

**2012 FIFRA SECTION 18 EMERGENCY SPECIFIC EXEMPTION
FOR THE USE OF HOPGUARD TO CONTROL VARROA MITE IN
HONEY BEE COLONIES IN MAINE**

General information requirements of 40 CFR 166.20(a, b) in an application for a specific exemption.

TYPE OF EXEMPTION BEING REQUESTED

SPECIFIC

SECTION 166.20(a)(1): IDENTITY OF CONTACT PERSONS

(i) Contact person:

This application to the Administrator of the Environmental Protection Agency (EPA) is for a specific exemption to authorize the use of HopGuard (potassium salt of hop beta acids) to control Varroa mites in honey bee colonies. This application is submitted by the Maine Board of Pesticides Control. Any questions related to this request should be addressed to:

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(ii) Qualified experts:

The following qualified expert is also available to answer questions:

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SECTION 166.20(a)(2): DESCRIPTION OF PESTICIDE

(ii) Unregistered pesticide product:

Common Chemical Name

(Active Ingredient): Potassium salt of hop beta acids (16% active ingredient (a.i.))

Trade Name: HopGuard

Registrant: BetaTec Hop Products
A Wholly Owned Subsidiary of John I. Haas, Inc.
P.O. Box 1441
Yakima a, WA 98907

(A) The Confidential Statement of Formula was previously submitted to the EPA by the registrant.

(B) The proposed Section 18 label and container label are included as attachments #1 and 2.

SECTION 166.20(a)(3): DESCRIPTION OF PROPOSED USE

(i) Sites to be treated (including locations within the State):

Use of potassium salt of hop beta acids is requested for honey bee colonies located in all Maine counties.

(ii) Method of Application:

Applications will be made by inserting cardboard strips treated with potassium salt of hop beta acids between brood frames within the honey bee colony.

(iii) Rate of application (weight of product per strip):

Strips will be applied at the rate of one strip per five deep combs covered with bees in each brood chamber or two strips per ten frame brood chambers when all the combs are covered with bees. Each strip contains approx. 1.92 grams of potassium salt of hop beta acids.

(iv) Maximum number of applications:

A maximum of six applications per year (usually spring, summer, and fall) or three applications for late summer and fall will be made.

(v) Total number of honey bee colonies to be treated:

The total number of honey bee colonies in Maine that could be treated with potassium salt of hop beta acids is estimated to be approximately 71,000 beehives (6,810 resident beehives and 64,219 commercial migratory beehives) registered in 2011 (Maine Department of Agriculture. 2011).

(vi) Total amount of pesticide proposed (active ingredient and product):

Assuming that 100% of the 71,000 honey bee colonies in Maine will be treated with four strips (two strips x two brood chambers) up to six times per year (usually spring, summer and fall); a maximum of 1,704,000 strips may be used. If 100% of the honey bee colonies in Maine are treated, then the total amount of hop beta acids applied in Maine will be 3,272 kg (1,704,000 strips x 1.92 grams of potassium salt of hop beta acids per strip), which is equivalent to 7,214.75 pounds.

(vii) Restrictions and requirements concerning the proposed use which may not appear on the labeling:

There are no restrictions or requirements for this proposed Section 18 that do not appear on the Section 18 label for HopGuard. The precautionary language, personal protective equipment, and other safety language on the container label are appropriate for the proposed Section 18.

(viii) Duration of proposed use:

The proposed use for HopGuard will be during the late summer and fall of 2012.

(ix) Earliest possible harvest dates:

Honey is typically harvested the end of July and mid-September depending on seasonal temperatures and environmental conditions.

SECTION 166.20(a)(4): ALTERNATIVE METHODS OF CONTROL

(i) Explanation why currently registered pesticides are not available and/or effective:

There are five pesticides currently approved by the EPA for control of Varroa mites and registered in Maine, but none are providing acceptable control when used in commercial, sideline, and hobby beekeeping operations. Varroa mites have developed resistance to two of these pesticides, rendering them useless in most areas in the continental USA. The other

pesticides are reported to cause bee mortality, provide inconsistent mite control and/or have use limitations that make them impractical for large commercial beekeeping operations (Sammataro et al. 2010).

Apistan (fluvalinate) is one of two pesticides formulated in a contact strip that has been available to beekeepers since the late 1980s. This pesticide worked well to control Varroa mite until repeated usage for many years allowed the Varroa mite to develop resistance to the chemical. With few exceptions, Apistan is no longer effective against the Varroa mite in Maine.

