

Evaluation Report for Category B, Subcategory 3.3, 3.6, 4.6 Application

Application Number: 2013-2327
Application: B.3.3 New or Changes to Product Labels-Application
Number or Frequency
B.3.6 New or Changes to Product Labels-Pre- Harvest
B.4.6 Conversion or Extensions to Ltd. or Term-Submission
to fulfill conditions of registration on a product with full
registration
Product: Mite Away Quick Strips
Registration Number: 30324
Active ingredients (a.i.): Formic acid
PMRA Document Number : 2319718

Background

Mite Away Quick Strips (guarantee 46.7% formic acid) was first granted full registration with conditions on January 18, 2012 to be used as an acaricide to control varroa and tracheal mites in honeybee colonies (Use Site Category 8 – Livestock for Food). In Mite Away Quick Strips, the technical grade active ingredient is bound into a gel matrix, and wrapped in a biodegradable paper wrapper.

Purpose of Application

The purpose of this application was to satisfy the conditions of full registration (storage stability and corrosion data) and to amend the registered label for Mite Away Quick Strips by decreasing the pre-harvest interval from 2 weeks to 0 days, reducing the maximum recommended ambient temperature at time of application, adding a half dose application rate and, if required, adding directions to include a honey super to the hive during treatment.

Chemistry Assessment

The storage stability and corrosion data provided to fulfill the conditions of full registration have been reviewed and found acceptable.

Health Assessments

As no changes were made to the formulation of Mite Away Quick Strips, no further toxicological information was required.

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.

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 Mite Away Quick Strips is not expected to result in a dietary risk from drinking water.

Incident Reports

Incident reports 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 Pest Management Regulatory Agency (PMRA) involving the active ingredient formic acid. In addition, no human or domestic animal incident reports involving formic acid were reported by the California Department of Pesticide Regulation, or the United States Environmental Protection Agency.

PMRA has received six incident reports of excessive hive damage as discussed under the Value Assessment section (see below).

Environmental Assessment

The use of 46.7% percent 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 is contained within the physical colony container where it readily volatilizes and dissipates; no liquid leakage to the environment is expected under these conditions.

Value Assessment

Eleven value studies provided by the applicant supported a maximum recommended ambient temperature at time of application of 29.5°C and the addition of a half dose application rate (one strip). Lower application rates were observed to reduce varroa mite loads, albeit at a reduced level compared to a full application rate of two strips per hive. This application rate has value as it will reduce varroa mite numbers and will provide an option for beekeepers who do not want to use a full application dose on every hive. Label wording informs the user that lower efficacy may occur with the lower application rate. A re-application interval of every two to six weeks for the half dose was also supported.

Adverse effects were observed in the submitted trials at temperatures >35°C. In addition, PMRA has received six incident reports of excessive hive damage in which the causality assessment concluded that there was a likelihood that the incidents were associated with applications of Mite Away Quick Strips (incident report numbers 2013-1658, 2013-0580, 2012-5928, 2012-5653, 2012-5597 and 2012-4525). It is not known what the maximum temperature was at the location

of the affected bee yards during the treatments associated with the incident reports.

However, based on the information submitted by the applicant, temperature was the only reported variable that was associated with excessive hive injury. Unless there is direct monitoring of temperatures at treated bee yards, the user may not be aware that temperatures at the treated location exceed the margin of safety due to microclimates and local variations in temperature. It cannot be assumed that beekeepers using Mite Away Quick Strips will have temperature monitoring equipment at treated yards, as many may rely on weather reports. Therefore, in order to mitigate the risk of injury to the hive the recommended maximum temperature during the first three days of application is 30°C.

Conclusion

The PMRA has completed an assessment of the information provided in support of the product, Mite Away Quick Strips, and has found the information satisfied conditions for registration and were sufficient to amend the currently registered label to include a decrease in the pre-harvest interval from 2 weeks to 0 days, reduce the maximum recommended ambient temperature at time of application from 33°C to 29.5°C, add a half dose application rate, and, if required, add a honey super to the hive during treatment.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
2297572	2011, Shelf Life Study by Storage and Concentration Determination of Mite Away Quick Strips, DACO: 3.5.10
2297573	2011, E.P.A. Storage Stability and Corrosion Resistance Test Results – Mite Away Quick Strips TM (MAQS), DACO: 3.5.10, 3.5.14

2.0 Human and Animal Health

PMRA Document Number	Reference
2297581	Mitchell, D. and D. VanderDussen. 2010. Mite-Away Quick Strip TM Mid Honey Flow Efficacy Trial, American Bee Journal, May 2010: 487-489. DACO: 10.2.3, 7.4.1
2297584	Villalobos, E, M. Wright, S. Nikaido, T. Ito, D. VanderDussen and M. VanderDussen. 2009. Report on the efficacy of Mite Away TM Quick Strips – An experimental test conducted by the University of Hawaii, UH Honeybee Varroa Project, August 2009: 1-6. DACO: 10.2.3, 7.4.1

