

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application

Application Number: 2017-7214
Application: B.2.1: New EP: Product Chemistry - Guarantee
B.2.3: New EP: Product Chemistry - Identity of Formulants
B.2.4: New EP: Product Chemistry - Proportion of Formulants
Product: Formic Pro
Registration Number: 33321
Active ingredients (a.i.): Formic Acid
PMRA Document Number : 2950954

Purpose of Application

The purpose of this application was to register the end use product, Formic Pro, based on a currently registered product registered.

Chemistry Assessment

Formic Pro is formulated as a slow-release generator containing formic acid at a concentration of 42.25%. This end-use product has a density of 1.9-2.1 g/cm³. The required chemistry data for Formic Pro have been provided, reviewed and found to be acceptable.

Health Assessments

The changes in formulation of Formic Pro compared to the precedent product are not expected to result in changes to the toxicological profile of Formic Pro. The primary endpoint of concern for formic acid is its corrosiveness. No end use product specific toxicology data was required to assess Formic Pro.

Health risks from exposure to Formic Pro for the applicator are acceptable if label directions, including precautionary statements and personal protective equipment, are followed. As Formic Pro is intended for direct application inside beehives in an apiary, bystander exposure is expected to be negligible. Post-application exposure is expected to be minimal as it only involves the removal of used strips from beehives for disposal.

When used according to label directions, Formic Pro is not expected to result in formic acid residues in honey or honey products at concentrations of toxicological concern. In addition, the application of Formic Pro to beehives should not result in exposures to sources of drinking water. Therefore, the use of Formic Pro is not expected to result in a dietary risk from drinking water.

Incident Reports

As of August 9, 2018, no human or domestic animal incident reports involving formic acid had been reported to the PMRA.

Environmental Assessment

The use pattern of the end-use product, Formic Pro, is within the currently registered use pattern of the active ingredient formic acid, and therefore, no additional risk is expected from the registration of Formic Pro.

Value Assessment

Three trials were submitted to support the use of Formic Acid Pro for control of varroa mites in honey bee hives. These trials tested the performance of Formic Acid Pro when used in single and double brood frame hives in both high and low ambient temperatures compared to untreated hives and hives treated with the registered precedent product, NOD Mite Away Quick Strips.

These trials demonstrated that Formic Acid Pro has comparable performance to NOD Mite Away Quick Strips. A claim that Formic Acid Pro will control varroa mites in honey bee hives when applied with a full dose treatments (2 strips, applied to hive for 14 days) or two half dose treatments (1 strip) with a 10-day application interval was supported.

Conclusion

The PMRA has reviewed the information provided in support of the new end use product. Based on the results of that review, Formic Pro is acceptable for registration.

References

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|---------|---|
| 2824792 | 2017, 10.0 Value Summary |
| 2824793 | 2017, MAQS vs MAQS+ 2015 Environmental Parameter Confirmation, DACO: 10.2.3.3 |
| 2824794 | 2017, MAQS vs MAQS+ 2016 Fall Comparison Study, DACO: 10.2.3.3 |
| 2824784 | 2017, Data Code 3 Non Confidential Chemistry Data, DACO: 3.0 |
| 2824785 | 2017, CHEMISTRY REQUIREMENTS FOR (EP) OR (TGAI), DACO: 3.0 CBI |

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