MEMORANDUM

Subject: PP# 1G2471. Chlorothalonil on almonds. Amendment of 11/22/83.

From: William L. Anthony, Chemist
RCB/HED (TS-769)

Thru: Charles L. Trichilo, Chief
RCB/HED (TS-769)

To: H. Jacoby, PH#21
FHB/RD (TS-767)

The SDS Biotech Corporation, Painsville, Ohio (former proprietor, the Diamond Shamrock Corporation) is requesting an extension of their Experimental Use Permit (677-EUP-21) for use of chlorothalonil(tetrachloroisophthalonitrile) and its 4-hydroxy-2,5,6-trichloroisophthalonitrile metabolite on almonds. A temporary tolerance of 0.05 ppm for residues of chlorothalonil and its metabolite 4-hydroxy-2,5-6-trichloroisophthalonitrile in/on almonds expire on 12/31/83.

The petitioners are also requesting removal of the label restriction on feeding treated almond hulls to livestock. Subsequent to the submission of this action, the petitioners were notified by RD, "...that tolerances for almond hulls can not be established without tolerances (at least temporary) on meat and milk." (Memo: Eugene Wilson, 10/18/83).

The petitioner is now proposing the following temporary tolerances for the combined residues of chlorothalonil and its metabolite, 4-hydroxy-2,5,6-trichloroisophthalonitrile:

<table>
<thead>
<tr>
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<th>ppm</th>
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<tbody>
<tr>
<td>almonds</td>
<td>0.05</td>
</tr>
<tr>
<td>almond hulls</td>
<td>0.1</td>
</tr>
<tr>
<td>meat</td>
<td>0.05</td>
</tr>
<tr>
<td>milk</td>
<td>0.1</td>
</tr>
<tr>
<td>poultry</td>
<td>0.1</td>
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<tr>
<td>eggs</td>
<td>0.1</td>
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The proposed use calls for ground applications at the rate of 6-8 pts. (3.1-4.2 lbs. a.i.)/A in 300-400 gals of water for dilute spray. Aerial application or concentrate ground sprays may be applied at the rate of 4.5-6 pts. Bravo®-500 (2.3-3.1 lbs. a.i.)/A/15-100 gals. water. The number of applications is limited to three.

Do not apply to almond trees after bloom period is complete. Do not allow livestock to graze treated areas. The restriction against feeding treated hulls to livestock is deleted.

Except for the deletion of the hulls feeding restriction, this is the same use as was permitted under the original EUP.

Residue Data

No new residue data was submitted with this extension request. We had previously concluded that the proposed tolerance of 0.05 ppm for residues of the a.i. and its 4-OH metabolite in/on almonds would be adequate to cover residues from the proposed use (PP# 1G2471, N. Dodd, 11/17/81).

We had also previously concluded that a temporary tolerance of 0.2 pfo r residues of chlorothalonil and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile in/on almond hulls is needed to cover residues from the proposed use (PP# 3F2875, M. Kovacs, 11/7/83).

Meat and Milk

Almond hulls may constitute up to 25% of the cattle's diet equivalent to 0.05 ppm chlorothalonil and its 4-OH metabolite in the diet.

Feeding studies were discussed in detail in our review of (PP# 3F2875, M. Kovacs, 11/7/83).

Based on these studies, we conclude that the proposed temporary tolerances of 0.05 ppm for meat and 0.1 ppm for milk will be adequate to cover secondary residues resulting from the proposed use.

When the temporary tolerances are established, they should be expressed as follows: 0.1 ppm in milk and 0.05 ppm in the meat, fat and meat products of cattle, goats, hogs, horses, and sheep.

There are no poultry feed items involved in this use, therefore no temporary tolerances are needed for poultry and eggs.
Conclusions

(1) Residues of chlorothalonil and its 4-OH metabolite in or on almond hulls resulting from the proposed use may exceed the proposed tolerance of 0.1ppm. A tolerance of 0.2 ppm would be more appropriate.

(2) The proposed temporary tolerance of 0.1ppm for milk and 0.05ppm for meat are adequate to cover any secondary residues resulting from proposed use. When established the temporary tolerances should be expressed in terms of meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep.

(3) There will be no problem with secondary residues in poultry and eggs since there is no poultry feed items involved. The proposed temporary tolerances for poultry and eggs should be withdrawn.

Recommendation

For reason stated in conclusion #1, we recommend that the proposed tolerance not be established.

Toxicological considerations permitting, we could recommend favorably if Section F were amended to propose a temporary tolerance of 0.2 ppm for residues of chlorothalonil and its 4-OH metabolite in or on almond hulls and the meat tolerance expressed as: 0.05 ppm in the meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep.

The requirements for a permanent tolerance are listed in our review of PP# 3F2875.

cc: R.F., Circu, Reviewer, TOX, EEB, EAB, PP#1G2471
FDA, Robert Thompson
RDI: R. Hummel, 2/9/84; R. Schmitt, 2/9/84