

Evaluation Report for Category B, Subcategory 3.13, 3.2, 3.4, 3.8 Application

Application Number: 2013-1875
Application: Product Label Amendments
Product: Tracheal Mite Treatment
Registration Number: 30106
Active ingredients (a.i.): Formic acid
PMRA Document Number: 2380500

Background

The purpose of this application was to amend the label precautions and use directions for the registered commercial end-use product (EP) Tracheal Mite Treatment (Registration Number 30106), for control tracheal mites in honey bee colonies.

Health Assessments

As there were no changes to the formulation of Tracheal Mite Treatment additional toxicology information was not required for Tracheal Mite Treatment and its active ingredient, formic acid. Incidents were searched and reviewed for the active ingredient formic acid. As of December 12, 2013, there were no human or domestic animal incident reports submitted to the PMRA involving the active ingredient formic acid.

The use pattern (method of application, rates, and timing) is consistent with that currently on the registered label for Tracheal Mite Treatment. The changes to the Precautions and Directions for Use sections of the label, including to the personal protective equipment (PPE) statement, are not expected to significantly alter the exposure scenario for this product and therefore are acceptable.

The changes to the Time of Application section of the Tracheal Mite Treatment label remain protective against formic acid residues in honey at concentrations of toxicological concern by restricting use to outside of honey flow, and inclusion of the pre-harvest interval of two weeks.

Environmental and Chemistry Assessments

Environmental and chemistry assessments were not required for this application.

Value Assessment

The amendments to the Tracheal Mite Treatment label do not change the application volume, timing, or methods for this product. The applicant rationale for these changes is acceptable from a value perspective.

Conclusion

The amendments to the Tracheal Mite Treatment label were accepted.

References

PMRA

Document

Number	Reference
2287060	2013, Letter and Rationale for label changes,

ISSN: 1911-8082

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