UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUL 11 1986

MEMORANDUM

SUBJECT: EPA File No. 275-12.
Gibberellic Acid (Gibberellin A3).
No Accession Number. Data Waiver Request for Chronic Feeding/Onco and Reproduction Studies.
Caswell No. 467

FROM: William S. Woodrow, Ph.D.
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Hazard Evaluation Division (TS-769C)

TO: Geraldine Werdig/B. Briscoe PM 50
Data Call-In Staff
Registration Division (TS-767C)

THRU: Albin B. Kocialski, Ph.D.
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ABK 7/8/86

Registrant: Chemical and Agricultural
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Action Requested:

According to the attached August 11, 1981 memorandum from Woodrow (scheme for human hazard evaluation of Gibberellins), which the Agency employs to designate gibberellic acid data requirements, any gibberellic acid used at 20 or less grams per acre (g/A) may be classed as a biochemical pesticide. A biochemical pesticide designation results in a requirement for Tier I biochemical toxicity data only. Registration of

gibberellins applied at more than 20 g/A involves submission of crop residue data; if such residue data show no increases in gibberellic acid above background levels, only Tier I Biochemical toxicity tests are required. If Tier I toxicity tests indicate hazard potentials, then Tier II biochemical testing would be required.

In summary, for specific gibberellic acid toxicity data base requirements (naturally occurring or synthetic g-acids that exactly duplicate a natural product):

1. Used at less than 20 g/A, toxicity data base incomplete:

   Perform Tier I toxicity tests
   (40 CFR Part 158.165 (c))

2. Used at more than 20 g/A, toxicity data base incomplete:

   a. Provide crop residue data. If residues are equal to or less than background gibberellic levels:

      Perform Tier I toxicity tests.

   b. Provide crop residue data. If residues are greater than background gibberellin levels:

      Perform Tier I toxicity tests using intended gibberellic application levels for animal dosing.

Recommendations:

The January 15, 1986 letter from Dr. Elizabeth M. Cozzi to Geraldine Werdig, Chief of the Data Call-In Program, stated that "since this study (a teratology study) has not been previously done, a teratogenicity study in one mammalian species is being initiated presently."

It should be pointed out that Woodrow's May 22, 1985 memorandum to Hoyt Jamerson of the Registration Division cited several toxicity studies that have not been previously done. At present, the Agency reiterates these data gaps for gibberellic acid (GA_3), that have not been previously submitted, or when submitted for evaluation, were found inadequate:

Required data (present data gaps for GA_3)

a. Primary eye irritation study

b. Primary dermal irritation study

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c. Studies to detect genotoxicity
A gene mutation test; such as an acceptable Ames Salmonella/reverse mutation assay.

A structural chromosome aberration test; such as a mammalian cell culture Sister Chromatid Exchange, or mouse heritable translocation test.

A test for other genotoxic effects; such as a microbial DNA damage and repair test.

d. An acute inhalation study

e. Teratogenicity study in one mammalian species.

f. The Agency still needs an acceptable 90 day feeding study [See Woodrow memo of 5/20/85 with regard to missing data parameters for rats (ie. hematology, clinical chemistry, urinalysis)]. This study was classified: Supplementary

Attachment