Checkmite (coumaphos) is the other pesticide formulated in a contact strip that has been used by beekeepers since the late 1990s. This product also worked well at controlling Varroa mite until repeated usage for the many years allowed the Varroa mite to develop resistance to the chemical. With few exceptions, it is no longer effective against the Varroa mite in Maine (similar to Apistan).

ApiGuard (thymol) is a vapor-action pesticide that is formulated as a gel. It was effective in controlling Varroa mites for some years, but has lost its efficacy, according to beekeepers in some areas. The product is useful only within a certain temperature range when bees are not producing honey and, if the temperature suddenly becomes too high, bee mortality occurs if the treatment is not quickly removed (Floris et al. 2004).

Api Life Var (thymol/eucalyptus oil/menthol) is another vapor-action/contact pesticide that is formulated as a tablet. It is dependent on optimum temperatures when bees are not producing honey and thus becomes too labor intensive for the large-scale beekeeper.

Mite-Away Quick Strips (formic acid) is a vapor-action pesticide formulated in a pre-soaked pad. This product is only useful within a certain temperature range.

(ii) Explanation why alternative practices would not provide adequate control or be economically feasible:

Apistan (fluvalinate) and Checkmite (coumaphos) are routinely detected in the wax combs in honey bee colonies, creating an additional negative impact on colony health.

ApiGuard (thymol) is too labor intensive for the large-scale commercial beekeeping operations due to its temperature dependency and bee mortality risk (Floris et al. 2004).

Api Life Var (thymol/eucalyptus oil/menthol) is not being used because it is reported by beekeepers to be ineffective in killing Varroa mites. In addition, bee mortality has been reported (similar to ApiGuard).

Mite Away II (formic acid) was another vapor-action pesticide that was formulated as a pre-soaked pad. The Maine registration for this product was discontinued by the company in 2011 and replaced by Mite-Away Quick Strips. The product was hazardous to the applicator unless it was handled very carefully. Control of mites was not adequate even when temperatures fell within the recommended range. The product was ineffective if the temperature was too cold and the bees may be driven out of the hive by the vapor if the temperature was too hot (Calderone, 2009).

Mite-Away Quick Strips (formic acid) is also hazardous to the applicator unless it is handled very carefully. It is also associated with queen loss, adult bee/brood mortality and absconding when used during hot temperatures.

Sucrose octanoate esters (Sucrocide) is a contact pesticide that is formulated as a liquid, but is not registered in Maine. It may be useful for hobby beekeepers with a few colonies; however, it is not useful for large commercial beekeeping operations because of the need to remove each individual frame and spray with product, thus making the procedure too labor intensive. This product can be very harmful to bees if not applied at the correct rate (Sammatro, et al., 2008).

SECTION 166.20(a)(5): EFFICACY OF PROPOSED USE

In the absence of an effective method of control for Varroa in the large commercial beekeeping operations, the need arose for a new product. The identification of a naturally occurring product extracted from hops (*Humulus lupulus*) having miticidal activity prompted the company BetaTec to conduct the necessary research to determine if this new product, HopGuard could be effective in controlling Varroa mites. The results obtained from *in vivo* studies have shown that HopGuard strips are effective in killing Varroa mites and do not harm the bees. Inside the colonies, HopGuard does not disrupt colony behavior, brood production, or queen egg-laying.

Dr. Jeff Pettis of the USDA-ARS Bee Research Laboratory in Beltsville, MD, Dr. Gloria DeGrandi-Hoffinan and Fabiana Auhumada-Segura of the Carl Hayden Bee Research Center in Tucson, AZ, conducted tests with HopGuard on Varroa mite on honey bees and showed good results for efficacy in the commercial beehive setting against the mite, with no harmful effects against the honey bee. The reports of these studies were previously submitted with the Oregon-Idaho-Washington Section 18 Request.

HopGuard was developed as a quick mite knockdown contact application. The strips are made of biodegradable material (cardboard) coated with HopGuard which is made of components that are all food grade, GRAS, and used commercially on a global scale. The strips are inserted between the frames. When the product has been delivered and is no longer on the strip, the bees chew the cardboard and remove it from the hive. The development and delivery system of HopGuard strips as a control for Varroa is compatible with commercial beekeeping because the strip delivery is a practice known to beekeepers, involves minimal labor, and HopGuard is a safer alternative for the bees and the beekeepers (DeGrande-Hoffman, 2010 memo, Appendix 1).

