

US EPA ARCHIVE DOCUMENT

Residue Chemistry Review

10/10/95

Comments:

Subject: Fipronil in or on Corn and Animal RACs. Amendment of 9/8/95. MRID#s 437601-01 & 437614-01. CBTS#s 16176, 16135 & 16200.

Document Class:

Product

Chem:

Residue

Chem:

860.1200 Directions for use
860.1340 Residue analytical method
860.1550 Proposed tolerances

Biochemicals:

DP Barcode: D218849, D218954, D219160

MRIDs: 43760101, 43761401

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; Cattle, Fat; Cattle, Kidney; Cattle, Liver; Cattle, Meat; Milk; Egg; Poultry, fat; Poultry, Liver; Poultry, Meat

Administrative #: 5F04426

Reviewers: G. F. Kramer

Review Approver: Bart Suhre

Approved on: October 10, 1995

WP Document:  - Fipronil_023.wpd

MEMORANDUM

10/10/95

SUBJECT: PP# 5F04426. Fipronil in or on Corn and Animal RACs. Amendment of 9/8/95. MRID#s 437601-01 & 437614-01. Barcodes D218954, D218849 & D219160. CBTS#s 16176, 16135 & 16200.

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

THRU: F.B. Suhre, Acting Section Head
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

TO: Rick Keigwin, Product Manager
Ann Sibold, Team 10 Reviewer
Registration Division (7505C)

And

Karen E. Whitby, Ph.D., Acting Section Head
Registration Section, RCAB
Health Effects Division (7509C)

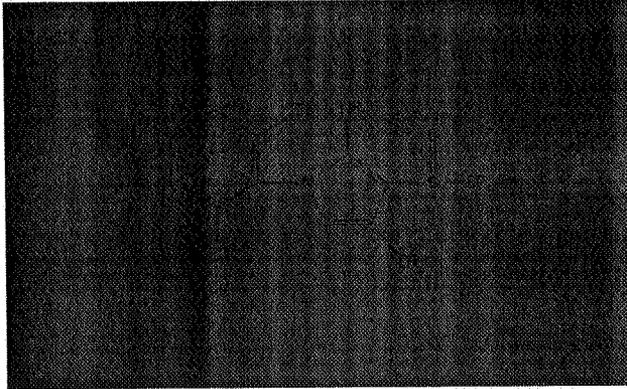
Rhône-Poulenc has submitted an application for permanent tolerances for the insecticide fipronil (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile) or its metabolites MB46136 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfonyl]-1H-pyrazole-3-carbonitrile) or 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 and animal RACs (expressed as parent or metabolites MB45950 or MB46136):

Corn Grain	--	0.02 ppm	Corn Fodder	--	0.15 ppm
Corn Forage	--	0.15 ppm	Liver*	--	0.02 ppm
Milk*	--	0.02 ppm	Eggs	--	0.02 ppm
Fat*	--	0.08 ppm	Poultry Skin/Fat	--	0.03 ppm
Muscle*	--	0.02 ppm	Poultry Muscle	--	0.02 ppm
Kidney*	--	0.02 ppm	Poultry Liver	--	0.02 ppm

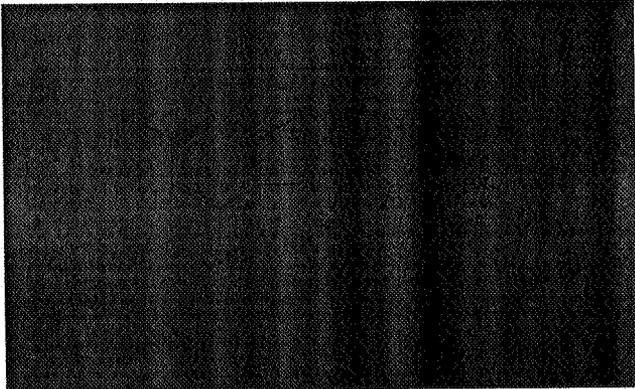
of Dairy Cows

The current amendment addresses some of the deficiencies pertaining to product chemistry and analytical methodology identified in CBTS's previous review (Memo, G. Kramer 7/25/95).

