

# Residue Chemistry Review

2/8/1995

**Comments:**

**Subject:** New Chemical- Fipronil in/on Corn RACs. Amendment of 1/31/95. MRID#s none. Case 285247. CBTS# 15054.

**Document**

**Class:**

**Product**

**Chem:**

**Residue** 860.1200 Directions for use

**Chem:** 860.1550 Proposed tolerances

**Biochemicals:**

**DP Barcode:** D211470

**MRIDs:**

**PC Codes:** 129121 1H-Pyrazole-3-carbonitrile, 5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-((trifluoromethyl)sulfi

**Actives/Inerts**

**CAS #:** 120068-37-3

**Commodities:** Corn

**Administrative** 3G04263

**#:**

**Reviewers:** G. F. Kramer

**Review** Philip V. Errico

**Approved on:** February 8, 1995

**Approver:**

**WP Document:**  - Fipronil\_012.wpd

# MEMORANDUM

SUBJECT: PP# 3G04263. New Chemical- Fipronil in/on Corn RACs.  
Amendment of 1/31/95. MRID#s none. Barcode D211470.  
Case 285247. CBTS# 15054.

FROM: G.F. Kramer Ph.D., Chemist  
Tolerance Petition Section III  
Chemistry Branch I, Tolerance Support  
Health Effects Division (7509C)

THRU: P.V. Errico, Section Head  
Chemistry Branch I, Tolerance Support  
Health Effects Division (7509C)

TO: Rebecca Cool, Acting Product Manager  
Daphne Waldo, Team 10 Reviewer  
Registration Division (7505C)

Rhône-Poulenc has submitted an application for an EUP and temporary tolerances for the insecticide fipronil (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile) and its metabolites MB46136 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfonyl]-1H-pyrazole-3-carbonitrile) and MB45950 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)thio]-1H-pyrazole-3-carbonitrile) on/in corn. The petitioner has proposed the following tolerances for corn RACs (expressed as parent plus metabolites MB45950 and MB46136):

|                    |   |          |
|--------------------|---|----------|
| Corn, Field, Grain | - | 0.02 ppm |
| Corn, Forage       | - | 0.05 ppm |
| Corn, Fodder       | - | 0.07 ppm |

The current amendment addresses deficiencies identified in CBTS previous review (Memo G. Kramer 6/7/94).

In the Detailed Considerations section of this Memo, the outstanding deficiencies, listed as presented in the Memo of G. Kramer (6/7/94), are followed by the petitioner's response and our conclusions.

## RECOMMENDATIONS

CBTS will recommend in favor of the proposed temporary tolerance for fipronil and its metabolites MB46136 and MB45950 on field corn grain provided the registrant submits revised Section F as detailed in conclusion 3.

**Note to PM:** The registrant was contacted by phone on 2/8/95 and informed of the deficiencies in Section F. They indicated that a revised Section F would be faxed to RD as soon as possible.

### CONCLUSIONS

1. With the exception of the grain feeding restriction, Section B has been revised as requested. The registrant argues that this feeding restriction is not needed as the residues of fipronil and metabolites MB45950 and MB46136 were <0.01 ppm in all grain samples from the field trials. CBTS also notes that in grain from the processing study treated at 20X, the residues of fipronil and metabolites MB45950 and MB46136 were also <0.01 ppm. Based on limited number of acres involved and the minimal potential for residues in grain, CBTS is willing to accept the revised label.

2. The petitioner is now proposing the following tolerances for corn RACs (expressed as parent and/or its metabolites MB45950 and MB46136): Corn, Field, Grain - 0.02 ppm. Due to the feeding restrictions on the label, tolerances for stover and forage are not necessary for this EUP.

3. The tolerance expression has not been revised as requested. Tolerances should be proposed for "fipronil or its metabolites MB45950 or MB46136." Also, the chemical names of fipronil and its metabolites MB45950 and MB46136 are not included in the revised Section F. The revised Section F should thus contain the chemical names of fipronil, MB45950 and MB46136.

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### DETAILED CONSIDERATIONS

#### Deficiency - Conclusion 2b (from Memo, G. Kramer 6/7/94)

2b) The directions for use are not adequate for this EUP. The registrant should add the following restrictions to the label: 1) "Do not plant any rotational crops except corn in treated fields within one year of fipronil application," 2) "Do not apply to sweet corn or pop corn," 3) "Do not feed treated corn grain, silage or stover to livestock," 4) "After grain harvest, plough under all remaining plant material" and 5) "Grain is to be used only for processing into corn by-products." A revised Section B is required.

**Petitioner's Response:** The registrant has added the following restrictions to the label: 1) "Do not plant any rotational crops except corn in treated fields within one year of fipronil application," 2) "Do not apply to sweet corn or pop corn," 3) "Do not feed treated silage or fodder to livestock," 4) "After grain harvest, plough under all remaining plant material." The registrant argues that a feeding restriction for grain is not practical and is not needed. The residues of fipronil and metabolites MB45950 and MB46136 were <0.01 ppm in all grain samples from the field trials. Also, the EUP acreage has been reduced by 76% to 242 acres.

**CBTS' Conclusion:** With the exception of the grain feeding restriction, Section B has been revised as requested. The registrant argues that this feeding restriction is not needed as the residues of fipronil and metabolites MB45950 and MB46136 were all <0.01 ppm in all grain samples from the field trials. CBTS also notes that in grain from the processing study treated at 20X, the residues of fipronil and metabolites MB45950 and MB46136 were also <0.01 ppm. Based on limited number of acres involved and the minimal potential for residues in grain, CBTS is willing to accept the revised label. This deficiency is now resolved.

**Deficiency - Conclusion 9b (from Memo, G. Kramer 6/7/94)**

9b) The registrant has proposed tolerances in grain and forage based on the sum of the LOQ of each metabolite as the observed residues were below the LOQ. In the case of fodder, the actual residue levels were used for MB46136. However, if tolerances are proposed for fipronil or its metabolites, then the LOQ can be used for the tolerances. Also, due to the feeding restrictions on the label, tolerances for stover and forage are not necessary for this EUP. The registrant should thus propose a tolerance for "fipronil or its metabolites MB45950 or MB46136" of 0.02 ppm in/on Corn, field, grain. **A revised Section F which includes these tolerances is required for this EUP.** This revised Section F should also contain the chemical names of fipronil, MB45950 and MB46136.

**Petitioner's Response:** The petitioner is now proposing the following tolerances for corn RACs (expressed as parent and/or its metabolites MB45950 and MB46136):

Corn, Field, Grain - 0.02 ppm

**CBTS' Conclusion:** The tolerance expression has not been revised as requested. Tolerances should be proposed for "fipronil or its metabolites MB45950 or MB46136." Also, the chemical names of fipronil and its metabolites MB45950 and MB46136 are not included in the revised Section F. **This deficiency remains outstanding.**

cc: PP#3G4263, Kramer, circ., R.F.

RDI: P.V. Errico (2/8/95), R.A. Loranger (2/8/95), E. Zager  
(2/8/95)

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