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PP # 4450

PC
121301



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MAY 3 1995

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#5E4450, Evaluation of Analytical Method and Residue Data. Cyromazine in/on Imported Mangoes. Chemical# 121301, DP Barcode: D212706, CBTS#: 15211, MRID#:434703-01-08

FROM: William D. Cutchin, Chemist *William D. Cutchin*
Chemistry Branch I: Tolerance Support
Health Effects Division (7509C)

THROUGH: Robert Quick, Section Head *Robert Quick*
Chemistry Branch I: Tolerance Support
Health Effects Division (7509C)

TO: George LaRocca
Product Manager 13
Fungicide-Herbicide Branch
Registration Division (7505C)

Ciba Crop Protection Division, Ciba-Geigy Corp. requests the establishment of a tolerance of 0.3 ppm in/on imported mangoes from Mexico for the combined residues of the insecticide/insect growth regulator cyromazine (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine) and its metabolite melamine (1,3,5-triazine-2,4,6-triamine) calculated as cyromazine. Tolerances have been established for cyromazine in/on other RACs: celery at 10 ppm, curcurbit vegetables at 2 ppm, and leafy vegetables (except brassica) at 10 ppm (40 CFR §180.414).

No Registration Standard for cyromazine has been issued.

Conclusions

1. The product chemistry of cyromazine and its metabolite melamine have been adequately described. A CSF is included in this petition. No further data is required for this proposed use.

2. The proposed use directions in Section B are adequate. No further changes are required for this proposed use.
3. The metabolism of cyromazine in plants has been described in detail. No further data is required for this proposed use. Based on data from other crops, the residues of concern are cyromazine and its metabolite, melamine. Total residues are expressed as parent.
4. There are no known animal feed stock uses for mangoes. No animal metabolism data are necessary for this proposed use.
5. Adequate enforcement methods for cyromazine and melamine are in PAM II. The method used here has been approved for publication for enforcement purposes, but has not as of this time appeared in PAM II. No further methodology is necessary for this proposed use.
6. Cyromazine is recovered by published multiresidue methods. Melamine is not recovered by those methods. This is not a deficiency for this proposed use.
- 7a. There are sufficient residue data to support the proposed use. Residues of cyromazine and melamine are not expected to exceed the proposed 0.3 ppm tolerance in/on mangoes. Additional residue data are not required for this proposed use.
- 7b. These studies were conducted entirely outside of the U.S. However, they were conducted in compliance with Swiss GLPs. These standards are comparable with EPA's GLPs.
- 7c. The geographic diversity of the studies in this petition are adequate to represent the mango growing regions of Mexico.
8. There were sufficient storage stability data presented with this petition. No further data is necessary for this proposed use.
9. There are no known animal feed stock uses for mangoes. Consequently, secondary residues in meat, milk, poultry, and eggs are not expected to be a problem.
10. Analytical standard materials for cyromazine and melamine are available.
11. There are no Codex, Canadian or Mexican limits established for residues of cyromazine or melamine in or on mangoes. The establishment of a 0.3 ppm tolerance for the combined residues of cyromazine and melamine, expressed as parent, in/on mangoes will create no compatibility problems.

Recommendations

TOX considerations permitting, CBTS recommends the establishment of the proposed cyromazine tolerance of 0.3 ppm in/on mangoes. A DRES run can be initiated at this time.

A footnote should be inserted into 40 CFR § 180.414 with the statement, "There are no U.S. registrations for mangoes as of (insert date)."

Detailed Considerations

Manufacture and Formulation

The product chemistry of cyromazine has been adequately described (PP#9G2230, 11/14/79 and PP#5F3177, 2/13/85). Included in this petition is a CSF for Trigard® 75 WP. No further data is required for this proposed use.

Proposed Use

The proposed use directions, Section B, are adequate. The Spanish label and an English translation are provided. The proposed use directions state that the product is to be applied to mangoes starting when the fruits are 1 inch long. The product is applied at a rate of 20-25 g (15-18.75 g ai)/100 L at a volume of 500 L/ha. Including a feed attractant, hydrolyzed protein, in the spray is recommended to encourage consumption of the product by larvae. The product may be applied up to a maximum of 5 times per season at 15 day intervals with a 15 day PHI.

Nature of Residue - Plants

The nature of the residue of cyromazine in plants is adequately understood. The metabolism of cyromazine has been studied in celery, head lettuce, and tomatoes (PP#5G3176, 2/4/85; PP#5F3180, 3/20/85; and PP#6F3329, 1/28/87). The residue of concern is cyromazine, per se, and its metabolite melamine. No further data is required for this proposed use.

Nature of Residue - Animals

There are no known animal feed stock uses for mangoes. Animals are not allowed to graze in mango orchards nor are parts of the plant used as supplemental feeds after processing. Animal metabolism data are neither submitted nor necessary for this proposed use.

Analytical Methods - Enforcement MRID#:434703

The Ciba-Geigy Method AG-408 is referenced in the petition as the enforcement method. No copy of the method was included in the petition. Samples are extracted by refluxing with aqueous methanol. An aliquot of the extract is evaporated until only water remains. The sample is diluted in 0.1 N HCl and partitioned with CH₂Cl₂ and hexane. The sample is cleaned up by cation exchange chromatography followed by an amino exchange cartridge. Both analytes are quantitated by HPLC with a two column switching system

and UV detector.

