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8EHQ-11-18229

January 4, 2011

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Via Federal Express

8EHQ-0111-18229A
DCN:88110000113s

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 Section 8(e): Results of a Prenatal Developmental Toxicity Screening Study in Wistar Rats with (Substance 1)

[REDACTED] (Substance 2)
[REDACTED] (Substance 3)
[REDACTED] (Substance 4)
[REDACTED] (Substance 5)

Dear Sir/Madam:

[REDACTED] is submitting results of a Prenatal Developmental Toxicity Screening Study in Wistar Rats [CrI:WI(HAN)] with (Substance 1)

[REDACTED] (Substance 2)
[REDACTED] (Substance 3)
[REDACTED] (Substance 4)
[REDACTED] (Substance 5)

conducted by [REDACTED]. All test substances are developmental pesticides.

The aim of this study was to obtain information on the effect of the test substance after repeated oral administration (gavage) to pregnant Wistar rats with regard maternal as well as developmental toxicity.

The test substance was administered to groups of 10 pregnant Wistar rats via gavage from gestational day (GD) 6 to GD 19. On GD 20, all dams were sacrificed and fetuses were removed from the uteri.

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The nominal dose levels are listed in the following table:

(Substance 1): 20 and 60 mg/kg body weight/day

(Substance 2): 20 and 60 mg/kg body weight/day

(Substance 3): 20 and 60 mg/kg body weight/day

(Substance 4): 10 and 30 mg/kg body weight/day

(Substance 5): 20 and 60 mg/kg body weight/day

In all low dose groups, the dams and fetuses had no treatment related findings.

In all high dose groups, the dams had a decreased mean body weight and decreased body weight change at the end of gestation, partially accompanied with decreased food and water consumption.

The following is a summary of the most relevant results in comparison to control:

(Substance 1):

60 mg/kg bw/d

- Significantly lower uterus weights (37%)
- Significantly increased postimplantation loss (54%)
- Significantly decreased live fetuses/dam (66 %)
- Significantly decreased fetal weights (56%) and placental weights (59%)
- Increased incidence of fetuses with cleft palate (14%)

(Substance 2):

60 mg/kg bw/d

- Significantly lower uterus weights (3%)
- Significantly increased postimplantation loss (96%)
- Significantly decreased live fetuses/dam (18%)
- Significantly decreased fetal weights (40%) and placental weights (50%)

(Substance 3):

60 mg/kg bw/d

- Significantly lower uterus weights (46%)
- Significantly increased postimplantation loss (54%)
- Significantly decreased fetal weights (73%) and placental weights (76%)
- Increased incidence of fetuses with cleft palate (4%)

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(Substance 4):

30 mg/kg bw/d

- Significantly lower uterus weights (20%)
- Significantly increased postimplantation loss (85%)
- Significantly decreased live fetuses/dam (30%)
- Significantly decreased fetal weights (52%) and placental weights (58%)
- Increased incidence of fetuses with cleft palate (25%) and brachydactyly (6 %)

(Substance 5):

60 mg/kg bw/d

- Significantly lower uterus weights (3%)
- Significantly increased postimplantation loss (100%)

[XXXXXXXXXX] 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 for the substances.

Sincerely,

Enclosures

5/11/11 2:15 PM

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