SECTION 166.20(a)(6): EXPECTED RESIDUE LEVELS IN FOOD

Hop beta acids include the closely related compounds lupulone (CAS# 468-28-0), colupulon (CAS# 468-27-9) (TOXNET, 2012) and adlupone (CAS# 31769-60-5) (Chemical Book, 2012) in different percentages (Betatech, 2012a). These compounds differ in one side chain and are virtually inseparable

by high performance liquid chromatography. Sigma Aldrich Chemical company sells the hop beta acids as “Colupulone, a mixture of homologues” with approximately 85% purity (Sigma Aldrich, 2012). EPA is recognizing the active ingredient in Hopguard as a mixture of these beta acids totaling 16%. Subtotals are not available and vary with the variety and the growing conditions of the hops (Betatech, 2012a).

The 2010 residue study was done at the USDA-ARS Carl Hayden Bee Research Facility in Tucson, AZ, using good laboratory practices. In this study hives with active honey flow were treated for 35 days with the Hopguard strips or considered controls. Mites from the hives were evaluated using sticky strips, at 48 hours; the average daily mite drop was almost 14 in the treated hives compared to two in the control hives. Hops beta acids were detected (four of the six hives, a maximum level of 9.52 ppm) in honey extracted from the bottom boxes of the hive (brood chambers where the strips were placed). Honey samples extracted from the top chambers were negative for hop beta acids (Ahumada-Segura, F., 2010a; Ahumada-Segura, F., 2010b).

During commercial treatment, Hop Guard strips will not be placed in a honey super, and it is anticipated that there will be no residues of hop beta acids in a honey super when the product used as directed (Betatech, 2012b; Betatech, 2012c).

SECTION 166.20(a)(7): RISK ASSESSMENT

HUMAN HEALTH

Hop beta acids are considered generally recognized as safe (GRAS) when used as an antimicrobial component of hotdog casings (FDA, 2001). Also hop leaves, hop vine and spent hops are used for cattle and/or sheep feed (Stanton and LeValley, 2012). The concentration of the hop beta acids in the finished feed is between 10 and 25 ppm (Betatech, 2012a). Hops and the specific hop component lupulin are on FDA’s generally recognized as safe list 21 CFR § 182.20 for “Essential oils, oleoresins (solvent- free), and natural extractives (including distillates) (21 CFR 182.20) (FDA 1997). Betatech is seeking a similar exemption for the use of hop beta acids in hives (Betatech, 2012a). Dietary risks would be negligible considering the lack of residue in honey and the proposed exemption from tolerance.

The registrant has petitioned EPA for waivers from the guideline studies regarding mammalian toxicity testing. The only toxicity testing for which EPA has specifically denied a waiver is ocular toxicity tests (40 CFR 158.2050; EPA, 2011). There is language on the proposed label requiring chemical resistant gloves and suggesting that protective eyewear be worn to protect against the irritant effects of the hop beta acids.

ENVIRONMENTAL FATE AND RISKS

Ecological and Environmental Fate Effects: Specific studies have not been conducted with HopGuard, but since the components are all food grade, GRAS, and commercially used on a global scale, there are no detrimental ecological or environmental impacts to be expected.

THREATENED AND ENDANGERED SPECIES

The proposed use of this product is intended to be applied only to the inside of the beehive and therefore expected to have no adverse effects on the threatened and endangered species or their habitats in Maine.

ENVIRONMENTAL FATE

Specific studies have not been conducted with HopGuard, but since the components are all food grade, GRAS, and commercially used on a global scale, there are no detrimental ecological or environmental impacts to be expected.

SECTION 166.20(a)(8): COORDINATION WITH OTHER AFFECTED FEDERAL, STATE, AND LOCAL AGENCIES

Other state and federal agencies will be informed, if necessary, when the exemption is approved.

SECTION 166.20(a)(9): ACKNOWLEDGEMENT BY REGISTRANT

BetaTec Hop Products, A Wholly Owned Subsidiary of John I. Haas, Inc., has been notified of this agency's intent regarding this application (letter of support from L. Schantz, attachment 3).

