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

OCT 14 1981

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: August 24, 1981

SUBJECT: EPA Reg.#201-279; 201-281; Bladex; teratology study; PP#9F2232; petition proposing a tolerance of 0.1 ppm for the pesticide, 2-[[4-chloro-6-(ethylamino)-5-triazin-2-yl]amino]-2-methyl-propionitrile, be established to cover negligible residues in or on soybeans CASWELL#188C Accession#243335

FROM: William Dykstra, Toxicologist
Toxicology Branch/HED (TS-769)

TO: Robert Taylor (25)
Registration Division (TS-767)

Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Recommendations:

1. The I.B.T. rabbit Bladex teratology study (No. 8580-11112) has been judged by the Agency to be invalid. The petitioner is required to submit teratology studies in two species to support the requested tolerance.

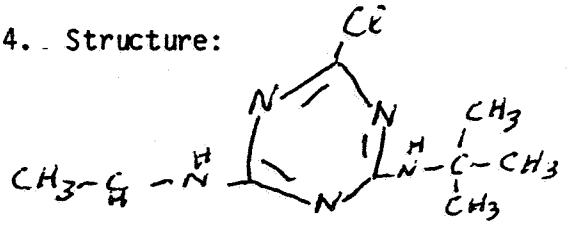
A. Substance Identification

1. Name: 2-[[4-chloro-6-(ethylamino)-5-triazin-2-yl]amino]-2-methylpropionitrile

2. Purity: >90%

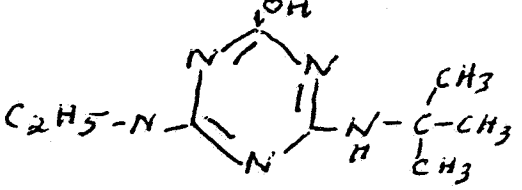
3. Synonyms: Bladex

4. Structure:

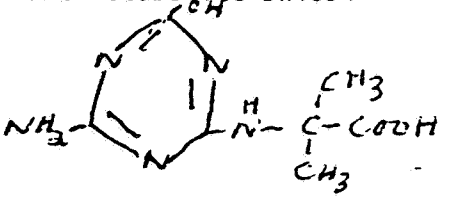


Bladex

Plant metabolite DW4385 +



Plant metabolite DW4394



B. Related Petitions: 9G0844, 0F0998, 3G1377, 5F1532, 5E1565, 5F1599, 6F1729

C. Tolerances established under 40 CFR 180.307.

D. Previously Submitted Toxicity Data

1. Memo of 3/15/71 from G. Whitmore in PP#0F0998

°2-year rat chronic/oncogenic study: oncogenic potential: negative; NOEL = 12 ppm
°2-year dog feeding study: NOEL = 50 ppm
°3-generation rat reproduction: NOEL = 80 ppm
°Major plant metabolite DW4394: 13-week rat feeding study; NOEL = 10,000 ppm (highest dose)
°Major plant metabolite DW4385: 13-week rat feeding study; NOEL = 10,000 ppm (highest dose)
°Acute oral (tech) = 334 mg/kg

2. Memo of 10/8/77 from D. Ritter in PP#6F1729

°Rabbit teratology: negative up to 3.2 mg/kg/day; IBT invalid
°Mouse dominant lethal assay: negative
°Host-mediated assay: negative
°Mouse bone marrow assay: negative

3. Memo of 5/11/77 from M. Rogoff regarding Nitrosamine action; Shell Bladex: No detectable amounts of nitroamine at a detection level of 1.0 ppm. Recommend that any registration or tolerance actions on subject pesticide which are held pending resolution of the nitroamine problem be released from such action moratorium.

E. Review:

1. Teratogenic study with SD 15418 Bladex technical in albino rabbits (IBT No. 8580-11112, 10/18/77)

Conclusion:

This teratology study has been determined to be invalid by the Agency.

Classification: Invalid

TS-769:th:TOX/HED:WDykstra:8-24-81:card 1