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March 22, 2011

This Report CONTAINS Confidential Business Information

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CONFIRMATION OF RECEIPT REQUESTED

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



SUBJECT: TSCA 8(e) SUBMISSION

Dear Sir or Madam:

( ) is submitting certain data which we believe to be reportable under TSCA 8(e). The information concerns isomer ( ), an experimental pyrethroid insecticide. isomer is identified by IUPAC as:

The CAS number assigned for this compound is

has imported for R&D on behalf of (" ").

The following reports concerning have been submitted to your agency: Two acute oral toxicity studies with rats (November 15, 2007: 8EHQ-07-16995 & 16996); a preliminary development toxicology study with rats (January 7, 2008: 8EHQ-08-17027); a micronucleus study with rats (February 19, 2008: 8EHQ-08-17081); an acute inhalation toxicity study in rats (July 11, 2007: 8EHQ-08-17209); a two week oral toxicity study in dogs (October 9, 2008: 8EHQ-08-17297); a micronucleus study with rats (February 16, 2010: 8EHQ-10-17866); an in-vivo unscheduled DNA synthesis (UDS) assay in rat hepatocytes (April 5, 2010: 8EHQ-10-17907); effects on pre- and postnatal development, including maternal function in rats (May 21, 2010: 8EHQ-10-17958); an in-vivo unscheduled DNA synthesis (UDS) assay in female rat hepatocytes (May 21, 2010: 8EHQ-10-17957); an acute oral toxicity study in rats (August 26, 2010); a thirteen week repeated dose oral (feeding) toxicity study in Wistar rats (8EHQ-10-18166); and a study for effects on pre- and postnatal development, including function administered orally to rats (February 21, 2011).

recently learned of new toxicological effects in acute oral toxicity studies of the cis and trans isomers in rats. Outlines of the following studies are listed below:

Acute oral toxicity study of \_\_\_\_\_ ( \_\_\_\_\_ ) in rats

Animals: Crl:CD(SD) rats, female, 8 weeks old, 3 animals/dose(50mg/kg: 2 animals)  
Body weight: 192 - 218 g  
Route of administration: Oral  
Dose levels: 50, 300 mg/kg  
Dosing volume: 10 mL/kg  
Vehicle: Corn oil  
Pre-dosing fast: about 20 hours  
Observation items: Clinical signs, Body weight, and Gross pathology  
Observation period: 3 days

Results:

LD<sub>50</sub> value (female): 50 - 300 mg/kg  
Mortality: No animals in the 50mg/kg died.  
All animals in the 300mg/kg died.  
Clinical signs: Besides the clinical sign described above, diarrhea and/or stains (around anus) were observed in the 50 and 300 mg/kg group.  
Body Weight: No treatment-related change was observed in the animals of 50 mg/kg group.  
Gross pathology: No treatment-related changes were observed in animals of the 50 mg/kg group. Red mucosa in the glandular stomach was observed in dead animals of the 300mg/kg group.

We believe that the neurotoxic signs noted are reportable under TSCA 8(e).

Acute oral toxicity study of \_\_\_\_\_ ( \_\_\_\_\_ ) in rats

Tremor was observed in female rats of the 300 mg/kg group.  
We judged to need this report, based on the criteria of clinical signs from the TSCA 8(e).

Animals: Crl:CD(SD) rats, female, 8 weeks old, 3 animals/dose  
Body weight: 198 - 212 g  
Route of administration: Oral  
Dose levels: 300 mg/kg  
Dosing volume: 10 mL/kg  
Vehicle: Corn oil  
Pre-dosing fast: about 20 hours  
Observation items: Clinical signs, Body weight and Gross pathology  
Observation period: 14 days

We believe that the NOEL and the neurotoxic signs are reportable under TSCA 8(e).

RESULTS:

LD<sub>50</sub> value (female) : >300 mg/kg  
Mortality: 1 of 3 animals in the 300mg/kg died.  
Clinical signs: Tremors diarrhea and stains (around anus) were observed in the 300 mg/kg group.  
Body Weight: No treatment-related changes were observed in survival animals of the 300mg/kg group.  
Gross pathology: No treatment-related changes were observed in survival animals of the 300mg/kg group. Red mucosa in the glandular stomach, and cannibalism of the head were observed in one dead animal of the 300mg/kg group.

We believe that the neurotoxic signs noted are reportable under TSCA 8(e).

**Substantiation of CBI Claims**

We wish to substantiate \_\_\_\_\_'s claims that certain information in this letter be treated as Confidential Business Information ('CBI'). All information which has been deleted from the sanitized version of this letter (copy attached) should be treated as CBI. In substantiation of this CBI claim, \_\_\_\_\_ wishes to protect its confidential business plan for the commercial development of this compound. Disclosure of this information would harm \_\_\_\_\_'s efforts to commercialize this compound. Please refer to the attached letter of March 17, 2010 to Mr. Edward Gross regarding substantiation of CBI claims.

If there are any questions on this submission please feel free to contact me at ( \_\_\_\_\_ ).

Yours sincerely,