SECTION 166.25(b)(ii): PROGRESS TOWARDS REGISTRATION

Dr. Michael Braverman, Manager, Biopesticide and Organic Support Program, IR-4 Project, was previously contacted regarding the company's desire to obtain a Section 3 registration. IR-4 received a Project Clearance Request (PCR) Form that was submitted to IR-4 by a member of the beekeeping industry. The registering company (Beta Tec® Hop Products, A Subsidiary of John I. Has, Inc.) was subsequently assigned EPA Company Number 83623. Information is currently being gathered and presented to IR-4 for the purpose of getting the proposed pesticide classified into one of the EPA pesticide categories. The intent is for hop beta acids to be classified as a biopesticide. Additionally, the registering company has developed a draft CSF for the product and is in the process of obtaining efficacy and toxicity data in conjunction with USDA-ARS researchers. (Note -The CSF is confidential and is on file at the EPA.)

SECTION 166.20(a)(10): ENFORCEMENT PROGRAM

The Maine Board of Pesticides Control (BPC) is the State Lead Agency for the regulation of pesticides. The BPC will monitor the application of the exempted pesticide as needed to determine that the provisions of the specific exemption are being followed.

SECTION 166.20(a)(11): REPEAT USES

This is the first year Maine has applied for this specific exemption for this product.

SECTION 166.20(b)(1): NAME OF PEST

Scientific and Common Name of the Pest: *Varroa destructor* (Varroa mite)

SECTION 166.20(b)(2): EVENTS OR CIRCUMSTANCES WHICH BROUGHT ABOUT THE EMERGENCY SITUATION

The ectoparasitic mite *Varroa destructor* appeared in the U.S., in 1987, and is a highly destructive pest of honey bee *Apis mellifera* colonies. The mites live in the colony, reproduce in the cells feeding on the developing larvae by sucking hemolymph and emerge from the cells to feed on the adult bees. This parasitic action vectors viral pathogens, deforms, and/or kills the young, shortens the life of the adults, and adversely affects the colony through an overall reduction in population size, vigor, and health.

Varroa is having a catastrophic effect on honey bee populations and the commercial beekeeping industry. Colony losses across the USA this past year were approximately 21.9%, according to the annual survey conducted by the USDA. USDA-ARS researchers believe that 75% of those losses could be attributed to the direct effects of Varroa (Pettis, 2010 letter, Appendix 2). The parasitic mite is considered the number one pest of honey bees worldwide and its control is necessary for successful beekeeping (Calderone, 2009); however control options are limited.

Colony inspection performed by the Maine Department of Agriculture determined Varroa mite infestation and the viral complex associated with Varroa infestation as the primary reason for colony mortality. In recent years, the symptoms of viral pathogens that are both activated and vectored by Varroa have become more common at lower mite infestations. Therefore, the Varroa treatment threshold is now lower due to the prevalence of these viral pathogens. Northern beekeepers can no longer rely on a single Varroa treatment during fall and, at times, need to treat hives during the short honey production period.

Maine's commercial migratory beekeeping operations are highly mobile and pollinate a diversity of crops that include: CA almonds, FL citrus, NY/ME apples, NJ/ME blueberries, and MA/ME/WI cranberries. Hives are also used to pollinate small fruit, vegetable, and oil crops such as strawberry, squash, and canola in ME. The commercial pollinators must treat multiple times during the year that conflict at times with honey production. Treatment is necessary when the Varroa population warrants in order to prevent excessive colony mortality.

Two EPA-registered pesticides, Apistan® (fluvalinate) and Checkmite® (coumaphos), were initially used to successfully control the Varroa mite; however, the repeated application of these products contributed to the widespread development of mite resistance to these products. Furthermore, fluvalinate and coumaphos are routinely detected in samples of wax combs used in honey bee colonies. The presence of these compounds in the combs has an additional negative impact in colony health and especially in queen rearing. With these two products no longer effective against the mites, additional products became available; however these additional products are reported to cause bee mortality, provide inconsistent mite control, and/or have use limitations that make them impractical for large commercial beekeeping operations.

SECTION 166.20(b)(3): DISCUSSION OF ANTICIPATED RISKS THAT WOULD BE REMEDIED BY THE PROPOSED USE

This emergency exemption is not expected to remedy any risks to threatened or endangered species or to the environment.

