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December 30, 1998

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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

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

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Dear Section 8(e) Coordinator:

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

Novartis submitted two 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.

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 information from the **draft report** of a 90-day subchronic dietary oral toxicity study in beagle dogs (Study No. 971011) 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." A CAS Registry Number has not yet been assigned.

In this subchronic oral toxicity study, CGA-362622 was administered in the diet to six groups of pedigreed beagle dogs with equal numbers (4, each) of males and females per dose group, for a period of at least 90 days. A total of 48 pedigreed dogs were used in the study and the nominal dietary levels per day were 0, 50, 500, 5000, 10000 or 20000 ppm, respectively. At the end of

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the treatment period, the animals were euthanatized and examined for various physiological parameters.

Results from the laboratory investigations of treated males and females were indicative of anemia (≥10000 and ≥5000 ppm), thrombopenia (≥10000 and ≥5000 ppm) and leukopenia (≥5000 and ≥5000 ppm), respectively. Treatment-related macroscopic changes included small testes (1 male at 10000 ppm) and large spleens (females at 5000 and 10000 ppm). In addition, absolute and relative weight decreases were also observed in thymus of both sexes at 5000 and 10000 ppm.

Microscopic changes were observed in treated males and females at≥5000 ppm and included myeloid hyperplasia of the bone marrow, extramedullary hematopoiesis in the liver, increased extramedullary hematopoiesis in the spleen, atrophy of the prostate gland, reduced spermatogenesis in the testes and increased atrophy of the thymus.

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. Modify the Material Safety Data Sheet to reflect these findings.

2. 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).

3. Provide copies of the study final report after we receive them.

Please contact the undersigned if you require additional information.

Very truly yours,

John Stone

John Stone, Ph.D.
Director
Safety and Health