MK# 341058

8EHQ-0112-16996J
89120000162S

8EHQ-07-16996

January 16, 2012 **This Report CONTAINS Confidential Business Information**

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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 , an experimental pyrethroid insecticide. is identified by IUPAC as:

The CAS number assigned for this compound is . 89120000162/S

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

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hepatocytes (May 21, 2010: 8EHQ-10-17957); an acute oral toxicity study in rats (August 26, 2010); and a thirteen week repeated dose oral (feeding) toxicity study in Wistar rats (8EHQ-10-18166).

recently learned of new toxicological effects in a 13week neurotoxicity (repeated oral feeding) study in rats. An outline of the study follows:

13-Week Neurotoxicity (Feeding) Study in Rats

was administered orally to rats daily by feeding in the diet at dose levels of 600, 2000 and 6000 ppm for 13 weeks.

Body weight effects were observed in males and females at 2000 and 6000 ppm. Therefore, the no observed adverse effect level (NOAEL) was 600 ppm, corresponding to an oral dose of 36.75 mg/kg/day in males and 40.50 mg/kg/day in females.

believes that the observed NOAEL that is below 100 mg/kg/day in a dosing period shorter than 3 months is reportable under TSCA 8(e).

Performing Laboratory:

Study methods:

Test substance:

Animals: RccHan™: WIST rats, males and females, 12 animals/sex/group

Animal age at initiation of treatment: Approximately 6 weeks (a minimum of 42 days)

Body weight range at initiation of treatment:

Males: 96.8 to 122.8 g, Females: 82.6 to 101.9 g

Administration route: Oral feeding in diet

Dose levels: 600, 2000 and 6000 ppm (corresponding to 36.75, 126.62 and 402.32 mg/kg/day for males and 40.50, 134.93 and 425.14 mg/kg/day for females)

Vehicle: Rodent maintenance diet

Treatment period: 13 weeks

Observation items: Clinical observations, detailed clinical observations, motor activity, functional observational battery, body weight, food consumption, ophthalmology, brain weight, necropsy, histopathological examination

Results:

Decreases in body weight and body weight gain were observed in males and females at 2000 and 6000 ppm.

Based on the above results, the NOAEL was established at 600 ppm, corresponding to 36.75 mg/kg/day in males and 40.50 mg/kg/day in females.

Substantiation of CBI Claims

We wish to substantiate 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. regarding substantiation of CBI claims.

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

Yours sincerely,

Encl.
cc: