

7/17/96

MEMORANDUM

SUBJECT: FAP#3F4187. Thiazopyr in/on Citrus. Revised Sections B and F. Multi-residue Analytical Methodology. No MRID#'s. CBTS#17252. DP Barcode #D226771.

FROM: Jerry B. Stokes, Chemist  
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THRU: Ed Zager, Acting Chief  
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TO: Steve Robbins  
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Rohm and Haas Company has submitted a cover letter dated May 23, 1996 and revised Section B and F in response to deficiencies cited by CBTS (See memo of 09/12/94, J. Stokes) in PP#3F4187.

Detailed Considerations

Section B:

The petitioner has submitted a revised label for the proposed end use product called Visor<sup>®</sup>2E Herbicide. This is the same formulation as previously proposed and used to generate the field trial data and only involves a name change to reflect new ownership by Rohm and Haas Company, who acquired this product from Monsanto. The proposed label includes a label restriction for livestock feeding and grazing of cover crops in treated citrus orchards as

requested by CBTS (See deficiency 4a, memo of 09/12/94, J. Stokes).

Deficiency 4a is now resolved.

Section F:

Rohm and Haas Company requests the establishment of permanent tolerances for residues of the selective herbicide thiazopyr (ISO common name) [3-pyridine carboxylic acid, 2-(difluoromethyl)-5-(4,5-dihydro-2-thiazolyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-, methyl ester] and its metabolites determined as 3-pyridine carboxylic acid, 5-(aminocarbonyl)-2-(difluoromethyl)-4-(2-methylpropyl)-6-trifluoromethyl-, methyl ester and 3-pyridine carboxylic acid, 2-(difluoromethyl)-4-(2-methylpropyl)-5-((2-sulfoethyl)amino)carbonyl)-6-trifluoromethyl and expressed as parent equivalents as follows: orange and grapefruit, whole fruit, 0.05 ppm. Previously, the petition was for orange, grapefruit, and cottonseed, but at this time the petitioner will only pursue the proposed use on orange and grapefruit.

If, and when tolerances are established, they must be established for orange and grapefruit. A crop group tolerance for citrus will not be established since the petitioner (Monsanto Company) submitted a revised Section F dated May 16, 1994 (See memo of 09/07/94, J. Stokes) to request a withdrawal of the proposed citrus group tolerance, and to propose a tolerance for orange and grapefruit, whole fruit only. Now, the new petitioner (Rohm Haas Company) has submitted a revised Section F dated May 23, 1996 for proposed tolerances for orange and grapefruit, and without a proposed tolerance for cottonseed. The Section F is adequate for the proposed use.

Other Considerations

Multi-Residue Methodology:

CBTS previously requested that the company submit copies of the multi-residue evaluation data without the company confidential or business security stamp on the submitted pages (See conclusion 6c, memo of 09/12/94, J. Stokes). CBTS had forwarded this information to FDA (See memo of 3/1/94, J. Stokes) but it was returned (See memo of 3/25/94, M. Wirtz, FDA) because multi-residue information cannot be accepted by FDA with a confidential stamp on the copy of

the method description.

The petitioner has not submitted a copy of the multi-residue evaluation data without a company confidential or security stamp on the pages.

Thus deficiency 6c (See memo of 09/12/94, J. Stokes) is not yet resolved.

Enforcement Analytical Methodology:

The petitioner's proposed analytical methodology is presently under validation at the Agency's laboratory in Beltsville, MD. CBTS cannot determine the adequacy of the methodology until this validation is completed.

Thus deficiency 6a (See memo of 09/12/94, J. Stokes) is not yet resolved.

Recommendation:

CBTS cannot recommend for the establishment of tolerances for orange and grapefruit until the above deficiencies 6a and 6c for analytical methodology are adequately resolved.

cc: PP#3F4187; J. Stokes (CBTS); J. Miller/E. Wilson (PM 23);  
Circu; R.F.

RDl:EHaeberer:07/09/96:RLoranger:07/10/96:EZager:07/16/96  
7509C:CBTS:CM#2:Rm803:JStokes:js:305-7561:07/17/96