

PMsD/FSB



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

JUN 22 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7F3476/#FAP#7H5524. RALLY™ (Myclobutanil)

Request for Petition Method Validation of Bound
RH-9090 Residues in Milk.

RCB No.: N/A.

MRID No.: 406458-01.

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

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

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

Rohm and Haas Company has recently submitted an additional analytical method,

"Bound RH-9090 Residue Analytical Method for Milk",
S. S. Stavinski, C. K. Brackett, W. O. Spencer,
June 1988, Technical Report No. 34S-88-15, 27 pp.,

which RCB had requested be developed as one of the enforcement methods needed in re the establishment of tolerances pending in PP#7F3476/FAP#7H5524 (myclobutanil plus selected metabolites in or on apples, grapes, meat, and milk).

We are requesting a petition method validation be conducted on this analytical procedure. Two copies of this method, TR 34S-88-15, are attached (as Attachment 2), along with recovery data and chromatograms.

Samples should be run in duplicate per the experimental design specified in Attachment 1. Please complete and return that Attachment as part of your petition method validation report.

Your report should also include any other information we should be made aware of, including copies of standard curves, sample calculations, and representative chromatograms for controls and fortified samples. Also, please provide an estimate of the detection limit.

If deficiencies in this analytical method as written are encountered during the petition method validation, we would appreciate your suggestions as to how the method should be rewritten by the petitioner to make it acceptable for enforcement purposes.

As for the analytical standards you will need, Rohm and Haas has informed us they utilized all the bound RH-9090 standard they had on hand in developing this method. They are in the process of preparing a new batch for your use in running the petition method validation. They have been advised to ship it directly to Ken Kissler.

We have recently confirmed with Ron Thomas that Beltsville does have a supply of the free RH-9090 standard, which also will be needed for running this petition method validation. The Pesticides Repository at RTP-NC also has this standard available.

The Registration Division Product Manager for myclobutanil, Ms. Lois Rossi, should be contacted directly concerning the priority for completion of this petition method validation.

Please address your written report to: Robert S. Quick, Section Head, Tolerance Petition Section I, Residue Chemistry Branch, Hazard Evaluation Division (TS-769C).

ATTACHMENTS (2)

1. Experimental design for conducting the petition method validation.
2. Two copies of the analytical method to be validated:

"Bound RH-9090 Residue Analytical Method for Milk", S. S. Stavinski, C. K. Brackett, and W. O. Spencer, June 1988, Rohm and Haas Co., TR 34S-88-15, 27 pp., MRID No. 406458-01.

cc (with both Attachments):

P. Corneliussen (FDA, HFF-426).

cc (with Attachment 1 only):

M. Nelson (RCB)
M. Bradley (RCB)
PP#7F3476/FAP#7H5524
Reading File
Circulation (7)

L. Rossi (PM#21/RD)
E. Eldredge (ISB/PMSD)
K. Kissler (COB)
W. Bontoyan (COB)
R. Thompson (RTP-NC).

TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7423:typist(mjn):6/21/88.
RDI:SectionHead:RSQuick:6/21/88:DeputyChief:RDSchmitt:6/21/88.

METHOD:

"Bound RH-9090 Residue Analytical Method for Milk"

S. S. Stavinski, C. K. Brackett, W. O. Spencer,
June 1988, Rohm and Haas Company, 27 pages.
Technical Report No. 34S-88-15
MRID No. 406458-01

Please do not use control values for recovery corrections.

Please do not report control values as zero; if less than the limit of detection, report as such.

Please confirm the petitioner's stated limit of detection.

<u>Commodity</u>	<u>Chemical Added</u>	<u>PPM Added</u>	<u>PPM Found</u>	<u>% Recovery</u>
Milk	Bound RH-9090	0.00		
		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 actually used:

Commercial source for any special chemicals or apparatus:

Comments:

Chromatograms: