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MR#351017

January 9, 2013

Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e) / Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004



Subject: Notice in Accordance with TSCA Section 8(e): Additional Results of a Prenatal Developmental Toxicity Study in Wistar Rats with a developmental pesticide

Dear Section 8(e) Coordinator:

[REDACTED] is submitting the results of the fetal skeletal and soft tissue evaluation Prenatal Developmental Toxicity Study in Wistar Rats [Cr:WI(HAN)] with [REDACTED] [REDACTED] conducted by [REDACTED] [REDACTED] in addition to the results already reported in a submission made September 6, 2012 with document control number 8EHQ-12-18814. The test substance is a developmental pesticide.

The study was performed according to the OECD Guideline for Testing of Chemicals 414.

The test substance was administered to groups of 24 or 25 pregnant Wistar rats via gavage from gestational day (GD) 6 to GD 19. On GD 20, all dams were necropsied. Fetuses were removed from the uteri and examined externally.

The dose levels were: 375, 100, and 30 mg/kg body weight/day

The following findings were observed:

375 mg/kg bw/d

- Increased litter incidence (96%) and increased number of affected fetuses/litter (89%) with fetal skeletal malformations. Most frequently altered structures were observed in skull bones (misshapen basisphenoid – shortened), ribs (bent), and humerus (shortened).
- Increased incidences of fetal skeletal variations on skull. Most frequently altered structures were incomplete ossifications of skull bones, vertebrae, sternbrae, and pubis.

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100 mg/kg bw/d

- Increased number of affected fetuses/litter (2.4%) with fetal skeletal malformations. Most frequently altered structures were observed in skull bones (misshapen basisphenoid – shortened), and ribs (bent).
- Increased incidences of fetal skeletal variations. Most frequently altered structures were incomplete ossifications of skull bones, and vertebrae.

30 mg/kg bw/d

- No treatment-related findings

[REDACTED] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,

Enclosures