January 27, 2014

Tawanda Maignan – Team Leader
Risk Integration, Minor Use, and Emergency Response Branch
U.S. EPA Office of Pesticide Programs (7505 P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

RE: Request for an amendment to the specific exemption for the use of potassium salts of hop beta acids in honey bee colonies to control Varroa mites in Washington.

Section 18 of the amended FIFRA provides the Administrator may exempt a state or federal agency from provisions of FIFRA if a determination is made that emergency conditions exist which require such exemption. The Washington State Department of Agriculture (WSDA) is requesting an amendment to the specific exemption for the use of potassium salts of hop beta acids in honey bee colonies to control Varroa mites (14-WA-01).

According to BetaTec, there are several issues with the current strip (HopGuard) used for the existing exemption: (1) the strip is very flexible and as a result it can be difficult to insert between the brood frames, (2) the strip is typically active for only 2 to 5 days and can require up to 3 consecutive applications in order to control Varroa, and (3) bees can remove the strip from the hive before the treatment is complete.

In order to address these issues, BetaTec has developed an improved strip (HopGuard II). The improved strip: (1) is thicker to increase rigidity, (2) includes corrugated fluting that increases the surface area for the active to absorb on the strip and thereby increases the length of activity, and (3) includes a mylar strip to increase rigidity and make it more difficult for the bees to remove the strip from the hive before the treatment is complete (attachment 1).

BetaTec has submitted abstracts from studies conducted in Arizona and Canada (attachment 2), and a proposed Section 18 container label for HopGuard II (attachment 3). The request for an amendment is supported by Dr. Gloria DeGrandi-Hoffman, USDA (attachment 4) and Mark Emrich (WSBA).
The differences between the existing specific exemption (HopGuard) and the requested amendment (HopGuard II) are summarized in Table 1.

Table 1 – Product Comparison

<table>
<thead>
<tr>
<th>Product</th>
<th>HopGuard</th>
<th>HopGuard II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of strip</td>
<td>Single layer</td>
<td>Corrugated</td>
</tr>
<tr>
<td>Amount of a.i./strip</td>
<td>1.92 grams</td>
<td>4 grams</td>
</tr>
<tr>
<td>Maximum number of applications/year</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Maximum amount of a.i./10 frames of brood</td>
<td>23.04 grams</td>
<td>24 grams</td>
</tr>
<tr>
<td>Maximum number of strips/year</td>
<td>984,000</td>
<td>492,000</td>
</tr>
</tbody>
</table>

Based on our analysis of the above information, WSDA supports the request for an amendment to the specific exemption for the use of potassium salts of hop beta acids in honey bee colonies to control Varroa mites in Washington. If you have any questions, please contact Erik Johansen of our office at (360) 902-2078 or email ejohansen@agr.wa.gov.

Sincerely,

PESTICIDE MANAGEMENT DIVISION

Ted Maxwell
Assistant Director, Pesticide Management Division

cc: Lloyd Schantz, BetaTec Hop Products
    Gene Probasco, BetaTec Hop Products
    Mark Emrich, WSBA
    Paul Lundy, WSBA
    Steve Sheppard, WSU
    Stacey Groce, EPA

Attachments:

1. Letter from BetaTec discussing the improved strip.
2. Abstract from studies in Arizona and Canada.
3. Proposed Section 18 container label for HopGuard II.
4. Letter of support from Dr. Gloria DeGrandi-Hoffman, USDA.
January 15, 2014

Mr. Erik W. Johansen
Special Pesticide Registration Program Coordinator
Washington Department of Agriculture
P. O. Box 42560
Olympia, WA  98504

Re: Request for HopGuard Section 18 Amendment

Dear Mr. Johansen,

The current insert strip used for the delivery of the HopGuard active to the bee hive requires a significant amount of manual effort to place the strip properly. Additionally, as the HopGuard active dries out quickly on the current insert strip in many cases the beekeepers are required to treat multiple times to insure adequate control of the Varroa mite. The beekeepers from all states who have approved HopGuard have requested that we improve the ease in application (i.e. they would prefer a “stiffer” strip) and we increase the length of time the strip stays active in the bee hive. The current strip is active from 2 to 5 days; the ideal time for the beekeeper is at least 12 days which coincides with the time the mite is developing under the brood cap.

With the cooperation of the USDA-ARS and the Canadian governmental Apiculturists, we have developed an improved insert strip. We have discussed this proposed strip change with the EPA and they are supportive of the change as we are responding to the needs of the end-user, have improved the overall efficacy of the active by improving the delivery device, and by eliminating the need for multiple treatments have reduced the amount of active that will ultimately be entering the hive. Accordingly we are requesting the state of Washington to submit a request for a Section 18 amendment to permit the use of the revised insert strip.

Rational/Specific Data to Support Change

1. The current insert strip is a single layer cardboard strip. When saturated with the HopGuard liquid, it becomes very “flexible” which takes time and significant effort to place the strip properly between the brood frames as directed. Additionally the active liquid dries very quickly once placed in the hive. As it dries, the efficacy is reduced. Typically the strip is only active from 2 to 5 days, thus requiring up to 3 consecutive applications to obtain adequate control.
2. We have made the following modifications to the single layer cardboard insert strip to address its shortcomings. We have attached pictures of the current and the revised strip below to provide for a better understanding of the modifications. Each picture shows the revised strip alongside the current strip with the revised strip having the corrugated surface.

a. We first made the single layer cardboard strip denser and thicker to improve the rigidity of the strip (i.e. to make it stiffer when saturated with the liquid active and thus making it easier to apply).

b. A corrugate fluting was added to only one side of the strip. This increases dramatically the surface area for the active to absorb onto the strip and thereby increases the activity of the strip from the current 2 to 5 days to more than 12 days. The current strip “holds” 12 grams of the HopGuard liquid…the new strip “holds” 25 grams of HopGuard liquid. The dosage rate of 2 strips per 10 frames of bees remains the same. This change all but eliminates the need for consecutive treatments.

c. We have also buried a thin, opaque strip of Mylar within the cardboard. This helps to increase both the rigidity of the strip and prevents “very aggressive” hygienic bees from literally cutting the strip in two and removing it from the hive in a matter of one or two days.
3. Field trial results using the revised insert strip:

a. Heavily infested 10-frame bee colonies (a mix of single and double stacked colonies) with an average Varroa mite infestation of 9.7% in the USDA Red Rock, AZ bee yard were treated with the revised insert strip for 14 days. An 86% efficacy was obtained with only one treatment (refer to Figure 1 below). Honey samples were collected before application, at 1 week, at 2 weeks and after 5 weeks…no residues of the active ingredient were detected. Normal bee activity in the hive was observed with no adverse effects on the bees or brood.

b. Varroa mite infested 10-frame single bee colonies with about a 3% mite load in Saskatchewan (Ministry of Agriculture hives) were treated with the revised strip for 30 days (refer to Figure 2 below). A 92% efficacy was obtained with one treatment. Additional sets of hives were treated with 2 applications of the revised insert strip at 10 days each and 3 applications of the current strip at 5 days each. Efficacy was 96% and 92% respectively. Normal bee activity in the hive was observed with no adverse effects on the bees or brood.
c. Heavily infested 10-frame double stacked bee colonies with about a 10% Varroa mite load in Alberta (Provencal Agriculture and Rural Development hives) were treated with the revised insert strip for 30 days. An 80% efficacy was obtained with one treatment (refer to Figure 3 below). Additional sets of hives were treated with 2 applications of the revised insert strip at 10 days each and 3 applications of the current strip at 5 days each. Efficacy was 97% and 94% respectively. Normal bee activity was observed with no adverse effects on the bees or brood. Note: The bee colonies used in this study were severely stressed and the number of bees in the colonies was very low. The researchers commented that it was difficult to place the insert strips in association with the remaining bees which reduced the typical bee to strip contact required for effective control. They feel this may have resulted in the lower than expected efficacy in the one application treatment. The most interesting observation was that all of these weak colonies survived.

![Fig. 3 - Efficacy of Revised Strip - Fall 2013](image)

4. Proposed amendment to the existing label text – Attached please find a revised copy of the HopGuard container label. The changes are highlighted in yellow. To avoid confusion in the market place when the new strip is introduced, we would propose to add the Roman numeral II after the brand name HopGuard (i.e. HopGuard II).

We at BetaTec Hop Products fully support the request by the nation’s beekeepers to change the insert strip so that it is easier to apply the insert strip and be efficacious with only one application. The evidence from the field trials presented above clearly show this change to the Section 18 is warranted. I have also attached a letter from Dr. Gloria DeGrandi-Hoffman, Research Leader, USDA-ARS, who also supports this amendment request.

Should you have any questions or need additional information, please do not hesitate to let me know.

Best regards,

Lloyd Schantz
Executive Vice President
BetaTec Hop Products, Inc.
Efficacy of Revised HopGuard Strip in Mite Infested Colonies in Arizona.

Fabiana Ahumada¹, Gloria DeGrandi-Hoffman², Gene Probasco³, Lloyd Schantz³.

1. AgScience Consulting, Tucson, AZ.
2. Carl Hayden Bee Research Center, USDA-ARS, Tucson, AZ.
3. J.I.HAAS, Yakima, WA.

Varroa destructor continues to be a threat for the beekeeping industry despite the efforts by beekeepers to control it. It has been brought to the attention of the public and the beekeeping community at virtually every bee related discussion – it is critical to have alternative, efficacious treatments to control the parasitic Varroa mite. Recent research by Dr. Dennis van Engelsdorp have shown that miticides are failing and signs of amitraz resistance are starting to show. Beekeepers are faced with the unfortunate reality of having to apply four mite treatments per year to be able to control the mite infestation levels in their colonies. Along with main topics such as nutrition and colony collapse disorder, the issue of high mite infestation levels that eventually lead to colony devastation is a major concern for the industry.

The development and improvement of the HopGuard insert strip to control Varroa will provide alternative treatments and help minimize the resistance issue. A revised HopGuard strip study was set up in Arizona in the fall of 2013. A total of sixteen heavily infested 10-frame honeybee colonies (2 singles, 7 double stacked) were involved in the study located at the University of Arizona Red Rock Ranch facility and managed by the USDA-ARS. Colonies had an average pre-treatment mite infestation of 9.7 % and were treated with two revised HopGuard strips per brood chamber for a period of 14 days. Post-treatment mite counts showed an 86% efficacy with only one treatment application (results are shown in Figure 1). Pre and post treatment mite counts were performed using the sugar shake method. Daily observations on bee interactions with the treatment and the effect on colony behavior were recorded. No adverse effects were observed on the bees or brood and bees showed signs of normal activity and behavior.

A honey residue study was carried out during the revised HopGuard strip treatment period. Honey shallow frame boxes were inserted on top of the colonies prior treatment and left on for 5 weeks. In sterile tubes, a total of 4 to 6 mls of uncapped honey was collected from each hive - pre-treatment, after 1 week of treatment, after 2 weeks of treatment, and after 5 weeks of treatment. After collection, samples were kept in a Styrofoam cooler with ice packs until brought back to the laboratory and stored at -20°C. Samples were then shipped in dry ice overnight to the J. I. HAAS laboratory in Yakima, WA for Beta Acid content analyses. All honey samples collected from the nine colonies during the treatment period were below the detection levels of the HPLC equipment used for the analysis (detection limit about 1 ppm). Accordingly, no Beta Acids residue was detected in the honey samples.
The results of this study have shown that the revised HopGuard strips have increased their efficacy to control mites with only one treatment to an average of 86% over a two-week period and no residues of beta acids were found in honey samples during the application.

Figure 1. Efficacy of Revised HG Strips after 2 weeks of Treatment-Fall 2013

- Pre-treatment
- Post-treatment

86% Efficacy
An Effective improved application method of HopGuard for Varroa Control in Canada

Nasr¹, M., S. Muirhead¹, G. Parson², and G. Wilson²

1. Crop Research and Extension, Agriculture and Rural Development, 17507 Fort Road NW, Edmonton, AB T5Y 6H3 Canada (Correspondence: Medhat.nasr@gov.ab.ca)
2. Saskatchewan Ministry of Agriculture, 800 Central Ave, Box 3003 Prince Albert, SK S6V 6G1 Canada

Varroa destructor is a serious parasite of the Western honey bee Apis mellifera. Beekeepers extensively relied on synthetic miticides, primarily Apistan, Checkmite and Apivar to control this parasite. Because of resistance development to applied miticides, beekeepers are advised to utilize several tactics including mite tolerant bees, the use of organic acids and synthetic miticides in an integrated pest management system to manage varroa populations. In order to manage miticides’ resistance and provide more tools to beekeepers for varroa control this study evaluated the efficacy of HopGuard for varroa control in Canada. Earlier trials showed the efficacy of one or two applications of HopGuard (one strip per 5 frames of bees) was approximately 40% (Vandervalk M. Sc. 2013). The current study expanded upon earlier trials by testing more applications and changing the substrate of HopGuard strips. In spring 2013 trials, HopGuard was applied 3 times at 5 day intervals at the same dose as described above, The estimated efficacy was 56.7% using Apivar as a finishing treatment. The HopGuard™ showed once again that it was effective right after application for 2-3 days, but quickly dried out and became ineffective after that time. In some cases dried strips were chewed out by bees.

The substrate of HopGuard strip was replaced with a corrugated cardboard strip to hold more material and prevent the strip from drying out as quickly. Consequently, the exposure period of bees to the hop material increased. This type of new strips was called HopGuard II and it is applied as one strip/5 frames of bees, similar to the original strip. HopGuard was tested in double brood chamber bee colonies. The efficacy for the following treatments was as follows; one application of HopGuard II, two applications at 10 day intervals, three applications at 10 day intervals, three applications of HopGuard at 5 day intervals and no treatment as a control was 80.0±10.7%, 97.0±1.4, 98.5±0.7, 93.7±4.0 and 22.0±4.0, respectively (Fig. 1). Similar results were achieved when HopGuard was tested in single brood chamber bee colonies. The efficacy was 92.0±5, 97.0 ± 13.3, and 92.3 ±4.1 for HopGuard II with one application, HopGuard II with 2 applications and HopGuard with 3 applications, respectively (Fig 2).

The results of this study show that the changing the strips to corrugated cardboard improved efficacy. A single application of one strip of HopGuard II will have an efficacy 80.0-92.0% against varroa mites. Moreover, these results show that HopGaurd II will become a useful effective miticide that will play a role in managing varroa in honey bees.
HOPGUARD® II

SECTION 18 SPECIFIC EXEMPTION

THIS IS AN UNREGISTERED PRODUCT AND MAY BE USED FOR DISTRIBUTION AND USE ONLY IN STATES WITH A VALID SECTION 18 EXEMPTION AUTHORIZATION. THE EXEMPTION IS EFFECTIVE FROM JANUARY 1, 2014 AND EXPIRES ON DECEMBER 31, 2014.

For use in beehives to control Varroa mites (Varroa destructor) on honey bees

ACTIVE INGREDIENTS: BY WEIGHT
Potassium Salt of Hop Beta Acids ......................... 16.0%

INERT INGREDIENTS: ......................................... 84.0%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS
Product may cause eye irritation – flood eyes with plenty of water if contact is made with eyes. Wearing protective eyewear when handling treated strips will reduce the potential for eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or smoking tobacco. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT
Applicators must wear chemical-resistant gloves when handling treated strips.

DIRECTIONS FOR USE
Package - Strips must be applied at the rate of three half strips per 2 lb. or 3 lb. package of adult worker bees. Cut strips in half and attach three half strips to the top of package so that the strips are hanging within the package. Place bees in the package after the strips are attached. The bees should remain in contact with the strips for at least 48 hours.

Colony - Strips must be applied at the rate of one strip per five deep combs covered with bees in each brood super or for example two strips per ten frame brood super (chamber) when all the combs are covered with bees. Strips are to be placed only in the brood chamber (not in the honey super). Folded strips must be opened and hung over one of the center brood frame with one-half of the strip on each side of the frame. If using a second strip, apply it to an adjacent center frame about four inches away from the first strip. Strips must be placed hanging between frames, and within the colony cluster, and not laid on top of the frames. Leave the strips in the colony for 30 days. Retreat, as necessary, up to 3 times per year.

A maximum of 3 applications per year (6 strips or approximately 24.0 grams of potassium salt of hop beta acids) per ten frame brood super (chamber) is allowed. This limit includes all applications to the package (if applicable) and to the colony. Application timing should be based on the levels of Varroa mites observed in the colony. Users may not take honey and wax from the brood chambers, only from the honey supers. For optimal results, apply HopGuard® II when little to no brood is present in the hive.

Any adverse effects resulting from the use of HopGuard® II under this emergency exemption must be immediately reported to your State Department of Agriculture.

RESISTANCE MANAGEMENT
Using this product in rotation with another approved miticide with a different mode of action will decrease the potential for Varroa mites to develop resistance. If the strip remains in the hive more than 30 days, remove.

STORAGE AND DISPOSAL
Unused strips should be stored in a tightly sealed, cool, dark area. Unused, unregistered product must either be returned to the manufacturer or distributor in unopened containers or disposed of in accordance with the Resource Conservation Recovery Act following the expiration of this emergency exemption.

NET CONTENTS
Each HopGuard® II kit contains 24 cardboard strips. Each strip is folded in half and contains 4.0 grams of potassium salt of hop beta acids, and the kit contains 96.0 grams (3.4 ounces) of potassium salt of hop beta acids.

Manufactured by: BetaTec Hop Products, Inc., A Division of John I. Haas, Inc., 1600 River Road, Yakima, WA 98902
January 14, 2014

To: Erik Johansen

From: Dr. Gloria DeGrandi-Hoffman

Re: Section 18 Emergency Amendment for hop beta acids

I support the request for the Section 18 Amendment for the new HopGuard strips. The new strips address the two major concerns beekeepers had with the original HopGuard strips. The first is that the strips were difficult to insert between frames because the cardboard was too thin. The new strips are composed of a stiffer cardboard, and are easier for beekeepers to fit between frames. The second improvement that beekeepers wanted was for the strips to remain effective for a longer period, so that mite populations in colonies with sealed brood could be reduced significantly with a single application. The new cardboard strips have a corrugated fluting so more beta acid is absorbed in the strip. The new HopGuard strips release the beta acids for 14 days, and with a single application reduce mite populations in colonies with sealed brood by about 85%. The beta acids are absorbed better in the new strips and distributed to the bees more efficiently, so less product is needed to obtain the same levels of mite drop achieved with multiple applications of the original HopGuard strips.

Sincerely,

Gloria DeGrandi-Hoffman

Gloria DeGrandi-Hoffman
Research Leader