PM SP/I S S
2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 11 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7F3476/FAP#7H5524. RALLY™ (Myclobutanil)
Request for Additional Method Trials.
RCB No.: N/A. MRID No.: N/A.

FROM: Maxie Jo Nelson, Ph.D., Chemist
Tolerance Petition Section I
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

mjn

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO Donald A. Marlow, Chief
Chemical Operation Branch
Benefits and Use Division (TS-768)

On July 1, 1987, RCB (R. Loranger) requested COB conduct two method trials (TR 310-84-13, as amended by TR 310-86-09; and, TR 310-84-27, as amended by TR 31H-86-15) for residues of myclobutanil (Rally™; RH-3866) in conjunction with proposed temporary tolerances on apples, grapes, their byproducts, meat, milk, and eggs (PP#7G3479/FAP#7H5523).

Rohm and Haas Company is now proposing permanent tolerances for combined residues of myclobutanil and its metabolites in or on these commodities (PP#7F3476/FAP#7H5524), including apples @ 0.5 ppm; grapes @ 1.0 ppm; beef liver @ 0.5 ppm; and, milk @ 0.1 ppm.

Toxicology Branch has recently advised RCB (memo of P. Hurley, 12/17/87) that several of the metabolites warrant inclusion in the permanent tolerance expression, based on toxicological considerations.

The petitioner has recently submitted, as amendments to this petition, residue analytical methods for the diol metabolite (RH-0294) in milk (TR 31S-87-02) and the alcohol metabolite (RH-9090) in meat, milk, and eggs (TR 31S-87-09).

Additionally, the petitioner has submitted an Addendum 2 (identified as Lab Memo No. 31S-87-46) to the RH-3866 Total Residue Analytical Method for Apple and Grape (TR 310-84-27). We are requesting these two additional analytical methods be tested, and Addendum 2 to the RH-3866 Total Residue Analytical Method be incorporated into your method trial of TR 310-84-27, if the trial with TR 310-84-27 has not yet been satisfactorily completed.

TR 31S-87-02 is to be tested for its ability to measure the diol metabolite (RH-0294) in milk.

TR 31S-87-09 is to be tested for its ability to measure the alcohol metabolite (RH-9090) in beef liver and milk.

If possible, Addendum 2 (Lab Memo No. 31S-87-46) is to be incorporated into your method trial of TR 310-84-27 on apples (or grapes), and tested for its ability to improve sample cleanup and RH-9090 quantitation.

You have already obtained copies of each of these methods (including supporting recovery data and representative chromatograms) through PMSD. If you need additional copies of these methods, let me know.

All samples should be run in duplicate at the requested fortification levels (see forms, Appendixes 1-3).

Please return the requested information on the attached forms and any other information we should be aware of, as well as copies of standard curves, sample calculations, and representative chromatograms for controls and fortified samples. Also, please provide an estimate of the detection limits for each method on the various commodities.

Rohm and Haas has been contacted (M. Nelson to M. Morelli, 215-592-3581, 1/7/88) by RCB regarding the need to supply an analytical reference standard for the diol metabolite (RH-0294). We understand Rohm and Haas has already sent this directly to COB/BUD, as well as an additional supply of the analytical reference standard for the alcohol metabolite, RH-9090. Rohm and Haas was also advised of the need to supply analytical standards to the Pesticides Repository at RTP.

Since a major reason for conducting method trials is to ensure that all necessary instructions are included in the method write-up as supplied by the petitioner, discussions of MTOs with Rohm and Haas personnel are discouraged prior to completion of RCB's review of the petition.

Since this petition is being reviewed on a priority basis, this should not be construed as preventing contact with Rohm and Haas to clarify minor points. RCB does request, however, that your method trial report include a summary of contacts made with Rohm and Haas, along with the reason for the contact(s) and what modifications, if any, were made in the method(s) under test as a result of such contact.

For major problems encountered during the method trial, RCB requests the COB chemist(s) contact this reviewer (557-7324) to discuss an appropriate course of action. Major problem(s) may result in termination of the method trial.

Your written report on any terminated method trial(s) should include a description of the problem(s) so that RCB can inform Rohm and Haas of the problem(s) and request appropriate revision(s) of the method(s) plus new validation data before RCB initiates a new method trial(s) request.

Myclobutanil is a "new" chemical, and this petition constitutes the first permanent tolerance requests. OPP considers this to be a priority review. RCB's deadline for submission of its review to RD is March 3, 1988. If possible, we would hope these, and the previously requested, method trials on this chemical can be completed before that date.

We realize this may present scheduling difficulties for you. In that event, RD will determine petition method validation (PMV) method trial (MTO) priorities. RCB would appreciate being informed if these additional method trials are going to be significantly delayed.

For your information, RCB's review of this petition will list a number of deficiencies the petitioner will need to address. Among these will be the need for additional residue enforcement methods (based on TOX Branch's decision that certain of the metabolites also warrant tolerance regulation, based on toxicological considerations). These will include methods for measurement of the diol and hydroxylactone metabolites in meat and eggs, and will require PMV (MTO) testing.

