

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.5, 3.4 Application

Application Number: 2011-2775
Application: B.2.1 (Product chemistry – guarantee)
B.2.3 (Product chemistry – identity of formulants)
B.2.5 (Product chemistry – formulation type)
B.3.4 (Product labels – application method)
Product: Mite Away Quick Strips
Registration Number: 30324
Active ingredients (a.i.): Formic Acid (FMA)
PMRA Document Number English PDF: 2135924

Purpose of Application

The purpose of this application was to register a new domestic end-use product, Mite Away Quick Strips (46.7% formic acid). Formic acid is currently registered as a technical grade active ingredient in Canada (NOD 95 % Formic Acid, Registration number 27834). In Mite Away Quick Strips, the active ingredient is bound into a gel matrix, and wrapped in a biodegradable paper wrapper. The end-use product is as an acaricide to control varroa and tracheal mites in honeybee colonies (Use Site Category 8 – Livestock for Food).

Chemistry Assessment

Mite Away Quick Strip is formulated as a slow release formulation containing formic acid at a nominal concentration of 46.7%. This end-use product has a density of 1.2 – 1.3 g/mL. The chemistry requirements for Mite Away Quick Strip are incomplete. The storage stability study and corrosion characteristics study must be provided to complete the chemistry data requirements for this product.

Health Assessments

Formic acid, is considered to be moderately acutely toxic via the oral route. As a volatile acid with a pH of 2, formic acid is extremely corrosive; therefore, it is considered to be highly acutely toxic via the dermal and inhalation routes of exposure. It is also considered to be corrosive to the skin and eyes, and is a potential skin sensitizer. Based on available information, and recognizing the long history of use of formic acid in foods and a lack of reporting of adverse effects of this nature, it is expected that exposure to formic acid from the proposed use is not likely to result in prenatal developmental toxicity, mutagenicity and/or genotoxicity. The primary endpoint of concern for formic acid is its corrosiveness, and there are no other reported toxicological endpoints of concern associated with acute or short-term exposure to formic acid.

As the end-use product consists of formic acid (46.7%) and three List 4A formulants that are of food grade, no product-specific toxicology data was required to assess Mite Away Quick Strips.

Significant risk from exposure to Mite Away Quick Strips for the applicator is not expected if label directions, including precautionary statements and personal protective equipment, are followed. As Mite Away Quick Strips are intended for direct application inside beehives in an apiary, bystander exposure is expected to be negligible and therefore not of concern. Post-application exposure is expected to be minimal as it only involves the removal of used strips from beehives for disposal. Because the formic acid concentration is expected to be lower at five to seven days post application, due to the high vapour pressure of formic acid resulting in dissipation of the active ingredient, post-application exposure is expected to be minimal and not of concern.

The information provided is sufficient to permit the use of Mite Away Quick Strips during honey flow or while supers are on the hive, assuming a pre-harvest interval of two weeks. When used according to label directions, Mite Away Quick Strips is not expected to result in formic acid residues in honey or honey products at concentrations of toxicological concern for individuals older than one year old. According to Health Canada's advisory on infant botulism (*Infant Botulism*, ISBN # 0-662-37527-0, updated May 2011), children under one year of age should not consume honey. In addition, the application of Mite Away Quick Strips to beehives should not result in exposures to sources of drinking water. Therefore, the use of this product is not expected to result in a dietary risk from drinking water.

Environmental Assessment

The use of 46.7% formic acid as a gel matrix in strips for control of mites in bee colonies is unlikely to result in significant environmental exposure. The product will be contained within the physical colony container where it will readily volatilize and dissipate; no liquid leakage to the environment is expected under these conditions.

Value Assessment

A total of eight efficacy reports were reviewed in support of the proposed label claims for varroa mites. The reviewed data indicate that an application rate of two strips Mite Away Quick Strips (MAQS) (i.e. 292 g product or 136 g formic acid) is effective in the treatment of honey bees infested with varroa mites. Reduction in phoretic varroa mites in these trials ranged from 85 to 96%. This variation in control of varroa mite is within expectations for formic acid, as efficacy of this active ingredient is dependent on ambient weather conditions (i.e., temperature and humidity). No studies were submitted for the label claim for treatment of honey bees infested with tracheal mites. Although no data or rationale were submitted to support treatment of honey bees infested with tracheal mites, use of 65% liquid formic acid for control of tracheal mites was formerly permitted under Note to CAPCO C94-05, *Proposed Scheduling of 65 Percent Formic Acid for the Detection and Control of Honey Bee Mites on the use of Formic Acid*, and this use is currently registered for formic acid (e.g., Tracheal Mite Treatment, Registration Number 30106).

As formic acid is known to control tracheal mite, and as the application rates and methods required to treat tracheal mite infested honey bees with formic acid are identical or similar to those for varroa mite, use of MAQS against tracheal mite was extrapolated from the data for varroa mite.

The label for MAQS has no restriction on time of year for use, other than directions to use only when temperatures are between 10 to 33°C. The intent is that this product can be applied during any season when temperature restrictions are met, including application during summer and when honey supers are present on the hive. Trials testing MAQS with supers present did not demonstrate any negative effect on the efficacy of MAQS when used during honey flow, therefore this use was supported.

Formic acid is known to have adverse effects on bees, which are exasperated by higher temperatures and severely weakened or small colonies. These adverse effects may include damage and death of brood, loss of queen, a break in egg-laying by the queen, adult bee mortality, and absconding of the colony. Despite this, provided that adverse effects are not too severe, colonies generally recover quickly following treatment. The label for MAQS restricts use to daytime high temperatures between 10°C and 33°C. The reason for the lower temperature limit is that formic acid will not evaporate at a rate which will provide effective control at temperatures below the lower limit. In support of the application temperature range of 10°C to 33°C, the data submitted in trial reports included observations on ambient temperature and damage to bees. In trials where daytime high temperatures ranged from 22°C to 35°C, damage to the hive was acceptable, with hive injury generally limited to the first three days following application. In two trials run in excessively high temperatures (38.0°C to 42.8°C) unacceptable levels of damage were observed in treated colonies. Based on the submitted data, an application temperature range of 10°C to 33°C was supported.

In addition to the temperature restriction, the MAQS label also has a precaution to not treat colonies smaller than six frames of bees as it will result in excessive brood mortality and even in colony mortality. While it is not possible, based on the reviewed data, to confirm if MAQS is detrimental to colonies smaller than six frames of bees, the data do support application to colonies that are at least six frames of bees in size. There is no objection to the inclusion of this precaution.

Application of two strips of MAQS (292 g MAQS, 136 g formic acid) per hive (single or double brood chamber) with honey bee colony clusters covering at least six brood frames when temperatures are between 10° and 33°C for treatment of honey bees infested with varroa mites or tracheal mites was supported from an efficacy and value perspective. No further efficacy data were required.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Mite Away Quick Strips (46.7 % formic acid), and has found the information sufficient to register this new domestic end-use product.

References

PMRA #	Documentation
2075644	2011, Chemistry, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1, 3.4.2, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.7 CBI
2027915	2011, Efficacy data 1, DACO: 10.2.3
2075640	2011, Value Summary, DACO: 10.1
2075641	2011, Hot Weather Trial, DACO: 10.1, 10.2, 10.3.1, 10.3.2, 10.3.3
2075645	2011, Toxicology Waiver Request, DACO 4.1.
2075646	2011, Occupational Exposure Waiver Request, DACO 5.1.
2075648	2011, Food, Feed and Tobacco Residue Waiver Request, DACO 7.1.

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