4-22-96

MEMORANDUM

SUBJECT: PP#4G04323 - Thiazopyr (MON 13200) in/on Peanuts and Tree Nuts. Amendment dated 6/2/95.
[No MRID #]
(CBTS #15722; Barcode #D216386; Chemical #129100; PRAT Case #285388)

FROM: Nancy Dodd, Chemist
Tolerance Petition Section II
Chemistry Branch I- Tolerance Support
Health Effects Division (7509C)

THROUGH: Edward Zager, Acting Chief
Chemistry Branch I- Tolerance Support
Health Effects Division (7509C)

TO: Joanne Miller/Eugene Wilson, PM Team #23
Fungicide-Herbicide Branch
Registration Division (7505C)

and

Debbie McCall, Acting Section Head
Registration Section
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Monsanto Company has submitted an amendment to PP#4G04323, which proposed temporary tolerances for residues of the herbicide thiazopyr [3-pyridinecarboxylic acid, 2-(difluoromethyl)-5-(4,5-dihydro-2-thiazolyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-, methyl ester] and its metabolites determined as 3-pyridinecarboxylic acid, 5-(aminocarbonyl)-2-(difluoromethyl)-4-(2-

1

methylpropyl)-6-(trifluoromethyl)-, methyl ester and 3-pyridinecarboxylic acid, 2-(difluoromethyl)-4-(2-methylpropyl)-5-{[(2-sulfoethyl)amino]carbonyl}-6-(trifluoromethyl)-, expressed as parent equivalents, as follows:

Tree Nuts (group tolerance)	
nutmeat	0.05 ppm
almond hulls	0.15 ppm
Peanuts	
nutmeat	0.05 ppm
forage	0.3 ppm
hay	0.5 ppm
hulls	0.25 ppm

The amendment consists of a letter dated 6/2/95 and revised Sections B and F. The amendment was submitted in response to the review of PP#4G04323 dated 8/23/94 (N. Dodd).

The petitioner indicates that RH-123652 2E for tree nuts, formerly called MON 13211-C, is now called Visor™ 2E. RH-123652 2E for peanuts, formerly called MON 13211-D, is now called Spindle™ 2E. The two products, Visor™ 2E and Spindle™ 2E, are chemically identical.

CONCLUSIONS

1. Deficiencies #3, 4, and 5 are resolved by submission of the revised labels for tree nuts and peanuts.

2. Deficiency #7b concerned residues in peanut hulls. Since peanut hulls are no longer included in Table II (September 1995) of "Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry", deficiency #7b is resolved.

3. Deficiency #21 is resolved by submission of the revised Section F which deleted the proposed tolerance for peanut forage.

4. A revised Section F should be submitted which deletes the tolerance proposal for peanut hulls since peanut hulls are not included in Table II (September 1995) of "Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry".

5. Registration Division has the responsibility to determine whether inerts are cleared under 40 CFR 180.1001.

6. The chemical expression for thiazopyr on the labels should be as follows:

thiazopyr [3-pyridinecarboxylic acid, 2-(difluoromethyl)-5-(4,5-dihydro-2-thiazolyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-, methyl ester]

7. There are no Codex, Canadian, or Mexican tolerances for thiazopyr on peanuts and tree nuts. Therefore, no compatibility questions exist with respect to Codex.

RECOMMENDATIONS

Toxicology Branch considerations permitting and provided a revised Section F is submitted as described in Conclusion #4 above, CBTS recommends for the proposed temporary tolerances for residues of thiazopyr [3-pyridinecarboxylic acid, 2-(difluoromethyl)-5-(4,5-dihydro-2-thiazolyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-, methyl ester] and its metabolites determined as 3-pyridinecarboxylic acid, 5-(aminocarbonyl)-2-(difluoromethyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-, methyl ester and 3-pyridinecarboxylic acid, 2-(difluoromethyl)-4-(2-methylpropyl)-5-{[(2-sulfoethyl)amino]carbonyl}-6-(trifluoromethyl)-, expressed as parent equivalents, as follows:

Tree Nuts (group tolerance)		
	nutmeat	0.05 ppm
	almond hulls	0.15 ppm
Peanuts		
	nutmeat	0.05 ppm
	hay	0.5 ppm

For a future permanent tolerance, Conclusions #'s 1, 2, 6, 8, 9, 11, 12, 14, 15, 23, and 25 from the review of PP#4G04323 dated 8/23/94 (N. Dodd) must also be addressed.

A DRES analysis can be conducted at this time using 0.05 ppm for nutmeats of tree nuts and peanuts.

DETAILED CONSIDERATIONS

The deficiencies from PP#4G04323 (N. Dodd, 8/23/94) which pertain to the proposed temporary tolerances are repeated below, followed by the petitioner's responses and CBTS's discussions/conclusions:

(Note: The deficiencies are numbered as in the 8/23/94 review.)

(Note: The deficiencies which apply to a permanent tolerance only are not repeated below. For those deficiencies, refer to the 8/23/94 review.)

Deficiency #3

A revised Section B/label for tree nuts must be submitted. The formulation contains 2 lb ai/gallon. The label indicates that the maximum application rate is 2 lbs ai/A/yr. This would be 4 quarts product, not 8 quarts as stated on page 3 of the label.

