

5.15 METHOPRENE (147)

RESIDUE AND ANALYTICAL ASPECTS

Methoprene, an insect growth regulator, was first evaluated by the JMPR in 1984 and evaluated for residues several times. The most recent residues evaluation was conducted in 2016. The ADI of 0–0.09 mg/kg bw was established for racemic methoprene (R and S enantiomers in ratio 1:1); a separate ADI of 0–0.05 mg/kg bw was established for S-methoprene (2001). An ARfD was unnecessary. The residue definition for methoprene and for S-methoprene for plant and animal commodities, for both compliance with MRLs and dietary risk assessment, is methoprene. The residue is fat soluble.

At the Fiftieth Session of the CCPR (2018), methoprene was scheduled for evaluation of additional use patterns by the 2019 Extra JMPR. The current Meeting received residue data for post-harvest use on stored peanuts.

Methods of analysis

Residues of methoprene were determined in peanuts using an HPLC-UV analytical method that was previously evaluated by the 2016 JMPR. New data validating the method for peanuts was received by the Meeting with the lower and upper levels of fortification validated being 1.3 and 2.7 mg/kg. Based on the residue levels found in the trials, the Meeting concluded that the available validation data are adequate to ensure the validity of the results.

Stability of residues in stored analytical samples

The 2005 Meeting concluded that “numerous laboratory and field trials have shown long term stability of methoprene in stored grain, not only at -20°C but even at room temperature”. Noting that residues of methoprene in wheat grain trials evaluated by the JMPR in 2005 remained stable over 180 days of ambient storage, the Meeting concluded that residues of methoprene in samples from the peanut supervised trials would be stable over the periods of frozen storage of up to 149 days.

Results of supervised residue trials on crops

Peanut

The critical GAP in the USA is application of S-methoprene at up to 36.4 g ai/1000 bushels (corresponding to up to 4.5 g ai/t) with no withholding period specified. Five residue trials from the USA at dose rates (2.4 g ai/t; 64, 66, 69, 76 and 76% of GAP rate in g ai/1000 bushels) below the critical GAP were provided to the Meeting.

Residues in peanuts in rank order (n=5) were: 1.8, 2.0 (3), and 2.1 mg/kg.

As in the trials, where S-methoprene was applied separately to different peanut lots simulating commercial application practice, the results reflected a high recovery of applied methoprene (75 to 88% of the 2.4 g ai/t applied in all the trials), the Meeting decided that the application rate determined the level of residue expected at the zero day withholding period of the GAP.

Based on the GAP, and with an anticipated variation in weights of different peanut varieties per 1000 bushels (the label expression reflecting amount of S-methoprene applied to 1000 bushels of peanuts), the Meeting considered that residues of up to about 4.5 mg/kg can be anticipated.

The Meeting estimated a maximum residue level of 5 (Po) mg/kg and a STMR of 5 mg/kg.

Residues in animal commodities

Peanut meal can be fed to livestock. The 2016 JMPR evaluated residues of methoprene in cereal grains and oilseeds (except for peanuts). Estimation by the present Meeting, now including peanuts, does not significantly increase the previously estimated (2016) maximum dietary burdens of 13.46 ppm in the diet of cattle and 10.62 ppm for poultry. The Meeting confirmed its previous conclusions for animal

commodities.

RECOMMENDATIONS

On the basis of the data obtained from supervised trials, the Meeting concluded that the residue levels listed in Annex 1 are suitable for establishing maximum residue limits and for IEDI assessment.

Definition of the residue for compliance with the MRL and dietary risk assessment for plant commodities: methoprene

Definition of the residue for compliance with the MRL and dietary risk assessment for animal commodities: methoprene

The residue is fat-soluble.

DIETARY RISK ASSESSMENT

Long-term dietary exposure

The ADI for S-methoprene is 0–0.05 mg/kg bw. The International Estimated Daily Intakes (IEDIs) for methoprene were estimated for the 17 GEMS/Food Consumption Cluster Diets using the STMR or STMR-P values estimated by the JMPR. The results are shown in Annex 3 of the 2019 Extra JMPR Report.

Assuming the residues are S-methoprene, the IEDIs ranged from 10–60% of the maximum ADI. The Meeting concluded that long-term dietary exposure to residues of methoprene from uses considered by the JMPR is unlikely to present a public health concern.

Acute dietary exposure

The 2001 JMPR decided that an ARfD for methoprene was unnecessary. The Meeting therefore concluded that the acute dietary exposure to residues of methoprene from the uses considered is unlikely to present a public health concern.