

Evaluation Report for Category B, Subcategory 1.3 Application

Application Number: 2010-1229
Application: Changes to TGAI chemistry: specifications
Product: Thiacloprid Technical Insecticide
Registration Number: 28428
Active ingredient (a.i.): Thiacloprid
PMRA Document Number English PDF: 2124354

Background

The active ingredient thiacloprid was first registered in Canada in 2007 for use in Calypso 480 SC Insecticide (Registration Number 28429) to control a variety of insect pests on pome fruit. The detailed review can be found in Proposed Registration Decision PRD2007-02, *Thiacloprid*.

Purpose of Application

The purpose of this application was to reassess the cancer endpoint for thiacloprid in a joint review with the United States. Supplemental studies were submitted related to the formation of uterine adenocarcinomas in female rats following chronic dosing.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessment

The potential for thiacloprid to cause uterine adenocarcinomas in female rats as a threshold carcinogen has been re-examined and the proposed mode of action was not supported. As a result, there was no change to the toxicology profile for thiacloprid as described in Proposed Registration Decision PRD2007-02, *Thiacloprid*.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The PMRA conducted an evaluation of the subject application and concluded there was insufficient information to revise the cancer endpoint.

References

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- 1882443 2010, Thiacloprid - Determination by HPLC analysis in aqueous methylcellulose, DACO: 4.8
- 1882446 2008, Thiacloprid - Determination by high performance liquid chromatography analysis in ground rodent diet, DACO: 4.8
- 1882452 2009, Thiacloprid - Investigation of effects on hormone levels in adult female Wistar rats following a single oral dose, DACO: 4.8
- 1882453 2010, Thiacloprid - Exploratory 28-day toxicity study in the rat by dietary administration, DACO: 4.8
- 1882454 2010, Thiacloprid - Exploratory 28-day toxicity study in the aged female rat by dietary administration, DACO: 4.8
- 1882455 2010, Thiacloprid - Mode of action (MOA) investigations to explain rat uterine adenocarcinomas, DACO: 4.8
- 1882456 2010, Thiacloprid: Investigation of *in vitro* effects on steroidogenesis using H295R cells, DACO: 4.8
- 1882457 2010, Thiacloprid: *In vitro* investigation of steroid sex hormone secretion in rat ovarian preantral follicles, DACO: 4.8
- 1882458 2010, Thiacloprid - Evaluation of hormone levels in female rats 2 and 8 hours after 4 days exposure by oral gavage, DACO: 4.8
- 1882459 2010, Thiacloprid - Evaluation of hormone levels in female rats 24 hours after 4 days exposure by oral gavage, DACO: 4.8
- 1930180 2007, Thiacloprid - Evaluation in the immature rat uterotrophic assay, DACO: 4.8
- 2012037 2007, Reference compounds for hepatotoxicity exploratory 28-day toxicity study in the rat by gavage, DACO: 4.8

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