121301

Date Out EFB: 11 JUN 1984

TO: Tim Gardner
Product Manager 17
Registration Division
TS-767

FROM: Samuel Creeger, Chief
Review Section No. 1
Exposure Assessment Branch
Hazard Evaluation Division

Attached please find the environmental fate review of:

Reg./File No.: 100-AGR and -AGE

Chemical: Cyromazine

Type Product: Insecticide

Product Name: Larvadex

Company Name: CIBA-Geigy

Submission Purpose: Response to previous EAB review

ZBB Code: Other

Date in: 3/19/84

Date Completed: 6/7/84

ACTION CODE: 111

EFB # 4239-4240

TAIS (level II)	Days
61	3

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

XXXXXXX Toxicology Branch

1.0 INTRODUCTION

Ciba-Geigy has responded to the previous EAB review of the application for conditional registration of Larvadex (cyromazine, as a. i.) for fly control. Based on submitted data, EAB (review dated 10/6/83) stated that a long term field dissipation study will be required to evaluate the potential for the build up of the soil metabolite, melamine from repeated applications of manure containing cyromazine residues. Other data showed that (1) cyromazine degraded to melamine which does not degrade further and (2) melamine has a potential to leach. Added emphasis was placed on the need for this study (to determine potential ground water contamination) when it was discovered that melamine was a potential oncogen.

RD informed EAB that FDA had concluded that melamine was not an oncogen and requested EAB reconsider the need for the long term study.

After considering the RD request, EAB (memo dated 12/20/83) had no objection to conditional registration of cyromazine for use in chicken manure for fly control provided the registrant can show that melamine residues will not leach into the lower soil depths and contaminate ground water. This could be accomplished by either actual field data or data showing that concentrations of melamine residues will be below detection limits of an analytical method for melamine residues in soil.

NOTE TO PM: This review supersedes the previous draft of our notes on this issue forwarded earlier.

1.1 CHEMICAL

See previous EAB reviews for chemical data

2.0 DIRECTIONS FOR USE

See previous EAB reviews for directions for use.

3.0 DISCUSSION

EAB's original conclusion will be presented followed by CIBA's reply and EAB's response:

3.1 EAB conclusion: EAB has no objection to conditional registration of cyromazine for use in chicken manure for fly control provided the registrant can show that melamine residues will not leach into the lower depths of soil and contaminate ground water. This can be accomplished either by actual field data or data showing that the concentration of melamine residues will be below detection limits of an analytical method for melamine residues in soil.

3.2 CIBA Reply: An assessment addressing the potential for melamine residues to be found in groundwater is provided to EPA. This assessment was developed by use of the PESTAN model developed by EPA. This model suggests that melamine residues resulting from surface application (5 tons/acre) of manure from poultry fed Larvadex treated feed (5.0 ppm) would not be detectable in the soil 0-3" depth. At a distance of 6.4 feet below soil surface, using a worst case (Georgia sand) analysis, melamine would not be detected even if method sensitivity was 1.0 part per billion.

The worst case analysis clearly shows that the use of Larvadex and subsequent application (5 tons/acre) of manure from poultry fed Larvadex treated feed will not result in detectable melamine residues in groundwater. We believe that this information should adequately address EPA concerns for groundwater and that a field dissipation study is not needed.

CIBA PESTANS Assumptions

- 5 ppm in manure applied at 5 tons/acre-incorporated 0-3" = 0.05 lbs. ai/A.
- It is shown that there was 12% melamine metabolite in maure-soil at 6 months. At 6 months, 60% of the radioactivity applied to the soil-manure was left.
- Therefore 60 X 0.12 = 7.2% of applied radioactivity was melamine.
- 0.05 lbs. ai/A X 0.072 = 0.0036 lb. ai/A (equivalent to 0.003 ppm melamine in the soil.
- Analytical method limit of detection in soil is 0.05 ppm.

PESTAN RESULTS

1. Worst case Georgia sand.
2. Melamine would not be detectable below 6.4 feet.
3. Assuming aquifer is below 6.4 feet, no melamine detectable at 1 part per billion (ppb).

