

MR#332400

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8EHQ-11-18239

**FEDERAL EXPRESS**

**REDACTED COPY**

January 12, 2011

8EHQ-0111-18239A  
DCN:88110000123s

U.S. Environmental Protection Agency  
EPA East Building  
Confidential Business Information Center  
Room 6428  
Attn: TSCA Section 8(e)  
1201 Constitution Avenue, NW  
Washington, DC 20004



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RECEIVED  
EPA  
MAIL

**Re: TSCA Section 8(e) Notice: 28-Day Oral (Diet) Toxicity Study in Mice with [redacted], a Substituted Benzamide, Seventh Submission**

Dear TSCA Section 8(e) Coordinator:

Syngenta Crop Protection, LLC requests that the specific chemical identity and code number shown in brackets in this letter be treated as Confidential Business Information. We enclose a redacted copy of this letter for the public file.

In accordance with EPA's March 16, 1978 policy on Section 8(e) reporting under the Toxic Substances Control Act, and EPA's June 1991 TSCA Section 8(e) Reporting Guide, Syngenta Crop Protection is bringing to your attention information from a 28-day oral (diet) toxicity study in mice conducted with the chemical substance [redacted]. This substance is known internally under the designation [redacted].

In this study groups of 5 male and 5 female Crl:CD-1 mice were fed diets containing 0, 100, 1000, or 1500 ppm of [redacted] for a period of up to 28 consecutive days. The overall mean achieved dosages were 0, 16, 149 and 231 mg [redacted]/kg/day for males and 0, 18, 158 and 219 mg [redacted]/kg/day for females. All animals were terminated and subjected to a detailed necropsy examination after the completion of 28 days of treatment.

Minimal to mild seminiferous epithelial degeneration of the testes was observed in males treated with 1000 and 1500 ppm. In males treated with 1000 ppm, inhibited spermiation (spermatid retention) was evident. In addition, minimal to moderate accumulation of exfoliated seminiferous epithelium and/or reduced sperm was observed in the epididymides of males treated with 1000 and 1500 ppm.

Group mean ovary weights were lower in females treated with 1500 ppm when compared with the controls. This decrease in ovarian weight was associated with a reduction in the number of corpora lutea.

**Company Sanitized**

On the basis of significant organ-specific changes in the testes/epididymides and ovaries, this study is considered to meet the technical criteria for referral.

Additional observations made during the study were a decrease in body weight in males, reduced body weight gain in males and females, and increased liver weights in animals treated with 1000 and 1500 ppm when compared with controls.

Increases in covariant liver weights:

	1000 ppm	1500 ppm
Male	+17%	+35%
Female	+53%	+64%

This increase in liver weight was associated with centrilobular hypertrophy and a number of changes in clinical chemistry parameters (ALP, AST, ALT, cholesterol, triglycerides and total protein).

The overall No Observed Effect Level (NOEL) for this study is considered to be 100 ppm, equivalent to 16 and 18 mg [ ]/kg/day for males and females, respectively, based on the liver findings in males and females, and testicular and epididymis findings in males at 1000 mg/kg/day and ovarian findings in females at 1500 ppm.

[ ] is a research and development compound being evaluated for pesticidal purposes. These evaluations are being conducted under the supervision of technically qualified personnel, knowledgeable in handling potentially hazardous chemicals.

Please contact the undersigned if you require additional information.

Sincerely,

*Melvin R. Witcher, Jr., CIH*

Melvin R. Witcher, Jr.  
TSCA Coordinator  
Syngenta Crop Protection