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August 20, 1998

EXPRESS MAIL
RETURN RECEIPT REQUESTED

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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

COMPANY SANITIZED

RE.: TSCA Section 8(e) Notice: R&D Pesticidal Chemical, CGA-279233

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.

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 necropsy of goats in a goat metabolism nature of the residue in livestock study conducted in the laboratories of Novartis in Vero Beach, Florida with the chemical substance, [

]. This substance, also known internally under the designation CGA-279233, may be referred to generically in the public file as a heterocyclic polycyclicfuranone.

At necropsy, fluid was found in the uterine of test goats. No conclusion was reached for the cause of this finding.

CGA-279233 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.

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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)

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.

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Memorandum

To: Novartis
From: P. D. Moon, D.V.M.
Date: 08/03/1998
Subject: Goat necropsies of 7/30/98

Two goats were necropsied on the above date. The results are as follows:

Goat #1:

Cardiovascular: Normal.

Respiratory: Normal. Exsanguination appeared to be complete.

Urogenital: Uterus was filled with 1.6 liters of colorless slightly turbid fluid. Open. Uterine lining mildly hyperemic and inflamed. Kidneys and bladder normal.

Musculoskeletal: Normal.

Lymph system: Normal.

Gastrointestinal: Normal.

Integument: Normal.

Goat #2:

Cardiovascular: Normal.

Respiratory: Normal. Exsanguination complete.

Urogenital: Uterus contained 2.9 liters of colorless slightly turbid fluid. Open. Endometrium was slightly hyperemic. Walls of uterus thin and stretched. Ovaries normal. Kidneys and bladder normal.

Musculoskeletal: Normal.

Lymph system: Normal.

Gastrointestinal: Normal.

Integument: Normal.

Comments:

Samples of the uterine fluids from both goats showed a specific gravity of 1.005. Both samples were acellular, with notable absence of polymorphonuclear cells and bacteria.

The lesions should be termed hydrometra. Hydrometra is a lesion seldom encountered in domestic species. The cause of the hydrometra in these goats was not revealed by postmortem examination. In the interest of radiation safety, samples of the fluid and uterine tissue were not submitted to outside laboratories for examination and histopathology.

It is my opinion that the degree of endometritis observed was not sufficient to produce the copious quantities of hydrometra fluid observed, and that the degree of suspected inflammation observed may well have been the result of the fluid distention rather than the cause.

The University of Florida College of Veterinary Medicine Department of Pathology was consulted regarding these findings, but no common or likely etiology for hydrometra was ascertained.

Without the use of outside laboratories, especially for histopathology, no conclusion can be reached as to the cause of the hydrometra in the test subjects. A test group of only 2 goats cannot be the basis of statistically valid conclusion regarding the incidence of hydrometra in goats exposed to the test compound.

Nevertheless, hydrometra is an extremely unusual lesion, and the cause of the lesion in these animals is unclear. The presence of hydrometra in 2 of 2 test subjects is therefore striking. Toxicity of the compound cannot be ruled out from these findings. The presence of such an unusual lesion in both test subjects warrants further investigation.



Signature

8/13/58

Date