US ERA ARCHIVE DOCUMENT



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

JUL 2 2 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject:

I.D. No.: 129099. Imidacloprid. Evaluation of 6(a)(2) data on imidacloprid

Myra 5,0thtr

impurities.

Tox. Chem. No.

497E

PC Code No.

129099

DP Barcode Nos.

D222899, D222958

Submission Nos.

\$500234, \$500321

From:

Myron S. Ottley, Ph.D.

Section IV, Toxicology Branch I

Health Effects Division (7509C)

To:

Portia Jenkins/Dennis Edwards, Jr. (PM19)

Registration Division (7505C)

Through:

Marion P. Copley, D.V.M., D.A.B.T.

Section Head

Review Section IV, Toxicology Branch I

Health Effects Division (7509C)

cc:

Debbie McCall, RCAB, HED (7509C)

I. CONCLUSIONS

The submitted data do not alter the toxicity profile of currently registered imidacloprid technical or formulations, and a detailed review of these data are not warranted at this time.

II. ACTION REQUESTED

TB-1 received for possible evaluation acute toxicity and mutagenicity data on two imidacloprid impurities as follows:

| Document Title | MRID |
|--|----------|
| Submission Letter, dated November 8, 1995 | 43845100 |
| NTN 33893 (Proposed c.n. Imidacloprid). Toxicological Assessment of Qualitative and Quantitative Differences in the Range of By-Products in the Toxicology Sample and Commercial Grades of Active Ingredient | 43845101 |
| NTN 33893 CNS (Proposed c.n. Imidacloprid). Study for Acute Oral Toxicity in Rats | 43845102 |
| NTN 33893 AMP (Proposed c.n. Imidacloprid). Study for Acute Oral Toxicity to Rats | 43845103 |
| GAW 727 (NK7). Salmonella/Microsome Test | 43845104 |
| NTN 33893 AMP. Salmonella/Microsome Test | 43845105 |
| Nitroguanidine. Summary Assessment of Toxicological Data | 43845106 |
| Submission Letter, dated January 6, 1996 | 43906800 |
| NTN 33893 (Proposed c.n. Imidacloprid). Occurrence and Assessment of Quantitative Differences in the Range of Certain By-Products (PEDA, DIPEDA) in the Toxicology Sample and Commercial Grades of Active Ingredient | 43906801 |

III. RESULTS/DISCUSSION

The memo dated 1/25/96 indicates that two impurities (PEDA and DIPEDA) present in imidacloprid low concentrations have weak mutagenic potential. The data, however, show that the technical, when tested with the impurities present, did not exhibit mutagenic effects, regardless of the manufacturing process.

Acute toxicity is within the same order of magnitude for both the commercial grade and the toxicology samples of imidacloprid. Therefore, TB-1 has declined detailed review of these documents at this time because the data presented will not alter the toxicity profile (including RfD) of imidacloprid technical or its formulations currently registered.