2297590	2011, Assessment of the effect of two application methods of NOD Mite Away Quick Strips (MAQS) on adult bee mortality and colony development, when applied to control varroa mites (<i>Varroa destructor</i> Anderson & Trueman) in naturally infested honey bee (<i>Apis mellifera</i> L.) colonies and a comparison of efficacies and comparative formic acid levels in honey, after treatment, under field conditions in the UK, DACO: 10.2.3, 7.4.1
2297576	2013, Application for Amendment to Reduce the Withdrawal Period from Two Weeks to Zero Days for Mite Away Quick Strips® PCPA Reg. No. 30324, DACO: 7.1, 7.2.1, 7.3, 7.6
2297586	2009, Controlling <i>Varroa destructor</i> with a flash formic acid strip, DACO: 7.4.1
2297589	2010, The efficacy of new formic acid formulations at controlling varroa mites (<i>Varroa destructor</i>) in honey bee (<i>Apis mellifera</i>) colonies in Florida, DACO: 7.4.1
2297591	2012, Study on Formic Acid Residues in Honey After Treatment of Hives with Mite Away Quick Strips™ (English translation from original article in Italian), DACO: 7.4.1
2297575	2013, Application for Amendment to Label for Mite Away Quick Strip® PCPA Reg. No. 30324, DACO: 5.1, 5.2

3.0 Value

PMRA Document Number	Reference
2297581	Mitchell, D. and D. VanderDussen. 2010. Mite-Away Quick Strip™ Mid Honey Flow Efficacy Trial, American Bee Journal, May 2010: 487-489. DACO: 10.2.3, 7.4.1
2297584	Villalobos, E, M. Wright, S. Nikaido, T. Ito, D. VanderDussen and M. Vander Dussen. 2009. Report on the efficacy of Mite Away™ Quick Strips – An experimental test conducted by the University of Hawaii, UH Honeybee Varroa Project, August 2009: 1-6. DACO: 10.2.3, 7.4.1
2297590	2011, Assessment of the effect of two application methods of NOD Mite Away Quick Strips (MAQS) on adult bee mortality and colony development, when applied to control varroa mites (<i>Varroa destructor</i> Anderson & Trueman) in naturally infested honey bee (<i>Apis mellifera</i> L.) colonies and a comparison of efficacies and comparative formic acid levels in honey, after treatment, under field conditions in the UK, DACO: 10.2.3, 7.4.1
2297593	2013, Application for Amendment to the Label to Include Directions for Use for a Half Dose and to Revise Upper Temperature Constraint for Day of Application for Mite Away Quick Strips® PCPA Reg. No.30324, DACO: 10.1, 10.2.3.1, 10.2.3.3.
2297597	2009, Formic Fudge Initial Screening trials, Gainesville, Florida, DACO: 10.2.3
2297600	2010, Final Report - Assessment of the Efficacy of NOD Formic Strips on Varroa and Assessment of the Toxicity of NOD Formic Strips on Honeybees (<i>Apis mellifera</i>) in Hive Conditions, DACO: 10.2.3

2297601	2010, Final Study Report - Assessment of the Efficacy of a Preparation Containing Formic Acid on Varroa (<i>Varroa destructor</i>) and of the Side-effects on Honeybees (<i>Apis mellifera</i>) in Field Conditions, DACO: 10.2.3
2297604	2009, Van Alten, A., Tam, J. and Kempers, M., Winter Colony Health Assessment After Using Mite Away™ Quick Strips (MAQS™) as a Control for Varroa Mites in the Fall of 2009, Ontario Bee Keepers Association, DACO: 10.2.3
2297608	Oliver R. 2011. Miticides 2011, American Bee Journal, February 2011: 145-151. DACO: 10.2.3
2297611	Oliver R. 2011. An Early Summer Test of Mite Away Quick Strips™, American Bee Journal, September 2011: 841-845. DACO: 10.2.3
2297612	2013, Mite Away Quick Strips™ - A New and Easy Way to Keep <u>Varroa</u> in Check?, DACO: 10.2.3

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

PMRA Document Number	Reference
2394266	Bogdanov, S., V. Kilchenmann, P. Fluri, U. Bühler and P. Lavanchy. 1999. Influence of Organic Acids and Components of Essential Oils on Honey Taste, Swiss Bee Research Centre, Dairy Research Station, Liebefeld, CH-3003 Bern, DACO 7.4.1.
2394260	Bogdanov, S., J.-D. Charrier, A. Imdorf, V. Kilchenmann and P. Fluri. 2002. Determination of Residues in Honey After Treatments with Formic Acid and Oxalic Acid Under Field Conditions, <i>Apidologie</i> , 33:399 – 409. DACO 7.4.1.
2394262	Bogdanov, S., A. Imdorf, J.-D. Charrier, P. Fluri and V. Kilchenmann. 2003. The Contaminants of the Bee Colony, Swiss Bee Research Centre, Dairy Research Station, Liebefeld, CH-3003 Bern, DACO 7.4.1.
2394265	Mato, I., J.F. Huidobro, J. SimaloLozano and M.T. Sancho. 2006. Rapid Determination of Non-aromatic Organic Acids in Honey by Capillary Zone Electrophoresis with Direct Ultraviolet Detection, <i>J. Agric. Food Chem.</i> 54: 1541–1550, DACO 7.4.1

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