

5.30 PROPICONAZOLE (160)

RESIDUE AND ANALYTICAL ASPECTS

Propiconazole was evaluated by the JMPR for residues in 1987, 1991, 1994, and within the periodic review program in 2007, when a number of maximum residue levels were recommended. Propiconazole has an ADI of 0–0.07 mg/kg bw and an ARfD of 0.3 mg/kg bw. Information and residue trial data on citrus, stone fruits and tomato following post-harvest applications of propiconazole were submitted to current Meeting.

The residue definition for plant and animal commodities is *propiconazole* for compliance with the MRL and *propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole* for the estimation of the dietary intakes.

Methods of analysis

Methods of analysis evaluated by the 2007 JMPR are divided into two groups. Methods where only propiconazole is analysed involves mostly LC-MS/MS detection, with LOQ of 0.01 mg/kg for citrus and tomato and of 0.05 mg/kg for stone fruits. The common moiety method measure all residues convertible to 2,4-dichlorobenzoic (2,4-DCBA) and are performed using mostly GC-MSD (after derivatisation of 2,4-DCBA to its methyl ester) with an LOQ of 0.05 mg/kg.

Stability of residues in stored analytical samples

A study to investigate the stability of residues in analytical samples in peach submitted to the 2007 JMPR showed that residues of propiconazole in peach samples are stable up to 36 months after frozen storage. New studies evaluated by the present Meeting have shown that propiconazole residues were stable for up to 207 days in orange, 154 days in juice and dried pulp, and 224 days in orange oil and 189 days in cherries. Propiconazole residues measured using the common moiety method in tomato (fortified with propiconazole at 0.5 mg/kg level) were stable up to 160 days, and the samples in the residue trials were analysed within this period. No storage stability study for total residues was performed in stone fruits (samples were stored for at least 560 days).

Results from supervised residue trials on crops

The 2007 JMPR agreed that, based on metabolism study, a factor of 3 needs to be applied to convert parent residues to total residues (all residues convertible to 2,4-DCBA and expressed as propiconazole). Data evaluated by the present Meeting are from post harvested uses, and it is unlikely that propiconazole metabolites are formed between treatment and sample preparation for analysis. Furthermore, residues of propiconazole will be used for dietary exposure assessment, without using the factor of 3.

Citrus fruits

In USA, propiconazole can be applied twice as post-harvest treatment as in line dip/drench twice at up to 0.054 kg ai/hL or in-line aqueous or fruit coating spray at up to 1.8 g ai/1000 kg fruit. Seventeen post-harvest trials on citrus were conducted in 2006 in USA according to GAP rate, but in eight trials the samples were washed before the second application.

In four trials conducted in orange using dip application conducted according to GAP, residues of propiconazole were 2.2, 2.5, 3.4 and 3.7 mg/kg (highest level of duplicate sample was 4.9 mg/kg).

The Meeting estimates a maximum residue level of 9 mg/kg, a STMR of 2.95 mg/kg and a HR of 4.9 mg/kg for propiconazole in oranges.

Stone fruits

In USA, propiconazole can be applied once as post-harvest treatment in stone fruits using in line dip/drench twice at up to 0.014 kg ai/hL or in-line aqueous or fruit coating spray at up to 0.56 g ai/1000 kg fruit. Nine post-harvest trials on stone fruits were conducted in 2007 in USA according to GAP. In all trials, fruits without stone was analysed, but the Meeting agreed that the residues found in whole fruit is within 10% (higher) of that found in the fruits without the stones and consider the data appropriate.

Residues of propiconazole from trials conducted using dip application were 1.2, 1.4, 1.7 and 2.1 mg/kg in peaches (highest value of duplicate samples of 2.2 mg/kg), 0.18 and 0.20 mg/kg in plums (highest value of duplicate samples of 0.22 mg/kg) and 0.67 and 0.85 mg/kg in cherry.

Residue of propiconazole in fruits without stone from trials conducted using in-line aqueous application were 0.14, 0.20, 0.49 and 0.50 mg/kg in peaches, 0.16 and 0.19 mg/kg in plum and 0.17 mg/kg in cherry.

