PP#7F3476

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

SEP 12 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7F3476/FAP#7H5524. Myclobutanil in or on Apples, Grapes, Their By-Products, Meat, Milk, and Eggs. Amendment of June 3, 1988.
DEB#: 3955-3959. MRID#: 406458-00, -01.

FROM: Maxie Jo Nelson, Chemist
Dietary Exposure Branch
Health Effects Division (TS-769C)

mjn

THRU: Robert S. Quick, Section Head
Dietary Exposure Branch
Health Effects Division (TS-769C)

RSQ

TO: Lois Rossi, P. M. 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch - HFA Support
Health Effects Division (TS-769C)

BACKGROUND

One of the deficiencies cited in the DEB review (M. Nelson) of 4/26/88 was the need for a residue analytical method for RH-9090 (bound) in milk.

By transmittal letter dated 6/3/88, the petitioner, Rohm and Haas Company (M. A. Morelli), submitted the required method:

"Bound RH-9090 Residue Analytical Method for Milk"
S. S. Stavinski, C. K. Brackett, and W. O. Spencer
Technical Report No. 34S-88-15
June 1988
MRID# 406458-01

By memo dated 6/22/88 (M. Nelson), DEB has requested a petition method validation (PMV) be conducted on this method by ACB/BEAD. That PMV has not yet been completed/reported on by ACB.

DISCUSSION

The analytical method for determining residues of bound RH-9090 in milk, Rpt. 34S-88-15, is a modification of the Total Residue Analytical Method for Apple and Grape (TR 310-84-27, Addendum 31S-87-46).

In brief, the bound RH-9090 analytical method for milk entails the following: Residues in milk are soxhlet-refluxed overnight with 0.5N HCl/MeOH (a 6-hour reflux may be used in lieu of an overnight one if this is more convenient to the analyst); the reflux hydrolyzes bound RH-9090 residues to free RH-9090. The extract is purified by petroleum ether partitioning, sodium borohydride reduction, methylene chloride partitioning, Chelex 100-Fe^{+++} affinity column chromatography, a second methylene chloride partitioning, and Bio-Sil A column chromatography. RH-9090 quantitation is performed by GLC using a Supelco Sup-Herb Megabore column (15 m, 0.53 mm ID) and an EC detector.

The sensitivity of the method for RH-9090 residues (bound or free) is claimed to be 0.01 ppm, based on actual fortifications of milk as follows (from 34S-88-15, p. 14):

Recovery Data from Fortified Milk

Spike	ppm Added	% Recovery
Free RH-9090	0.01	79,69,79
	0.02	95, 70
	0.04	90
	0.08	80
	0.10	77
	0.125	91
	0.135	95,78
Bound RH-9090	0.01	78,85,67,80,93,106
	0.02	74
	0.03	76,90, 83
	0.04	75

Confirmatory analysis for RH-9090 residues is via a GLC equipped with a N/P detector, using direct on-column injection of a Supelco SPB-608 column, 15 m, 0.53 mm ID. Via a comparative recovery study in milk (0.125 ppm RH-9090 spike), 91% recovery was reported using the EC detector and 90% using the N/P detector.

Standard curves and representative chromatograms (spiked milk samples; control milk) accompany the method to support the reported validation data.

CONCLUSIONS

1. We defer judgment on the adequacy of this analytical method, 34S-88-15, for residue data gathering and/or enforcement purposes pending completion of PMV of this method by ACB/BEAD and review by DEB of ACB's report thereon.

2. All the other outstanding deficiencies to be resolved in re this petition remain as stated in our 4/26/88 review (M. Nelson).

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We reiterate that once all outstanding deficiencies raised by DEB have been adequately addressed by the petitioner, a revised version of the "RCB [now DEB] New Chemical Residue Chemistry Review of Myclobutanil", will be issued in the Registration Standard Format. That revision will be accompanied by a Table A - Generic Data Requirements for Myclobutanil.

cc: M. Nelson (DEB)
PP#7F3476/FAP#7H5524
Myclobutanil Registration Standard File
Reading File
Circulation (7)
H. Jacoby (SACS/EFED)
ISB/PMSD (Eldredge)

TS-769C:DEB:Reviewer(MJN):CM#2:Rm804:557-7324:typist(mjn):9/12/88.

RDI:SectionHead:RSQuick:9/12/88:DeputyChief:RDSchmitt:9/12/88.