PROPICONAZOLE (160)

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EXPLANATION

Propiconazole was evaluated by the JMPR in 1987, 1991 and 1994 when an ADI of 0-0.07 mg/kg bw and an ARfD of 0.3 mg/kg bw were established, and a number of maximum residue levels were estimated.

The cranberry industry performed a number of supervised trials within the Interregional Research Project No. 4 to provide data for the establishment of US tolerances for propiconazole residues in cranberry. The relevant labels and reports of supervised trials were submitted for evaluation by the 2006 JMPR.

RESIDUE ANALYSIS

Analytical methods

The harvested fruit samples were analyzed by a total residue method determining propiconazole and its metabolite as 2,4 dichlorobenzoic acid by capillary gas chromatography (Toth and Manuli, 1989). The method validation recoveries from test portions spiked at 0.05, 0.5 and 1 mg/kg ranged from 63.6 to 86.2% with an overall average of 77.5% and standard deviation of 6.2. Concurrent recoveries, performed at 0.05 and 1 mg/kg levels during the analyses of samples ranged from 71 to 120% with an average of 93% and standard deviation of 14.6%.

No quantifiable residues were observed in the control samples.

Stability of pesticide residues in stored analytical samples

The maximum storage interval for field-treated samples was 78 days. To evaluate storage stability, control samples were fortified with 1.0 mg/kg propiconazole, stored at < -20°C and analyzed after 92 days of frozen storage. The average residues that survived in fortified samples (86%) were not significantly different from the analytical average recovery (77.5–93%).

The JMPR reported the results of numerous studies on various plant commodities that indicated that propiconazole residues were stable for more than 6 months (FAO 2004).

USE PATTERN

The Orbit 3.6E containing 41.8% and Tilt 250E containing 250g/L propiconazole are registered in Canada and the USA to control various fungal diseases of cranberry. They can be applied to protect cranberry as shown in Table 1.

Table 1. Use pattern of Propiconazole on cranberry.

<table>
<thead>
<tr>
<th>Application</th>
<th>Method</th>
<th>Product</th>
<th>No</th>
<th>Interval, days</th>
<th>Rate kg ai/ha</th>
<th>PHI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ground</td>
<td>USA</td>
<td>3.6E</td>
<td>Max 4</td>
<td>10</td>
<td>0.3-0.42</td>
<td>45</td>
</tr>
<tr>
<td>Ground¹</td>
<td>Canada</td>
<td>250E</td>
<td>Max 2</td>
<td>10-14</td>
<td>0.31</td>
<td>45</td>
</tr>
</tbody>
</table>

¹ Apply with a minimum of 200 L water/ha to runoff
RESIDUES RESULTING FROM SUPERVISED TRIALS

During the 1995–1999 growing seasons’ three field trials were conducted on cranberries in two geographical regions of the USA (Thompson 1997, Thompson and Chen 1999).

The cranberry crops were grown and maintained according to typical agricultural practices for each geographical region.

Each treated plot received four foliar broadcast applications of the test substance at a rate of approximately 0.4–0.42 kg ai/ha each. The first two applications were made at bud break and 14 days later, the third and fourth applications were made at early bloom and 10 or 14 days later.

One control and duplicate treated samples were collected at 43–44 days after the last (fourth) application.

The residue results from the supervised field trials are presented in Table 2.

Table 2. Residues of propiconazole in/on cranberry fruits following four foliar broadcast applications 14 days apart.

<table>
<thead>
<tr>
<th>Field Trial Location</th>
<th>Dosage kg ai/ha</th>
<th>PHI (days)</th>
<th>Residue mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Total</td>
</tr>
<tr>
<td>Warrens, WI</td>
<td>0.42</td>
<td>44</td>
<td>0.59, 0.46</td>
</tr>
<tr>
<td>Wisconsin Rapids, WI</td>
<td>0.42</td>
<td>44</td>
<td>0.18, 0.22</td>
</tr>
<tr>
<td>Oregon</td>
<td>0.42</td>
<td>43</td>
<td>0.23, 0.23</td>
</tr>
</tbody>
</table>

APPRAISAL

Propiconazole was last evaluated by the JMPR in 1987 1991,1994 and 2004 when an ADI of 0-0.07 mg/kg bw and ARfD of 0.3 mg/kg bw were established, and a number of maximum residue levels were estimated. The residue was defined as propiconazole for regulatory and dietary intake assessment purposes.

