



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PMSD/ISB
2254

APR 7 1988

MEMORANDUM

SUBJECT: Maneb (014505)
Protocol for Storage Stability data in
Apple Processed Fractions
Special Review (Storage Stability)
Data Call In of 3/31/87
[No MRID No., RCB No. 3504]

FROM: Susan V. Hummel, Chemist
Special Registration Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *Susan V. Hummel*

THRU: Edward Zager, Section Head
Special Registration Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *E. Zager*

TO: Valerie Bael, PM#77
Special Review Branch
Registration Division (TS-767C)

Pennwalt Corporation has submitted a revised protocol for Storage Stability Studies in Apple Processed Fractions. Their submission is in response to Conclusions 3 and 4 in our review of 7/31/87 (M. Kovacs, RCB No. 2535) and Agency letter of December 15, 1987. The deficiency, followed by the registrant response and our comments is given below.

CONCLUSIONS

All deficiencies in the storage stability protocols for maneb have been resolved. The deficiency regarding storage stability in apple processed fraction has been resolved by the submission of the protocol dated June 23, 1987, entitled, "Determination of the Stability of Maneb and ETU Residues in Processed Commodities," Morse Laboratories, Inc., Sacramento, CA.

RECOMMENDATION

The registrant should be advised that their protocol for storage stability in apple processed fractions is acceptable. The registrant should be informed that the Agency letter of

12/16/87 was correct in stating that the protocols for storage stability studies in animal products are acceptable.

Detailed Considerations

Deficiency

The revised June 19, 1987 draft storage stability study protocol, "Determination of the Stability of Maneb and ETU Residues in Processed Commodities," Morse Laboratories, Inc., Sacramento, CA, is acceptable, provided the registrant submits residue data on the following apple processed fractions: fresh juice, cooked/canned juice, wet pomace, dry pomace, cooked/canned applesauce, and strained baby food.

Registrant Response

Pennwalt Corporation has submitted a new protocol dated June 23, 1987, entitled, "Determination of the Stability of Maneb and ETU Residues in Processed Commodities," Morse Laboratories, Inc., Sacramento, CA. Collection of storage stability data on the following apple processed fractions is specified: fresh juice, cooked/canned juice, wet pomace, dry pomace, cooked/canned applesauce, and strained baby food. The balance of the protocol is identical to the previously submitted protocol (June 19, 1987).

RCB Comment

Since the required processed commodities are specified, and the balance of the protocol is identical to the previously submitted protocol, this deficiency is satisfied. The protocol for storage stability studies in apple processed fractions is acceptable.

Deficiency

The (MTF) Maneb Task Force has not addressed the outstanding protocol deficiencies cited in the May 28, 1987 RCB Memorandum for the following protocols:

- a. Draft protocol "Pilot Study for the Determination of the Stability of Maneb and Ethylene Thiourea Residues in Stored Frozen Samples of Milk, Eggs, Beef Tissues, and Poultry Tissues," prepared by Hazleton Laboratories America, Inc., Madison, WI 53704, dated March 24, 1987.

b. Draft protocol "Determination of the Stability of Maneb Residues in Stored Frozen Samples of Milk, Eggs, Beef Tissues, and Poultry Tissues," prepared by Hazleton Laboratories America, Inc., Madison, WI 53704, dated March 24, 1987.

Registrant Response

Protocol deficiencies cited in the Agency's May 28, 1987 review were addressed in our submission of September 25, 1987. The protocols were accepted in a letter from the Agency dated December 16, 1987.

RCB Comment

The registrant is correct. The registrant's submission of September 25, 1987 regarding animal products protocols, was reviewed in our memo of 11/4/87 (M. Kovacs, RCB No. 2847). Our review stated that the animal products protocols were acceptable. This was communicated to the registrant in the Agency letter of December 16, 1987.

cc: R.F., circu, S. Hummel, Maneb S.F., Maneb S.R.F. (Hummel),
Maneb R.S.F. (Hazel), V. Bael (SRB/RD), S. Lewis (PM#21),
PMSD/ISB
RDI:EZ:04/05/88:RDS:04/05/88
TS-769:RCB:RM810:CM#2:SVH:svh:04/06/88