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CODING FORMS FOR SRC INDEXING

Microfiche No.		
OTS0573991		
New Doc ID	Old Doc ID	
88000000079S	8EHQ-0100-14640S	
Date Produced	Date Received	TSCA Section
01/21/00	01/24/00	8E
Submitting Organization		
CONFIDENTIAL		
Contractor		
Document Title		
INITIAL SUBMISSION: LETTER TO USEPA SUBMITTING SUMMARY DATA ON ACUTE ORAL TOX OF PYRETHROID INSECTICIDE, [], IN MICE AND RATS, DATED 01/21/00 (SANITIZED)		
Chemical Category		
PYRETHROID INSECTICIDE (CONFIDENTIAL)		

A 02

INITIAL SUB-MISSION

A-03

8EHQ-0100-146405

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January 21, 2000 **SANITIZED OF TSCA Confidential Business Information**

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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 , a novel experimental pyrethroid insecticide identified as:

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

recently observed toxicological effects in three acute oral toxicity studies performed with rats and mice. Summarizations of these findings are as follows:

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Acute Oral Toxicity Study of in Rats

Animals:	Crj:CD-(SD) rats, male, 7 weeks old, 4 animals/dose
Doses:	100 & 300 mg/kg
Pre-dose fasting:	About 20 hours
Vehicle:	Corn oil
Dosing volume:	10 ml/kg
Body weight:	209-225 g
Observation period:	30 minutes and four (4) hours post-administration, and once daily for seven (7) days thereafter.

Summary: One out of four rats died in those receiving the dose of 100 mg/kg. All rats dosed with 300 mg/kg of died within one day after dosing. Therefore, the acute oral LD_{50} value for male rats was estimated to be 100 to 300 mg/kg. Tremor was observed in rats receiving either dose level. Urinary incontinence was observed in rats receiving 100 mg/kg.

Acute oral toxicity study of in rats

Animals:	Crj:CD-(SD) rats, male & female, 7 weeks old, 5 animals/sex/dose
Doses:	30, 100, & 300 mg/kg
Pre-dose fasting:	About 20 hours
Vehicle:	Corn oil
Dosing volume:	10 ml/kg
Body weight:	Males 187-209 g; females 145-167 g
Observation period:	30 minutes and four (4) hours post-administration, and once daily for seven (7) days thereafter.

Summary: No rats died in the 30 mg/kg dose level. Two males and three females died after being dosed with 100 mg/kg of . Five males and four females of the 300 mg/kg dose level died. All five males receiving the 300mg/kg died, and four of the five females receiving the same dose died. The deaths were discovered within one to three days after dosing. Therefore, acute oral LD_{50} value for male rats was estimated to be 100 to 300 mg/kg. For female rats, this value was estimated to be about 100 mg/kg. Rats receiving the 30 mg/kg dose were observed to excrete an oily substance. Those rats receiving the 300 mg/kg dose were observed to have tremors, ataxic gait, salivation, urinary incontinence and irregular respiration. Male rats receiving the 100 mg/kg dose were observed to have tremors and urinary incontinence. These same observations were made in male rats dosed with 300 mg/kg of . Female rats dosed with 100 mg/kg and those dosed with 300 mg/kg displayed signs of tremors, ataxic gait, and urinary incontinence.

Acute oral toxicity study of in mice

Animals:	Crj:CD-I (ICR) mice, male, 6 weeks old, 4 animals/dose
Doses:	30, 100, & 300 mg/kg
Pre-dose fasting:	About 20 hours
Vehicle:	Corn oil
Dosing volume:	10 ml/kg
Body weight:	25-29 g
Observation period:	30 minutes and four (4) hours post-administration, and once daily for seven (7) days thereafter.

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Summary: Although no mice died in the 30 and 100 mg/kg dose levels, all mice dosed with 300 mg/kg of were found dead within 4 hours after being given this dose. Tremors were observed in mice receiving all three dose levels. The LD_{50} value for male mice was estimated to be 100 to 300 mg/kg.

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 and the commercial development of this compound. Disclosure of this information would harm 's efforts to commercialize this compound. Please refer to separate letter regarding substantiation of CBI claims.

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

Yours sincerely,

, Ph.D, B.C.E.

Encl.
cc:

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