

121301

Date Out EFB: 06 OCT 1983

TO: T. Gardner/Heyward
Product Manager 17
TS-767

FROM: Dr. Richard Moraski
Acting Chief
Review Section No. 1
Exposure Assessment Branch
Hazard Evaluation Division



Attached please find the environmental fate review of:

Reg./File No.: 100-AGR

Chemical: Cyromazine

Type Product: Insecticide

Product Name: Larvadex

Company Name: CIBA-Geigy

Submission Purpose: Review response to previous EAB review

ZBB Code: Other

ACTION CODE: 111

Date in: 6/29/83

EFB # 3435

Date Completed: 10/6/83

TAIS (level II) Days

63

2

Deferrals To:

Ecological Effects Branch

Residue Chemistry Branch

Toxicology Branch

1.0 INTRODUCTION

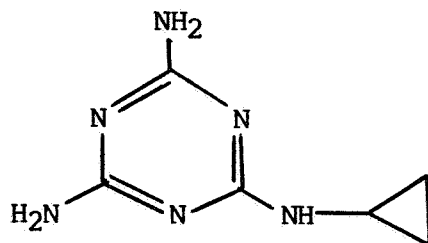
CIBA-Geigy has submitted a response to EAB review dated May 18, 1983. Previously, CIBA-Geigy submitted data in support of an application for registration of Larvadex (Cyromazine, as a. i.) for fly control in chicken manure. EAB review of these data is dated 10/1/82.

1.1 Chemical

Common name: Cyromazine

Chemical name: N-cyclopropyl-1,3,5-triazine-2,4,6-triamine

Chemical structure:



2.0 DIRECTIONS FOR USE

See EAB review dated 10/1/82 for use directions.

3.0 DISCUSSION OF DATA

EAB original comment will be presented, the registrant's reply will follow then the EAB response.

3.1 EAB comment: EAB noted an additional data gap. No adequate field dissipation study had been submitted. Since the laboratory leaching studies indicated that cyromazine had a potential to leach in sandy soils, the soil in the field study should be sampled to a depth sufficient to determine extent of leaching. The registrant should be informed that a field dissipation study determining field soil dissipation and leaching potential will be necessary as a condition of registration of cyromazine for the proposed use.

3.2 CIBA-Geigy reply: We believe that the data currently on file with the Agency addresses the above concerns relative to its (Cyromazine) soil dissipation and leaching potential. Specifically, your attention is directed to:

EPA Accession No.: 070914

Pages: 10-13 (stamped) (8 of 65 through 11 of 65)

20-27 (stamped) (18 of 65 through 25 of 65)

The data contained within the referenced document illustrate soil dissipation under field and laboratory conditions as well as leaching properties. Calculations have been presented, page 24 (stamped), which further indicate the remoteness of potential for soil accumulation and subsequent leaching resulting from application of manure. At five tons per acre, maximum Larvadex contribution would approach only 0.05 lbs. ai/acre. After soil incorporation of the manure, the limit of detection of current methodology aimed at finding Larvadex would become the critical factor and not leaching properties. In the case of Larvadex and its incidental inclusion in manure and in the absence of expanded uses, (the additional data requirement) seems to be an excessive requirement.

3.3 EAB response:

EAB agrees that the studies submitted in the referenced document provide adequate data on the soil dissipation and leaching potential of cyromazine under laboratory conditions. EAB disagrees with the registrant that the submitted studies provide sufficient data to describe the soil dissipation and leaching potential of cyromazine under field conditions. The only conclusion from the review of the studies relative to field leaching properties is the observation that no radioactivity was found below the 3 inch soil/manure layer in the field/greenhouse rotational crop study. (In this study, field (silt loam) soil was amended with chicken manure containing 5 ppm cyromazine at a rate of 20 tons per acre (soil concentration of 0.2 ppm cyromazine). After aging in the field for several months, the soil was removed and placed to a depth of 3 inches over untreated soil and maintained in the greenhouse.)

EAB could accept the argument that the limit of detection (0.05 ppm) of the analytical method will be the limiting factor in a field dissipation study and not the leaching potential of cyromazine. This acceptance would be based on the registrant's calculation that, if 5 tons per acre of manure are used and the treated manure contains 5.0 ppm cyromazine the concentration of cyromazine in the 0-3 inch layer of field soil would be about 0.05 ppm. At day 0 then soil concentration would be at the limit of detection of the analytical method. Determination of rates of decline or leaching potential would not be possible.

However, EAB has been informed that data have been submitted to the Agency which bring the toxicological safety of the metabolite of cyromazine, melamine, into question. Limited field/greenhouse soil dissipation data submitted to EAB indicate that cyromazine has a soil half-life of about 12 weeks (compared to about 1 year, based on the lab aerobic soil metabolism study). Melamine is the major (and only) identified soil degradation product of cyromazine.

Melamine appears to be stable in soil, has a potential to leach in sandy soils and has potential to be taken up by some rotational crops (namely, small grains) and remains as intact melamine within the plant. Residues of melamine could build up in soil from repeated yearly applications of manure containing cyromazine residues.

4.0 RECOMMENDATION

- 4.1 EAB objects to the registration of Larvadex (Cyromazine, as A. I) for use as a poultry feed-through pesticide for control of flies in manure. The chicken manure treated with cyromazine is intended for use as a soil amendment of fertilizer supplement. Dissipation of the soil degradation product of cyromazine, melamine, under field conditions has not been defined.
- 4.2 The registrant should be informed that a long term field dissipation study will be required to support the registration of Larvadex (Cyromazine, as A. I.). This requirement is based on the evidence that the toxicological safety of melamine, the soil degradation product of cyromazine, has been questioned. Data submitted to EAB indicate that melamine will persist in the soil, has potential to leach in sandy soils and has the potential to be taken up by some rotational crops. Residues of melamine could build up in soil from repeated applications of manure containing cyromazine residues.

This long term field dissipation study is necessary to evaluate the potential for the build up of the soil degradation product, melamine. The duration of this study need not exceed 3 years or extend two years beyond the length of the field dissipation study for field and vegetable crop uses. The soil should be sampled and analyzed for residues of cyromazine and its degradation product, melamine. The soil should be sampled to a depth sufficient to define the leaching potential of the degradation product, melamine.

The registrant should consult Section 164-5 of the Subpart N of the Guidelines for additional information on conducting this long term field dissipation study.

- 4.3 No rotational crop data have been submitted for a small grain crop which show a rotational crop interval wherein residues of melamine will not occur in the mature dry straw.



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