



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

JAN 24 1992

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: MONITOR® 4, EPA Reg. No. 3125-280, (Mobay Corporation)
and MONITOR® 4 Spray, EPA Reg. No. 59639-56, (Valent
U.S.A. Corporation). Impact of Craven Analytical Data
on 24(c) Registrations.

FROM: Michael T. Flood, Ph.D., Chemist *Michael T. Flood*
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THROUGH: Debra F. Edwards, Acting Chief *Debra Edwards*
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TO: Robert Forrest, PM 14
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and

Lois Rossi, Chief
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Special Review and Reregistration Division (H7508C)

Background

In a letter to registrants dated 2/27/91, EPA (Linda Fisher) requested identification of all data generated at Craven Laboratories. A subsequent letter, dated 6/20/91, requested alternative data which could support continuation of existing registrations/tolerances until replacement data could be generated. This information was required because the Agency has received allegations concerning the reliability of certain residue and environmental fate studies conducted by Craven Laboratories. The Agency will not rely on Craven data for regulatory decisions before the issues surrounding the validity of data generated at Craven Laboratories are resolved.

Mobay Corporation responded to these letters with two submissions, dated 4/26/91 and 7/12/91. Mobay Corporation is the registrant for MONITOR® 4, whose active ingredient is methamidophos, O,S,-dimethyl phosphoramidothioate. The company's two submissions identified melons as one of the crops for which

File 3125-280
SPAD to do DCI

Monitor residue data were generated at Craven Laboratories.

There is currently an import tolerance of 0.5 ppm for residues of methamidophos in/on melons (40 CFR 180.315). Mobay Corporation proposed a tolerance of 1.5 ppm in PP#6F3317/6H5480. Residue data from all but one of the supporting field trials were generated at Craven Laboratories. CBTS (Mike Flood) concluded in its memo of 9/27/91 that EPA would take no action on this petition before issues surrounding Craven data have been resolved. If the company wished to submit additional residue data, data from at least ten field trials should be submitted. We asked that methamidophos be applied to cantaloupes and watermelons at the maximum proposed rate in CA, TX, FL, AZ, IN, and SC or GA.

Mobay's submission did not mention Special Local Need (SLN/24(c)) registrations. It subsequently came to our attention that there were indeed a number of existing SLN registrations for Monitor® 4 held by Mobay Corporation and also registrations for Monitor® 4 Spray held by Valent U.S.A. Corporation. The data supporting these registrations were generated at Craven Laboratories. Monitor Technical, EPA Reg. No. 3125-341, is manufactured by Mobay Corporation. Hence, any DCI should initially be sent to that firm.

Conclusions and Recommendations

1. SLN (24c) registrations for Monitor® 4 and/or Monitor® 4 Spray in/on melons are active in AZ, CA, FL, GA and LA. The residue data used to support these registrations were generated at Craven Laboratories. EPA will not state that adequate data are available to support the SLN registrations before issues surrounding the validity of data generated at Craven Laboratories are resolved.

2. CBTS recommends that a DCI be issued for the following:

Residue data reflecting application of Monitor® 4 or Monitor® 4 Spray to cantaloupes and watermelons in two field trials held in each of the states for which SLN registrations are active. These states are AZ, CA, FL, GA and LA.

Alternatively, Mobay Corporation may wish to submit residue data from at least ten field trials held in CA, TX, FL, AZ, IN, and SC or GA. These data would support a national registration/tolerance for Monitor®/methamidophos. (See our memo of 9/27/91.)

3. Available non-Craven data on cucumbers support the interim use of Monitor in/on melons while requested

data are generated.

Detailed Considerations

SLN's for both Monitor formulations were recently discussed in two reviews by CBRS. B. Cropp-Kohlligian in her memo dated 7/10/91 reviewed SLN registration amendments to include aerial applications of Monitor to cucumbers and melons in Georgia (GA900004 and GA900005, for Monitor® 4 and Monitor® 4 Spray, respectively). She recommended against the proposed amendment and noted that "the legitimacy of the current Special Local Need registrations in Georgia should be closely scrutinized because tolerance-exceeding residues in or on melons may result from the lower PHI allowed in Georgia (7-days PHI) compared to that in Florida (14-day PHI)." She also noted that all of the methamidophos residue data on melons pertinent to these registrations were generated by Craven Laboratories.

C. Swartz in her memo dated 11/6/91 reviewed SLN registrations LA910009 (Monitor® 4 on cucumbers/melons) and LA910010 (Monitor® 4 Spray on cucumbers) and concluded that "Effectively, there are no adequate residue data available to support the subject SLN registration for Monitor® on melons (LA910009)....A DCI for methamidophos residue data on melons should be issued, in order to generate residue data to replace Craven data to support the SLN registrations in FL and GA. In the interim, cucumber data may be translated to melons to support the existing SLN registrations." She reiterated the recommendation given in M. Flood's 9/27/91 memo that a DCI be issued to replace Craven data. We note that a SLN registration also exists for Monitor® 4 Spray on melons (LA910011).

A review of EPA/OPP's Reference Files System has revealed that in addition to the Georgia and Louisiana SLN registrations, Monitor is also registered under 24(c) in CA, AZ and FL. Mobay Corporation is the sole registrant in CA and AZ (CA880021, AZ910006); Valent U.S.A. Corporation is the sole registrant in FL (FL890011).

Data produced from two field trials from one growing season in Mexico were reviewed in the Methamidophos Registration Standard (2/12/82). Four or six applications of methamidophos were made to cantaloupes using ground equipment at 600 gm. ai/hectare (0.53 lb ai/A/application). B. Cropp-Kohlligian noted in her 7/10/91 memo that these data were not adequate to support the proposed use specified in the Georgia SLN registrations because they were not geographically representative and were conducted at approximately half or less of the maximum use rate specified in the Georgia registrations.

Comment

Because the data used to support 24(c) registrations for Monitor in/on melons were generated at Craven Laboratories, CB 1 will not state that adequate data are available to support these registrations before issues surrounding the validity of data generated at Craven Laboratories are resolved. We recommend that a DCI be issued to replace the Craven data:

1. Residue data should be submitted reflecting application of Monitor® 4 or Monitor® 4 Spray to cantaloupes and watermelons in two field trials held in each of the states for which SLN registrations are active. These states are AZ, CA, FL, GA and LA.
2. Alternatively, Mobay may wish to submit residue data from at least ten field trials held in CA, TX, FL, AZ, IN, and SC or GA. These data would support a national registration and tolerance for Monitor®. (See our memo of 9/27/91.)

As stated in C. Swartz's 11/6/91 memo, available data on cucumbers support the interim use of Monitor in/on melons while replacement data are generated.

cc: RF, SF, SF(Craven), Reg. Std. File (Methamidophos), 24(c) file (Methamidophos), Circu., PIB/FOD(C.Furlow), E.Haeberer, M.Flood, Pat Bagley(H7505C).
 H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:305-6362:typist(mtf):1/24/92.
 RDI:SectionHead:ETHaeberer:1/23/92:BranchSeniorScientist:RALoranger:1/23/92.