

# Oxathiapiprolin

## Summary

Food Safety Commission of Japan

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of oxathiapiprolin (CAS No. 1003318–67–9), a fungicide of piperidinyl thiazole isoxazoline-type, based on results from various studies. Major adverse effects of oxathiapiprolin observed are reduced gain of body weight and delayed preputial separation in rat offsprings in a two-generation reproductive toxicity study. No neurotoxicity, carcinogenicity, reproductive toxicity, teratogenicity or genotoxicity was observed. Oxathiapiprolin (parent compound only) was identified as a chemical for the residue definition for dietary risk assessment in agricultural products. The lowest no-observed-adverse-effect level (NOAEL) obtained in all the studies was 346 mg/kg bw/day in a two-generation reproductive toxicity study in rats. FSCJ specified an acceptable daily intake (ADI) of 3.4 mg/kg bw/day, applying a safety factor of 100 to the NOAEL. FSCJ considered it unnecessary to specify an acute reference dose (ARfD), since no adverse effects would be likely to be elicited by a single oral administration.

### Conclusion in Brief

The Food Safety Commission of Japan (FSCJ) conducted a risk assessment of oxathiapiprolin (CAS No. 1003318–67–9), a fungicide of piperidinyl thiazole isoxazoline-type, based on results from various studies.

The studies include data on the fate in animals (rats), fate in plants (potatoes, lettuce, etc.), residues in crops, sub-acute toxicity (rats, mice and dogs), chronic toxicity (dogs), combined chronic toxicity/carcinogenicity (rats), carcinogenicity (mice), two-generation reproductive toxicity (rats), developmental toxicity (rats and rabbits), genotoxicity and immunotoxicity.

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FSCJ considered it unnecessary to specify an acute reference dose (ARfD), since no adverse effects would be likely to be elicited by a single oral administration.

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