

10/25/96

MEMORANDUM:

SUBJECT: PP#3F4187. Thiazopyr (MON13200) in/on RAC's Orange and Grapefruit. Amendments Dated August 13, 1996 and August 14, 1996. MRID #440858-00. CBTS #'s 17536 and 17537. DP Barcodes D229554 and D229560. Chemical No. 129100. Case No. 284389.

FROM: Jerry B. Stokes, Chemist
Chemistry Branch I/Tolerance Petition Team 2
Health Effects Division (7509C)

THRU: Elizabeth Haeberer, Acting Chief
Chemistry Branch I/Tolerance Support
Health Effects Division (7509C)

TO: Steve Robbins
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Rohm and Haas Company has submitted two cover letters dated August 13, 1996 and August 14, 1996 in response to deficiencies cited in PP#3F4187 (See memo of 09/12/94, J. Stokes). The petitioner has requested the establishment of a 0.05 ppm permanent tolerance for residues of the selective herbicide thiazopyr, [3-pyridine carboxylic acid, 2-(difluoromethyl)-5-(4,5-dihydro-2-thiazolyl)-4-(2-methylpropyl)-6-(trifluoromethyl)-, methyl ester] and its metabolites expressed as parent equivalents in the RACs orange and grapefruit as defined in 40 CFR 180.1 (h).

Conclusions and Recommendation:

All deficiencies in this PP#3F4187 (See memo of 09/12/94, J. Stokes) have been completely satisfied except 3b (correct nominal concentration for the active ingredient) and 6a (proposed enforcement methodology). Although the petitioner has clarified the nominal concentration for the active ingredient, the petitioner should submit a corrected copy of the CSF to RD. CBTS needs to review this corrected copy to satisfy deficiency 3b. The proposed enforcement methodology has been submitted to the Agency laboratory for a petition method validation (See memo of 03/26/96, J. Stokes).

Deficiency 1, Memo of 09/12/94, J. Stokes:

"Additional data are needed for Guideline 61-2. The petitioner must provide additional information for [REDACTED] as discussed in the Confidential Appendix."

Petitioner's Response Dated 08/13/96:

See Confidential Appendix Attachment, this memo.

CBTS Comment/Conclusion:

Deficiency 1 is now resolved.

Deficiency 2a, Memo of 09/12/94, J. Stokes:

"Additional data are needed for Guideline 61-3. The petitioner must explain the connection between the production of dithiopyr and the production of thiazopyr as discussed in the Confidential Appendix."

Petitioner's Response Dated 08/13/96:

See Confidential Appendix Attachment, this memo.

CBTS Comment/Conclusion:

Deficiency 2a is now resolved.

Deficiency 2b, Memo of 09/12/94, J. Stokes:

"The petitioner must provide additional information for the impurities #'s 105, 107, 109, 110, and 134 as discussed in the Confidential Appendix."

Petitioner's Response Dated 08/13/96:

See Confidential Appendix Attachment, this memo.

CBTS Comment/Conclusion:

Deficiency 2b is now resolved.

Deficiency 3a, Memo of 09/12/94, J. Stokes:

"However, if a Section 3 registration is established for thiazopyr uses on cotton and citrus, and when the commercial production begins, the petitioner must provide the Agency with 5 batch analyses of the TGA and its impurities. These data must be provided within a reasonable period after the commercial process is operating."

Petitioner's Response Dated 08/13/96:

This data will be supplied subsequent to the start of commercial production.

CBTS Comment/Conclusion:

Deficiency 3a is now resolved.

Deficiency 3b, Memo of 09/12/94, J. Stokes:

"The submitted data are not adequate for Guideline 62-2. The nominal concentration listed for the active ingredient in MRID# 246197-02 does not agree with the nominal concentration on the CSF dated 12/11/92. Please submit the correct value."

Petitioner's Response Dated 08/13/96:

The correct value is listed in MRID #246197-02.
(See Confidential Appendix Attachment, this memo).

CBTS Comment/Conclusion:

Although the petitioner has clarified the nominal concentration for the active ingredient, the petitioner should also submit a corrected copy of the CSF to RD. CBTS needs to review this corrected copy to satisfy deficiency 3b.

Deficiency 3b remains outstanding.

Deficiency 6b, Memo of 09/12/94, J. Stokes:

"CBTS requests that the company submit copies of the multi-residue testing results using the prescribed protocols without the company confidential or business security stamp on the submitted pages."

Petitioner's Response Dated 08/13/96:

A clean copy free of confidential stamp has been submitted. Since only the report has been printed on clean paper, then the previous MRID #422755-09 for the first submission of this data in March 1992 (Monsanto Company) should be retained for this copy submitted now.

CBTS Comment/Conclusion:

Deficiency 6b is now resolved. CBTS notes that the identical MRID has been assigned by RD. The data will be submitted again to FDA for review.

Attachment: Confidential Appendix

cc with Attachment: PP#3F4187, J. Stokes, J. Miller/E. Wilson
(PM 23), R.F.

cc without Attachment: Circu., E. Haeberer

RDI: TPT2:09/96:RLoranger:10/18/96:EHaeberer:10/23/96
7509C:CBTS:JStokes/js:CM#2:Rm803:305-7561:10/25/96