

Evaluation Report for Category B, Subcategory 3.6 Application

Application Number: 2013-2320
Application: B.3.6 Changes to Product Labels Pre-Harvest/Slaughter/With-Holding
Product: Granuflo-T
Registration Number: 30548
Active ingredients (a.i.): Thiram
PMRA Document Number : 2459256

Purpose of Application

The purpose of this application was to revise the PHI for apples from 1 day to 28 days for Granuflo-T. The active ingredient, thiram, is currently under re-evaluation.

Chemistry, Environmental and Value Assessments

Chemistry, environmental and value assessments were not required for this application.

Health Assessments

Acceptable residue decline trials conducted in the United States, including growing regions representative of Canada, were submitted and reviewed to support the revision of the pre-harvest interval (PHI) on the Granuflo-T label from 1 day to 28 days for apples. The residue decline data indicate that thiram residues generally decrease with increasing pre-harvest intervals. Residues of thiram in/on apples as a result of this label amendment will be covered under the MRL of 7 ppm specified for thiram in/on apples. Dietary exposure to thiram residues will not increase as a result of this label amendment and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Conclusion

The PMRA conducted an evaluation of the subject application and found the information sufficient to revise the PHI for apples for Granuflo-T. The regulatory status of Granuflo-T may be affected by the outcome of the re-evaluation of the active ingredient, thiram.

References

PMRA Document Number	Reference

2385665	1998, Determination of the Magnitude of Residues of Thiram in Apple RACs from Trees Treated with a Thiram 75 Water-Dispersible Granule Formulation, DACO: 7.4.1
2385669	1995, Magnitude of Thiram Residue in Apples, DACO: 7.4.1

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