3.3 EAB RESPONSE

3.3.1 CIBA reports that with available analytical method for melamine the limit of dtection for residues in soil is 0.05 ppm (50 ppb). At this level of sensitivity, no melamine residues would be detectable in soil from the proposed chicken feed use (5 ppm cyromazine application with subsequent field application of 5 tons/acre of treated manure or 0.05 lb/A).

Using the PESTAN leaching model, CIBA concluded that melamine residues will not be detectable below the 6.4 foot depth and assuming aquifer is below 6.4 feet, no melamine detectable at 1 ppb.

3.3.2 EAB tested CIBA's conclusion using the Pesticide Root Zone Model* (PRZM, a leaching model more technically developed than PESTANS which models leaching through the soil root zone) using CIBA's input parameters. The simulation indicated that 1 part per billion (ppb) melamine will be present in the soil water at the six foot depth 3 months after application of cyromazine-treated manure (0.05 lb/A cyromazine or 5 ppm in manure applied at 5 tons/A or 0.0036 lb/A melamine).

From this PRZM simulation, EAB concludes that melamine residues in the soil water could contaminate ground water at the six foot depth, albeit at nondetectable levels. See Table 1.

3.3.3 In addition, EAB used the following different input parameters for another PRZM run:

1. The application of 0.05 lb/A ~~of~~ cyromazine equates to 0.05 lb/A (or 0.055 kg/ha) application of melamine. Application was made yearly in April for 5 years. This value is based on the fact that cyromazine degrades to melamine which appears to not further degrade.

2. The degradation rate coefficient is 0.00004/hr. This value is based on a 2 year half-life and the fact that degradation is slower at deeper soil depths.

---

* The Pesticide Root Zone Model (PRZM): A Procedure for Evaluating Pesticide Leaching Threats to Ground Water. R. F. Carsel, et al. Submitted to Environmental Science and Technology.

This simulation indicates that within a year after application, melamine soil water concentration will be greater than 5 ppb and less than 10 ppb at the 16 foot depth. See Table 2.

From this simulation, EAB concludes that within one year after application melamine residues in soil water could contaminate ground water at the 16 foot depth or less depth, albeit at non-detectable levels.

3.3.4 A PESTANS simulation using the same changed imput parameters (in 3.3.3, above) plus a changed soil density value to 1.3 gm/cc) indicated that:

- After 13 months, a peak level of 0.46 ppb melamine residues would be present at depth of 14.7 feet. Residues of 0.033 ppb would be present as far down as 55 feet after one year.

- After 26 months, a peak level of 0.094 ppb melamine residues would be present at depth of 25.7 feet. Resisues of 0.014 would be present as far down as 62.3 feet after 26 months. See Table 3.

4.0 CONCLUSION

4.1 The registrant has taken the position showing that residues of melamine in soil at depths greater than 6.4 feet will be below the reported limit of detection of the analytical method for melamine residues in soil.

4.2 The PRZM simulations (above) indicate that leaching of melamine residues could occur and contaminate groundwater even though the level of residues will be below the limit of detection for the analytical method.

However, leaching of more residues could occur in the event that cyromazine-treated manure is applied to the same field over several years; it is applied to soils of greater porosity than represented here; a higher recharge occurs; slower degradation occurs and more melamine can be formed from the degradation of the remaining cyromazine.

4.3 EAB defers to Toxicology Branch as to an assessment of the risk from ground water contamination at the predicted levels of 1-10 ppb melamine.

5.0 EXECUTIVE SUMMARY

5.1 EAB concludes that requiring a long term field monitoring study is not scientifically defensible because calculated levels of melamine residues are below the reported limit of detection of the analytical method.

5.2 However, leaching of melamine residues to ground water can occur albeit at non-detectable levels.

5.3 EAB defers to Toxicology Branch as to an assessment of the risk of exposure to ground water contaminated at the predicted levels of 1 to 10 ppb melamine.

NOTE TO PM: As mentioned in the introduction, this review supercedes the previous draft of our notes on this issue forwarded earlier.

S. Creeger for Clint Fletcher

Clinton Fletcher
Review Section No. 1
Exposure Assessment Branch
Hazard Evaluation Division