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January 28, 2011

8EHQ-0111-18248A
DCN:88110000132s

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Subject: Notice in Accordance with TSCA Section 8(e): Results of a Toxicity Study on [teratology study] with {}

Dear Sir/Madam,

{}, submits this letter under section 8(e) of the Toxic Substances Control Act (TSCA) to inform the U.S. Environmental Protection Agency (EPA) of the results of toxicity testing with an early stage experimental pesticide being screened for potential registration and development in the United States.

The subject study was conducted with {}, no CAS No. available. Details of the study are attached.

{ } understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy. { } has not made a determination at this time that any substantial risk of injury to human health or the environment is presented by the findings within the subject study.

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 substance.

If you have any questions with regard to this submission, please contact me at {}.

Sincerely,

{}

Attachments

Company Sanitized

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Study title: Preliminary teratology study in rats with _____

The following results should be reported in compliance with TSCA Section 8(e).

- (1) Dark red fluid adhesion in abdomen and suppressed body weight gain were observed in the 25 mg/kg and higher dose groups. Therefore, the NOEL in this study was 12.5 mg/kg.

(In the case of oral study with the dosing period shorter than 4 weeks, it is reportable when NOEL is below 200 mg/kg.)

- (2) Embryo-fetal mortality tended to be increased, and accordingly number of survival fetuses tended to be low in the 25 mg/kg group.

(Biologically or statistically-significant changes on embryo-fetal mortality and number of survival fetuses are reportable.)

- (3) Fetal body weight in the 25 mg/kg group was statistically lower than that in the control group.

(Biologically or statistically-significant changes on fetal body weight are reportable.)

- (4) Anogenital distance in male fetuses was reduced in the 25 mg/kg group.

(Biologically or statistically-significant changes on sexual differentiation are reportable.)

- Comments

Study methods:

Animals; BrlHan:WIST@Jcl(GALAS) rat, 7 pregnant animals/group

Dosage level; 12.5, 25, 50 and 100 mg/kg

Administration route; orally by gavage (vehicle: 0.5% MC)

Treatment period: Day 6-19 of gestation

Results:

In maternal animals, suppressed body weight gain was observed in the 25 mg/kg and higher dose groups. In the 100 mg/kg group, one animal was dead on day 14 of gestation and the other animals were euthanized during day 12 to 16 of gestation due to severe condition. In the 50 mg/kg group, administration was ceased on day 15 of gestation due to severe condition, and three animals were euthanized during day 15 to 19 of gestation. In the 25 mg/kg group, dark red fluid adhesion in abdomen was observed.

In embryo-fetuses, lower fetal body weight, reduced anogenital distance in male fetuses, tendency of increased embryo-fetal mortality and tendency of lower number of survival fetuses were observed in the 25 mg/kg group.