The Meeting agreed that trials conducted using dip application in peach gave the highest residues and recommends a maximum residue level of 5 mg/kg (Po), a STMR of 1.55 mg/kg and a HR of 2.2 mg/kg for propiconazole in peaches.

Residues in plums from dip and spray application are similar and can be grouped as 0.16, 0.18, 0.19 and 0.20 mg/kg. The Meeting recommends a maximum residue level of 0.6 mg/kg, a STMR of 0.185 mg/kg and a HR of 0.22 mg/kg for propiconazole in plums.

The Meeting agreed that there is not enough trials to estimate a maximum residue level for cherry.

Tomato

In USA, propiconazole can be used in tomato as a post-harvest treatment in line dip or drench at up to 0.27 kg ai/hL or high volume spray application at 4.5 g ai/1000 kg fruit. Nine post-harvest trials on tomato were conducted in 2009 in USA according to GAP.

In six trials using dip or drench application, residues of propiconazole in tomatoes were 0.47 (2), 0.80 (2), 0.87 and 1.4 mg/kg. In three trials using in-line spray, residues were 0.37, 0.74 and 1.5 mg/kg.

The Meeting agreed that the dip/drench and the in-line spray trials gave similar results that can be grouped as (n=9) 0.37, 0.47 (2), 0.74, 0.80 (2), 0.87 and 1.4 and 1.5 mg/kg (highest level among the samples was 1.5 mg/kg)

The Meeting estimates a maximum residue level of 3 mg/kg, a STMR of 0.80 mg/kg and a HR of 1.5 mg/kg for propiconazole in tomato.

Fate of residues in storage and processing

Effect on the nature of the residues during processing

The hydrolytic stability of [triazolyl-U-¹⁴C]-propiconazole was investigated in aqueous buffer solutions at three pH values and temperatures to simulate processing practices. The study was performed at pH 4 and 90 °C for 20 minutes to simulate pasteurisation, pH 5 and 100 °C for 60 min to simulate baking/brewing/boiling, and at pH 6 and 120 °C for 20 min to simulate sterilisation. Only the parent compound was detected in the buffer solutions throughout the study, indicating that propiconazole is hydrolytically stable under the conditions of the tests.

Residues in processed commodities

In one study, oranges were processed to oil, juice and dried pomace using procedures simulating commercial practice. Residues of propiconazole in oranges were 0.94 mg/kg, not detected in juice (< 0.01 mg/kg), 1.29 mg/kg in dried pulp and 174 mg/kg in oil, giving processing factors of < 0.011 for orange juice and of 184 for orange oil.

Based on a STMR of 1.95 mg/kg in oranges, the Meeting estimated a STMR-P of 0.02 mg/kg in orange juice.

Residues in animal commodities

Dried orange fruit can contribute to animal diets and is listed on the OECD animal diet. However, in commercial practice, post-harvest treatment is normally reserved for high value commodities and is unlikely that dried fruit from treated fruits would be fed to livestock. The Meeting considered that the estimations for propiconazole in orange will not change the dietary burden calculated by the 2007 JMPR meeting, and confirms its previous recommendations for animal commodities

RECOMMENDATION

Residues: For plant and animal commodities is *propiconazole* for compliance with the MRL and *propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole* for the estimation of the dietary intakes.

DIETARY RISK ASSESSMENT*Long-term intake*

The IEDI of propiconazole based on the STMRs estimated by this and previous Meetings for the 13 GEMS/Food regional diets were 1–20% of the maximum ADI of 0-0.07 mg/kg bw (see Annex 3 of the Report). The Meeting concluded that the long-term dietary intake of residues of propiconazole is unlikely to present a public health concern.

Short-term intake

The ARfD for propiconazole is 0.3 mg/kg bw. The International Estimated Short-Term Intake (IESTI) for propiconazole was calculated for the plant commodities for which STMRs, HRs and maximum residue levels were estimated by the current Meeting and for which consumption data were available. The results are shown in Annex 4. The IESTI represented a maximum of 100% of the ARfD for oranges (children 2–6 years). The Meeting concluded that the short-term intake of propiconazole residues from uses considered by the current Meeting were unlikely to present a public health concern.