The method, Ciba-Geigy AG-408, has been approved as an enforcement method (PP#6F3329, 1/28/87). Adequate methods are available in PAM II for enforcement purposes (PP#1F4016, 12/9/92). No further methodology is necessary for this proposed use.

Analytical Methods - Multiresidue MRID#:434703

Multiresidue methods data indicate the recovery of cyromazine via FDA Multiresidue Protocol III while no recovery of melamine via any of the multiresidue methods was accomplished (PP#1F4016 & 2F4053, 7/16/93). No further methodology is necessary for this proposed use.

Magnitude of Residue MRID#:434703

Data from six field studies conducted in Mexico were presented here. In each test the maximum use rate of 25 g (18.75 g ai)/100L and 500L/ha was sprayed 5 times at 15 day intervals over the growing season for the maximum use rate of 625 g/ha/season. With the exception of study 1065/93 in Veracruz, samples from each study site were taken at 0, 7, 14, 21, and 28 days after the final application. Samples from study 1065/93 in Veracruz could not be collected after 21 days due to a lack of mature fruit. Control samples were collected from an untreated plot by hand from the top, middle, and bottom of four trees, a total of 12 fruit. Treated samples from the top, middle, and bottom of eight trees were collected for each sampling date, a total of 24 fruit. All of the samples were placed directly into sampling bags and frozen. None were subject to post-harvest treatment (washing, wiping, etc.) that would be typical of marketable fruit. The samples were prepared at the laboratory by separating the fruit from the stone, homogenizing the fruit and discarding the stone. The fruit was then placed in polyethylene bags and returned to the freezer for later analysis.

The analytical part of the residue studies was performed by Ciba-Geigy AG, Basel, Switzerland. The limit of quantitation (LOQ) for cyromazine and melamine was 0.05 and 0.10 ppm respectively. Limits of detection were 0.03 and 0.05 ppm for parent and metabolite respectively. Residues of cyromazine ranged from 0.04 (NQ) to 0.25 ppm on day 0 samples to <0.03 (ND) to 0.10 ppm on day 28. No melamine residues were found on any sample <0.05 ppm (ND). All control samples were ND for both cyromazine and melamine. Fresh recoveries for fruit fortified with 0.05 or 0.25 ppm cyromazine ranged from 84 to 98%, averaging 93%. Fresh recoveries fortified with 0.10 or 0.50 ppm melamine ranged from 76 to 89%, averaging 83%.

Chromatograms from control, samples, and fortifications, as well as standard curves were provided with the petition. The data presented here is sufficient to support the requested tolerance.

Geographic Representation

The petitioner has requested the tolerance be established on mangoes from Mexico. The studies presented were in Veracruz (2), Sinaloa (2), and Nayarit (2) which represent east and west coast regions of southern Mexico. The geographic diversity of the studies presented here are sufficient to represent the area requested by the petitioner.

Storage Stability

The longest harvest-to-analysis time for fruit in these residue studies was 6 months. The interim storage stability data presented here on mangoes was adequate to cover that interval. Stability data for 12 months will be available at a later date. Cyromazine recoveries were 94% for a 6 month storage interval. Melamine recoveries were 95% for the same interval. The storage stability data presented here is sufficient to support the residue data. No further data is necessary for this proposed use.

Meat, Milk, Poultry, and Eggs

Mangoes or mango by-products are not used for animal feed stock. No food stock residue data are necessary for this proposed use.

Other Considerations

An International Residue Limit Sheet is attached to this review. (Attachment 1). No Codex, Canadian or Mexican limits have been established for residues of cyromazine in or on mangoes. The establishment of a 0.3 ppm tolerance for cyromazine in/on mangoes will create no compatibility problems.

Attachment: International Residue Limit Sheet

cc: RF, PP#5E4450, circ., Cutchin, SAB (B. Doyle)
7509C: CBTS, Reviewer (WDC), CM#2, Rm 804P, 305-7990, WDC:5/3/95
R/I: Sec. Head: R. Quick, 4/28/95; Br. Sr. Sci.: R. Loranger,
5/1/95; Br. Chief: E. Zager, 5/2/95

Attachment:

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INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Cyromazine

CODEX NO. 169

CODEX STATUS:

No Codex Proposal
Step 6 or Above

Residue (if Step 8): _____

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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PROPOSED U.S. TOLERANCES:

Petition No. 5E4450

DEB Reviewer Cutchin

Residue: Cyromazine and
melamine (expressed as parent)

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
Mango	0.3

CANADIAN LIMITS:

No Canadian Limit

Residue: _____

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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MEXICAN LIMITS:

No Mexican Limit

Residue: _____

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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NOTES

Form Revised 1989

JWC 4/21/95

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R061935

Chemical: Gentamicin; Cyromazine

PC Code: 006324; 121301

HED File Code: 11500 Petition Files Chemistry

Memo Date: 05/21/2003 12:00:00 AM

File ID: DPD220862; DPD222421; DPD211362; DPD211399; DPD211413; DPD218030;
DPD220856; DPD228418; DPD242798; DPD242799; DPD242801; DPD242802;
DPD236184; DPD236189; DPD236190; DPD236187; DPD236185; DPD212706

Accession Number: 412-04-0136

HED Records Reference Center
06/28/2004