Petitioner's Response to Deficiency #3

A revised label dated 5/20/95 for tree nuts (RH-123652 2E; Visor™ 2E) has been submitted. The revised label contains the following statement:

> "This product can be applied in one single or two to three separate sequential applications at a maximum total use rate of 4 quarts per acre per year (2 pounds active ingredient per acre per year)."

CBTS's Conclusion #3

Deficiency #3 is resolved by submission of the revised Section B/label for tree nuts.

Deficiency #4

A revised Section B/label for tree nuts must be submitted. A label limitation/restriction for any one of the pesticides applies to the tank mixture of pesticides as well. (For example, simazine is registered for use on individual tree nuts but not on the crop

group.) A note to this effect must be added to the proposed label.

Petitioner's Response to Deficiency #4

A revised label dated 5/20/95 for tree nuts (RH-123652 2E; Visor™ 2E) has been submitted. The revised label contains the following statement:

> **"TANK MIXTURES**
> IMPORTANT: READ AND OBSERVE ALL LABEL DIRECTIONS BEFORE USING. WHEN TANK MIXING, ALWAYS READ ALL INDIVIDUAL MANUFACTURERS' LABELS. IN INTERPRETING ALL LABELS FOR THE TANK MIXTURE THE MOST RESTRICTIVE SITUATION MUST APPLY."

CBTS's Conclusion #4

Deficiency #4 is resolved by submission of the revised Section B/label for tree nuts.

Deficiency #5

A revised Section B/label for peanuts must be submitted. A label limitation/restriction for any one of the pesticides applies to the tank mixture of pesticides as well. A note to this effect must be added to the proposed label.

Petitioner's Response to Deficiency #5

A revised label dated 5/20/95 for peanuts (RH-123652 2E; Spindle™ 2E) has been submitted. The revised label contains the following statement:

> **"TANK MIXTURES**
> IMPORTANT: READ AND OBSERVE ALL LABEL DIRECTIONS BEFORE USING. WHEN TANK MIXING, ALWAYS READ ALL INDIVIDUAL MANUFACTURERS' LABELS. IN INTERPRETING ALL LABELS FOR THE TANK MIXTURE, THE MOST RESTRICTIVE SITUATIONS MUST APPLY."

CBTS's Conclusion #5

Deficiency #5 is resolved by submission of the revised Section B/label for peanuts.

Deficiency #7b

In the table on page 9, residues for the hulls (189 days, SI/THI) were 0.1999 ppm on combustion and corresponding residues in the table on page 10 were 0.241 ppm on extraction. The petitioner must verify and explain how residues on extraction could be higher than on combustion.

Petitioner's Response to Deficiency #7b

The petitioner will address this issue in a separate submission.

CBTS's Conclusion #7b

Deficiency #7b concerned residues in peanut hulls. Since peanut hulls are no longer included in Table II (September 1995) of "Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry", deficiency #7b is resolved.

Deficiency #21

As indicated in the revised Table II (6/7/94) of the "Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry", a tolerance on peanut forage is no longer required. Therefore, a revised Section F should be submitted with the proposed temporary tolerance for forage deleted.

Petitioner's Response to Deficiency #21

A revised Section F has been submitted with the proposed temporary tolerance for peanut forage deleted.

CBTS's Conclusion #21

Deficiency #21 is resolved by submission of the revised Section F.

Other Considerations

Section F

The revised Section F (6/2/95 revision) proposes that temporary tolerances be established for residues of 3-pyridinecarboxylic acid, 2-(difluoromethyl)-5-(4,5-dihydro-2-thiazolyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-, methyl ester and its metabolites determined as 3-pyridinecarboxylic acid, 5-(aminocarbonyl)-2-(difluoromethyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-, methyl ester and 3-pyridinecarboxylic acid, 2-(difluoromethyl)-4-(2-methylpropyl)-5-{[(2-sulfoethyl)amino]carbonyl}-6-(trifluoromethyl)-, expressed as parent equivalents, as follows:

Tree Nuts (group tolerance)	
nutmeat	0.05 ppm
almond hulls	0.15 ppm
Peanuts	
nutmeat	0.05 ppm
hay	0.5 ppm
hulls	0.25 ppm

Conclusion

A revised Section F should be submitted which deletes the tolerance proposal for peanut hulls since peanut hulls are not included in Table II (September 1995) of "Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry".

Inerts

Registration Division has the responsibility to determine whether inerts are cleared under 40 CFR 180.1001.

Tolerance Expression

The chemical expression for thiazopyr on the labels should be as follows:

thiazopyr [3-pyridinecarboxylic acid, 2-(difluoromethyl)-5-(4,5-dihydro-2-thiazolyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-, methyl ester]

Codex

An International Residue Limits (IRL) Status sheet is attached (Attachment 1). There are no Codex, Canadian, or Mexican tolerances for thiazopyr on peanuts and tree nuts. Therefore, no compatibility questions exist with respect to Codex.

DRES

A DRES analysis can be conducted at this time using 0.05 ppm for nutmeats of tree nuts and peanuts.

Attachment 1: International Residue Limit Status sheet

cc: RF, Circu., N. Dodd (CBTS), E. Haeberer (CBTS), PM#23, PP#4G04323, R. Griffin (RCAB)

RDI:E. Haeberer:4/18/96:R. Loranger:4/19/96
7509C:CBTS:CM#2:Rm 804F:305-5681:N. Dodd:nd:4/22/96