Results of supervised trials, carried out on cranberry according the US registered uses, were submitted for evaluation.

Results of supervised trials on crops

During the 1995 and 1999 growing seasons three field trials were conducted with maximum dosage on cranberries in two geographical regions of the USA.

For each trial, four broadcast foliar applications of propiconazole were made with single application rates of 0.42 kg ai/ha. The samples were collected at 43 and 44 days (US GAP: max application rate is 0.42 kg ai/ha with a PHI of 45 days)

The cranberry samples were analysed with a total residue method determining propiconazole and its metabolite as 2,4 dichlorobenzoic acid by capillary gas chromatography. The concurrent recoveries ranged from 71 to 120% with an average of 93% and standard deviation of 14.6%.

Concurrent storage stability tests indicated that the residues in samples spiked at 1.0 mg/kg level and stored at < -20°C for 92 days did not degrade.

The residues measured in samples at harvest and expressed as propiconazole equivalent were: 0.2, 0.23 and 0.53 mg/kg.

The 1994 JMPR reported that over 30 days after the last application the proportion of the parent compound in the total residue was 8–11%, 21% and 18–23% in peanut, grapes and grape leaves, respectively (Evaluation 1994, part 1, vol 2. p1048). The residue composition obtained in various kinds of plant matrices indicate that the parent compound would not amount to more than 25% of the total residue in plant commodities including cranberry 45 days after last application.
Taking into account the proportion of parent compound in propiconazole residues in plant commodities, and the minimum data requirement (3 trials) specified for commodities which are insignificant in trade and do not raise any intake concern (2004 JMPR Report, pp. 30-31), the Meeting estimated a maximum residue level of 0.3 mg/kg an HR of 0.13 mg/kg and STMR of 0.058 mg/kg.

**RECOMMENDATION**

On the basis of the data from supervised trials, the Meeting concluded that the residue levels listed below are suitable for establishing maximum residue limits and for dietary intake assessment.

Summary of the recommendation for the MRL, STMR and HR for propiconazole.

<table>
<thead>
<tr>
<th>CCN</th>
<th>Commodity</th>
<th>MRL, mg/kg</th>
<th>STMR or STMR-P, mg/kg</th>
<th>HR or HR/P mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>FB 0265</td>
<td>Cranberry</td>
<td>0.3</td>
<td>0.13</td>
<td>0.058</td>
</tr>
</tbody>
</table>

**DIETARY RISK ASSESSMENT**

**Long-term intake**

The GEMS Food specifies the following long-term cranberry consumption (g/day/person) for various cluster diets: A (0.1); D (0.3); F (0.6); M (2.5). The consumption of cranberry in the other regions is nil.

The highest IEDI in the 13 GEMS/Food regional diets, based on estimated STMR, was < 0.01% of the maximum ADI (0.07 mg/kg bw).

The Meeting concluded that the long-term intake of residues of propiconazole use on cranberry will not practically increase the intake of residues from other uses considered earlier by the JMPR.

**Short-term intake**

The GEMS/Food regional diet specifies the large portion sizes of cranberry of 3.53 g/kg bw for adults and 6.78 g/kg bw for children (both from the USA).

The IESTIs of propiconazole calculated on the basis of the large portion size and the estimated HR of 0.13 mg/kg are 0.15% and 0.3% of the ARfD for adults and children, respectively.

The Meeting concluded that the short-term intake of residues resulting from the use of propiconazole on cranberry that have been considered by the JMPR is unlikely to present a public health concern.

**REFERENCES**

Author, Date, Title, Institute, Report Reference, Document No.

D.C. Thompson 1997 Propiconazole: Magnitude of residues, IR-4 Project Headquarters, Rutgers IR-4 No. 06320

D.C. Thompson and Hong Chen 1999. Propiconazole: Magnitude of residues, IR-4 Project Headquarters, Rutgers IR-4 No. 07359

Toth J. and P.J. Manuli 1989. Determination of total residues of propiconazole as 2,4 dichlorobenzoic acid, Ciba-Geigy Corporation, Greensboro AG 454B