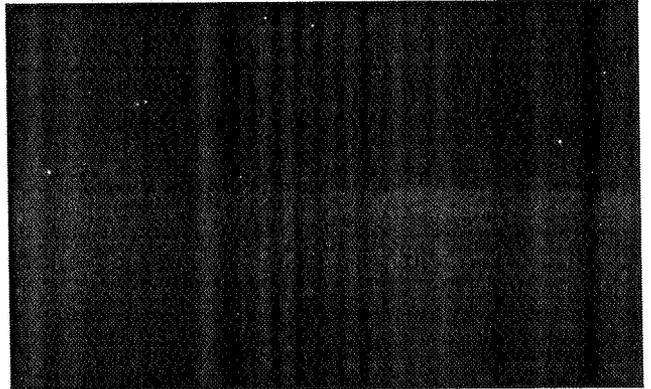
The structures of fipronil and its metabolites MB45950 and MB46136 are shown below:



Fipronil



MB46136



MB45950

RECOMMENDATIONS

CBTS continues to recommend against the proposed tolerances for fipronil in/on corn and animal RACs for reasons detailed in conclusions 1a.i, 1a.ii, 2a, 2b, 3, 5b, 5c, 6e, 7d, 7e, 8b, 10c, 10d, 11b, 12b, 12c and 13b of the Memo of G. Kramer (7/25/95); in conclusion 3 of the Memo of G. Kramer (8/30/95) and in conclusion 1 below.

CONCLUSIONS

1. The testing of the stability of the TGAI employed only one metal ion. In order to fulfill the requirements of GLN § 63-13, at least one more ion should be tested. Also, the submission of legible thermograms for each metal tested is required.
2. The proposed enforcement method has been revised as requested and analytical standards have been submitted to the Pesticide Repository.

DETAILED CONSIDERATIONS

Deficiency - Conclusion 1a.iii (from Memo, G. Kramer 7/25/95)

1a. iii) for GLN § 63-13, submit data on the sensitivity of the TGAI to metal ions and legible thermograms for each metal tested.

Petitioner's Response: Submission of MRID# 437614-01 in which the stability of fipronil to ferric ions was investigated. Fipronil was found to be unstable in the presence of this ion at temperatures above 100 °C.

CBTS's Conclusion: The testing of the stability of the TGAI employed only one metal ion. In order to fulfill the requirements of GLN § 63-13, at least one more ion should be tested. Also, the submission of legible thermograms for each metal tested is required. **This deficiency remains outstanding.**

Deficiency - Conclusion 7b (from Memo, G. Kramer 7/25/95)

7b. The method has been validated by ACL (Memo, G. Kramer 3/28/95). Acceptable recoveries were obtained for fipronil, MB45950, MB46136, RPA105048 and RPA200766. The LOQ for each compound is 0.01 ppm in grain and 0.02 ppm in forage and fodder. The registrant should submit a revised version of the proposed analytical enforcement method specified in conclusions 1-3 of Memo, G. Kramer (3/28/95). Analytical standards of fipronil and its metabolites should be sent to the EPA Repository, RTP. Until the receipt of the standards and the revised method, the requirements for analytical enforcement methodology will remain unfulfilled.

Petitioner's Response: Submission of MRID# 437601-01 in which the analytical method was revised to include the comments made by ACL and a letter from the registrant to the Pesticide Repository verifying the submission of the analytical standards.

CBTS's Conclusion: The proposed enforcement method has been revised as requested and analytical standards have been submitted to the Pesticide Repository. This deficiency is now resolved.

cc: PP#5F04426, Kramer, Circ., R.F., B. Madden (RCAB)
RDI: F.B. Suhre (10/6/95), R.A. Loranger (10/6/95), M.S. Metzger (10/6/95)
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