

8EHQ-0500-13897s

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April 27, 2000

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Document Processing Center (7407)
(Attn.: Section 8(e) Coordinator)
Office of Pollution Prevention and Toxics
U. S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

PAR 35255
Company Sanitized

RE.: TSCA Section 8(e) Notice: R&D Pesticidal Chemical, CGA-362622, 8EHQ-0497-13897, Supplemental Submission

Substituted heterocycle amide

Dear Section 8(e) Coordinator:

Novartis Crop Protection, Inc. (Novartis), formerly a division of Ciba-Geigy Corporation (Ciba), requests that the specific chemical name and CAS number shown in brackets in this letter be treated as Confidential Business Information. We enclose a sanitized copy of this letter for the public file.

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Novartis submitted three previous 8(e) notices for this same chemical substance. The first, on October 24, 1997 reported effects from a rat oral teratogenicity study. The second, on December 10, 1997, reported effects from a subchronic oral toxicity study in rats. The third on December 30, 1998, reported effects from a subchronic oral toxicity study in beagle dogs.

In accordance with EPA's March 16, 1978 policy statement on Section 8(e) reporting under the Toxic Substances Control Act and EPA's June 1991 TSCA Section 8(e) Reporting Guide, Novartis wishes to bring to your attention certain preliminary findings from an 18-month mouse oncogenicity study (Study No. 971013) conducted in the laboratories of Novartis in Stein, near Basle, Switzerland, with the chemical substance, [

]. This substance, also known internally under the designation CGA-362622, may be referred to generically in the public file as "substituted heterocyclic amide." The CAS Registry Number is [].

In this study, CGA-362622 was administered in the diet to five groups of Tif:MAGf(SPF) mice with equal numbers (50, each) of males and females per dose group, for a period of 18 months. A



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total of 500 mice were used in this study and the nominal dietary levels per day were 0, 50, 200, 1000 or 7000 ppm, respectively.

Preliminary result from microscopic observations indicate a statistically significant increase in the incidence (18%, or 9/50) of bronchio-alveolar adenomas in the high dose (7000 ppm) females receiving CGA-362622. This incidence is slightly outside the historical control range (13.3%) in female mice. Increased incidence in bronchio-alveolar adenomas were not found in male mice. Additionally, increased incidence in bronchio-carcinomas were not found in either male or female mice.

CGA-362622 is a research and development compound being evaluated for pesticidal purposes. Some of these evaluations are being conducted in the United States, under the supervision of technically qualified personnel, knowledgeable in handling potentially hazardous chemicals.

In response to these findings, Novartis will do the following:

1. Notify persons working with this compound of the new findings in accordance with notification requirements of OSHA's Hazard Communication Standard (29 CFR 1910.1200).
2. Provide copies of the study final report after we receive them.

Please contact the undersigned if you require additional information.

Very truly yours,

A handwritten signature in cursive script that reads 'John Stone'.

John Stone, Ph.D.
Director
Safety and Health