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January , 2004

SANITIZED of 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

~~COMPANY SANITIZED~~

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:

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

first submitted adverse findings (two separate oral toxicity studies with rats, and a single oral toxicity study with mice) on this substance to your Agency on (Document Control Number). A second report (Document Control Number) was submitted on (preliminary dose-range finding in non-pregnant rats & preliminary prenatal developmental toxicity in rats). A third report (acute inhalation in rats) was submitted on (Document Control Number not yet assigned). A fourth report (4-week repeated inhalation in rats) was recently submitted on (Document Control Number not yet assigned) A fifth and sixth report (acute dermal toxicity in rats and 90-day oral toxicity in rats, respectively) were submitted on October 21, 2003 (Document Control Numbers not yet assigned) .

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recently learned of observed toxicological effects in a subacute 90-day oral toxicity study performed with rats. Summarization of the findings are as follows:

28-day Rat Oral Toxicity Study of

Study conducted by:

(Reference No.)

Animals: SD rats, SPF male & female, 6 weeks old, 6 animals/sex/dose at initiation of study

Doses: 0 (basal diet only), 100, 300, 1000, and 1500 mg/kg in the diet

Administration: (Lot # ; . % purity) was administered in the diet.

Body weight: males: 92.7-123.3 g females: 84.6-114.4 g at the start of the study

Observation: The animals were monitored for signs of adverse effects from the test substance once daily for 28 days thereafter.

Examinations were : clinical signs, body weight, food consumption, urinalysis, ophthalmology, hematology, blood chemistry, organ weight, gross necropsy, and histopathology.

Certain adverse health effects were noted during the course of this study which Sumitomo believes to be reportable under TSCA 8(e). Specifically, clinical signs suggesting neurotoxicological effects (tremors) and focal or diffuse necrosis of liver cells were observed. Additionally, the calculated NOEL was lower than 200 mg/kg/day. See summary below for further details.

Summary: For the rats ingesting 1000 and 1500 mg/kg of the test substance in their diet, generalized tremor (6/6 males & 6/6 females) was observed from the beginning of dosing.

Focal necrosis of liver cells was found in 1 male in the 1000 mg/kg group, and in 1 female in the 1500 mg/kg group. Diffuse necrosis of liver cells was seen in 1 female in the 1500 mg/kg group.

Animals exposed to 1500 mg/kg of this substance died (3 males and 3 females, including 2 females sacrificed *in extremis*).

Nasal secretions were observed on rats dosed with 1000 mg/kg (1 male and 1 female) and 1500 mg/kg (1 male and 2 females).

No other clinical signs were observed during the course of this study.

The no-observed-effect level (NOEL) was calculated as follows:

Males: 300 mg/kg diet (29.20 ± 1.30 mg/kg/day)

Females: 300 mg/kg diet (33.40 ± 2.01 mg/kg/day)

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 efforts to commercialize this compound. Please refer to the attached copy of a letter to regarding substantiation of CBI claims.

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

Yours sincerely,

Encl.

cc: