Memorandum

Subject: ID# 059639-TL: Registration for Orthene 15G (Granular) (Acephate) on Cotton: In-Furrow Application. CBTS# 10512. MRID# 424505-01. DP Barcode# D182124.

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To: Marilyn Mautz/Robert Forrest (PM14)
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Valent U.S.A. Corporation has submitted an amendment to their application for registration of Orthene 15 Granular for in-furrow use on cotton at planting. In its original request (reviewed in W.T. Chin’s memo of 8/13/92), Valent requested a waiver from residue data requirements. CBTS stated that, without the submission of additional data, we had no objections to this registration if the label were changed so that the later, foliar use of Orthene was restricted. Furthermore, we stated:

"If it is the registrant’s intention to use both the proposed at-plant use and the registered foliar sprays of acephate and methamidophos formulations, field residue data reflecting both at-plant and foliar applications at maximum rate and minimum PHI’s will be needed. Such data should reflect use of the granular formulation for the in-furrow application. Based on our past experiences, we will not translate data from liquid formulations to a granular."

In response, Valent has submitted a study showing that "data from three recently completed residue trials demonstrate that the substitution of Orthene for in-furrow liquid spray and early-season foliar application of Orthene results in residue levels comparable to those observed from
a program employing maximum foliar applications alone."

Under 40 CFR §180.108, tolerances are established for the combined residues of acephate (O,S-dimethyl acetyl phosphoramidothioate) and its cholinesterase-inhibiting metabolite methamidophos (O,S-dimethyl phosphoramidothioate) at 0.1 to 15 ppm in or on numerous commodities, including cottonseed at 2 ppm, eggs, meat, milk, and meat by-products of cattle, goats, horses, hogs, poultry, and sheep at 0.1 ppm. Under 40 CFR §186.100, tolerances are established for the combined residues of acephate and methamidophos at 8.0 ppm on cottonseed meal and 4 ppm on cottonseed hulls.

A Registration Standard has been issued for acephate which is a List A chemical. The Residue Chemistry Chapter is dated 1/22/82. The Guidance Document to the Acephate Registration Standard is dated September, 1987.

Detailed Considerations

Proposed Use. Orthene 15 Granular is a new granular formulation containing 15% acephate by weight. For control of thrips, aphids, and cutworms, apply 1 lb ai/A with in-furrow granular application equipment at planting. Minimize surface application by ensuring adequate application depth (2" minimum) and immediate coverage of furrow with soil. Calibrate and adjust application equipment to insure proper rate and accurate placement. Soil incorporate (disc) any surface material present in turn-rows immediately after application.

Orthene is currently registered on cotton for seed treatment uses, in-furrow spray at planting and foliar sprays at up to 1 lb acephate per acre with a PHI of 21 days.

Residue Data. Valent has submitted MRID# 424505-01, "Magnitude of the Residues of Acephate in Cotton [In Support of the Registration of Orthene 15 Granular]", by J.C. Lai, Chevron Chemical Co., Agricultural Chemicals Division, Richmond, CA, March 4, 1992 (Lab. Proj. No. TSR7736). (Appropriate GLP compliance statements have been included.) Three residue trials on cotton were conducted, in GA, MS, and TX. At each site, there was one control plot and two treatment plots. Of the latter, to one plot nine foliar applications were made of Orthene 90S (soluble powder), and to the other plot 2 applications were made of Orthene 15G (granular), followed by 7 applications of the 90S formulation (hereafter referred to as the "mixed" application scheme). In all cases, applications were made at the rate of 1.0 lb ai/surface acre. At a given site, applications #2-8 were made on the same day for the foliar and "mixed" plots. Application #1 was made first on the "mixed" plot, with the corresponding foliar application occurring 5-22 days later. All samples were harvested 21 days after the last application (the minimum PHI specified on the label).

All samples were shipped frozen (dry ice or freezer truck) from the field to the laboratory. Upon arrival, samples were stored frozen at ~ -20°C until analysis. Interval time between harvest and analysis was approximately one month. Residues would be stable in this environment for this length of time.
Cottonseed samples were ginned and then analyzed with Valen analytical method RM-12A-6. This method was used previously for collection of residue data and has been considered by the Agency to be adequate for data collection purposes. Briefly, samples are extracted with ethyl acetate or ACN/hexane, and then subjected to cleanup by ACN/hexane partitioning and silica gel chromatography. Measurement is by GC using a flame photometric detector. Recovery samples were analyzed concurrently with each set of samples by fortifying an untreated control sample. Fortification levels were 0.05 and 0.25 ppm for acephate and 0.02 and 0.10 ppm for methamidophos. Recoveries averaged 93 ± 4.9% (n=6) for acephate and 76 ± 13% (n=6) for methamidophos. The limits of detection are 0.02 ppm for acephate and 0.01 ppm for methamidophos.

Residue data for acephate and methamidophos in cottonseeds is presented in Table 1. This data shows that residues from granular in-furrow applications plus later foliar applications will not exceed the existing tolerance level of 2 ppm in cottonseed. It also shows that the "mixed" application scheme does not result in residues in cottonseed higher than those seen from an equivalent foliar application scheme. The petitioner did not determine residues in cottonseed hulls or in cottonseed meal; however, from the similarity of the residue data for the rac between the "mixed" and foliar application it is likely that residues in those processed commodities also will not exceed tolerance levels after exposure to the "mixed" treatment scheme.

<table>
<thead>
<tr>
<th>Site</th>
<th>Treatment Pattern</th>
<th>Date First Application</th>
<th>Acephate (ppm)</th>
<th>Methamidophos (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS</td>
<td>Mixed</td>
<td>5/13/91</td>
<td>0.09 0.08</td>
<td>0.01 0.01</td>
</tr>
<tr>
<td></td>
<td>Foliar</td>
<td>5/18/91</td>
<td>0.12 0.09</td>
<td>0.01 0.01</td>
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<tr>
<td></td>
<td>Foliar</td>
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<td>0.26 0.23</td>
<td>0.01 &lt;0.01</td>
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<tr>
<td>TX</td>
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<td>5/7/91</td>
<td>0.03 0.04</td>
<td>&lt;0.01 &lt;0.01</td>
</tr>
</tbody>
</table>

**Conclusion.** The petitioner has shown that residues from the mixed application of the granular (in-furrow) and soluble powder (foliar) formulations will not result in residue levels that exceed the current tolerance levels in cottonseed, cottonseed meal, and cottonseed hulls. Therefore, CBTS has no objection to this registration for Orthene 15G on cotton as an at-plant in-furrow application.
CBTS did not review the inerts for the granular formulation. Clearance of inerts is under the purview of Registration Division.

H7509C:CBTS:RLascola/rjl:CM#2:Rm805B:305-7478:12/17/92


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