison to the means recorded for the control group. In addition, the mean adjusted final body weight and adjusted weight change from Day 0 of the 750 mg/kg/day dose group were also statistically lower than the corresponding means reported for the control group. Although the mean final body weight of

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the 400 and 750 mg/kg/day dose groups were not statistically lower; both means were noticeably lower than that of the control group.

Except for the mean fetal body weight of males at 100 mg/kg/day, all other mean fetal body weights (males, females and males + females combined) at 20, 100, 400 and 750 mg/kg/day were statistically lower when compared to the control group. In addition, the total number of litters (100%) and total number of fetuses (56%) within those litters of the high dose group were noted with a skeletal variation, non-ossified sternbra(e), which was statistically increased when compared to the control group.

Sincerely,

A handwritten signature in cursive script, appearing to read "John A. Biesemeier".

John A. Biesemeier
Manager, Regulatory Toxicology
Regulatory Affairs

JAB/jab