Please forward the results of your method trials on myclobutanil and its metabolites directly to R. S. Quick, Section Head, Tolerance Petition Section I, Residue Chemistry Branch.

Appendix 1 (2 pages - to all copies)

Appendix 2 (2 pages - to all copies)

Appendix 3 (3 pages - to all copies)

Attachments: None; COB/BUD already has obtained copies of all these methods.

cc: RF, Circ, PP#7F3476, MTO File, M. Bradley, M. Nelson, L. Rossi (PM 21), H. Jacoby (HED), R. Thompson (RTP-NC), K. Kissler (BUD), W. Bontoyan (BUD), E. Eldredge (PMSD).

TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7324:typist(mjn): 1/7/88.

RDI:SectionHead:RSQuick:1/7/88:DeputyChief:RDSchmitt:1/11/88.

METHOD:

"RH-0294 Residue Analytical Method in Milk", Nancy J. Mamo, 3/30/87, Rohm and Haas Co., Spring House, PA, Technical Report No. 31S-87-02. (MRID# 403662-01)

Do not use control values for recovery corrections.

Do not report control values as zero; if less than the limit of detection, report as such. Please confirm the petitioner's claim for his limit of detection on the commodity listed below.

Commodity	Chemical Added	PPM Added	PPM Found	% Recovery
Milk	RH-0294	0		
		0.05		
		0.10		

Modifications to method (major or minor):

Special precautions to be taken:

Source of analytical reference standards:

If derivatized standard used, give source:

Instrumentation for quantitation:

Instrumentation for confirmation:

If instrument parameters differ from method given, list parameters used.

Commercial source for any specifal chemicals or apparatus:

Comments:

Chromatograms:

METHOD:

"RH-9090 Residue Analytical Method and Validation Data for Meat, Milk, and Eggs", John J. Martin, 10/30/87, Rohm and Haas Co., Spring House, PA, Technical Report No. 31S-87-09. (MRID# 404092-04)

Do not use control values for recovery corrections.

Do not report control values as zero; if less than the limit of detection, report as such. Please confirm the petitioner's claim for his limit of detection on the commodities listed below.

Commodity	Chemical Added	PPM Added	PPM Found	% Recovery
Milk	RH-9090†	0		
		0.05		
		0.10		
Beef Liver	RH-9090†	0		
		0.3		
		0.6		

† Alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole propanenitrile.

Modifications to method (major or minor):

Special precautions to be taken:

Source of analytical reference standards:

If derivatized standard used, give source:

Instrumentation for quantitation:

Instrumentation for confirmation:

If instrument parameters differ from method given, list parameters used.

Commercial source for any specifal chemicals or apparatus:

Comments:

Chromatograms:

NOTE: The attached method trial was one of two requested by RCB in its (R. Loranger) Method Trial Request memo of July 1, 1987.

IF THIS METHOD TRIAL HAS NOT YET BEEN COMPLETED, OR HAS NOT BEEN SATISFACTORILY COMPLETED, PLEASE AMEND IT AT THIS TIME TO INCORPORATE ADDENDUM TWO, AND RUN THE TRIAL WITH ADDENDUM TWO INCLUDED.

"Addendum 2 to RH-3866 Total Residue Analytical Method for Grape and Apple (Technical Report No. 310-84-27), R. O. Deakyne, et al., Rohm and Haas Co., Spring House, PA, Lab Memo Number 31S-87-46. (MRID# 404092-02)

The commodities, chemicals added, and ppm added are to remain the same as originally requested. (See page 2 of this Appendix.)

NOTE: IF THE METHOD TRIAL, AS ORIGINALLY REQUESTED, HAS ALREADY BEEN SATISFACTORILY COMPLETED, DO NOT REPEAT IT JUST TO INCORPORATE ADDENDUM TWO.

Modifications to method (major or minor):

METHOD:

"RH-3866 Total Residue Analytical Method for Apple and Grape" (Technical Report No. 310-84-27; completed November 16, 1984). Include "Addendum to RH-3866 Total Residue Analytical Method for Grape and Apple (TR 310-84-27)" (Laboratory Project I.D. 31H-86-15; completed July 8, 1986).

Do not use control values for recovery corrections.

Do not report control values as zero; if less than the limit of detection, report as such. Please confirm the petitioner's claim for his limit of detection on the commodities listed below.

Commodity	Chemical Added	PPM Added	PPM Found	% Recovery
Apples or Grapes	RH-3866	0		
		0.5		
		1.0		
"	RH-9090	0		
		0.5		
		1.0		

Modifications to method (major or minor):

Special precautions to be taken:

Source of analytical reference standards:

If derivatized standard used, give source:

Instrumentation for quantitation:

Instrumentation for confirmation:

If instrument parameters differ from method given, list parameters used.

Commercial source for any specifal chemicals or apparatus:

Comments:

Chromatograms:

//