SECTION 166.20(b)(4): DISCUSSION OF ECONOMIC LOSS

Economic conditions in the beekeeping industry have become increasingly adverse since the Varroa mite was introduced into the U.S. in 1987. Control of Varroa in the colony became an added cost to beekeeping. Commercial beekeepers are suffering large colony losses due to Varroa. In the meantime, Colony Collapse Disorder (CCD) appeared and added to the economic woes of the beekeeper. The cause of CCD has not been determined, but the Varroa mite is

certainly a part of the disorder. Annual colony losses in the U.S. have been greater than 30% per year in recent years (vanEngelsdorp et al., 2012, [Attachment 4](#)). While these losses are not entirely due to Varroa, Dr. Jeff Pettis (USDA-ARS) estimates that Varroa mites could account for as much as 75% of these annual losses (Appendix 2). In Maine, the majority of colony losses occur during late fall and winter months. Maine beekeepers suffered colony losses greater than 45% during 2010-2011 (vanEngelsdorp et al., 2012).

(ii) Anticipated yield in the absence of the emergency and expected losses due to the emergency:

The USDA National Agricultural Statistic Service reported 6,000 honey producing hives in Maine during 2010 that averaged 41 pounds (lbs)/colony totaling 246,000 lbs of honey. The yield expected for 2011 was approximately the same given that the yields increased each year from 2006 with 23 lbs per colony through 2009 with yields of 50 lbs per colony (Appendix 3, Table 1).

The USDA-NASS 2011 Bees and Honey Survey documented a lower colony count, lower honey production/hive, and overall yield compared to the 2010 survey. In 2011, the USDA-NASS report estimated 4,000 honey producing hives in Maine that produced a 30 lb/hive average totaling 120,000 lbs valued at \$229,000. The 2011 average production was substantially lower than 2010 due to excessive hive mortality from Varroa and associated viral complex during the previous fall and winter (2010-11). Overall, a 54.8% loss in honey production from the five-year baseline prior to the emergency was experienced by the industry (Appendix 3, Table 2).

(ii) Anticipated prices in absence of the emergency and changes in prices and/or production costs due to the emergency:

According to USDA-NASS 2010, honey production was valued at \$519,000 (Appendix 3, Table 1). The projected valuation in 2011 was expected to have been approximately equal to 2010. However, the value of production in 2011 fell to \$229,000, a loss of 49.8% when compared to the five year average value of \$456,185 (Appendix 3, Tables 1, 2).

The primary income for commercial beekeepers in Maine is derived from crop pollination. In 2011, approximately 65,000 colonies were used to pollinate the state's wild blueberry and apple crops. The state's processed wild blueberry crop was valued at \$70.1 million in 2011 and the apple crop at \$ 13.4 million in 2010 (2011 data is not available yet). The value of pollination for Maine's commercial agricultural crops is estimated to be in excess of \$100 million when miscellaneous fruit, vegetable, and oil crops are included.

Compensation for blueberry crop pollination is based upon colony quality with payment according to "grade" after a percentage of colonies are inspected and prorated for the beekeeping operation. Strong, healthy colonies are paid 20-25% greater than the "base rate" and substandard colonies are paid at a reduced rate (20%) or not at all. Pollination compensation ranges from \$75/colony (base) to greater than \$100/colony (with bonus) according to contract stipulations.

Commercial beekeepers have three methods to replace lost colonies:

- (1) Buy full strength replacement colonies for a cost of approximately \$150 each, which is the most expensive, but quickest method.
- (2) Buy nucleus colonies for a cost of approximately \$65 apiece. A nucleus colony is three frames of bees and a queen that are placed into an empty brood chamber. Over time, a nucleus colony will become a full strength colony.
- (3) Split existing parent colonies for a cost of approximately \$60 each. This method involves buying a queen and taking half of the brood frames from an existing parent colony and put these frames into an empty brood chamber. Over time, a split colony will become a full strength colony.

The replacement cost for hives managed by sideline and hobby beekeepers in Maine is greater than commercial beekeeper costs. The price for a nucleus colony ranges from \$90 to \$135, package bees at \$90, and full strength colonies at \$160-\$200.

Colony losses due to Varroa greatly influence the beekeeper's pollination income according to the need for replacement colonies by one or all of the aforementioned methods. When many colonies are split or "nuced" in order to compensate for losses, income is lost by way of replacement cost and pollination income since the nuclei hives and split hives are of lower quality. For example, the national survey reported that colony mortality in 2010-11 was approximately 45%. If 75% of these losses are attributed to Varroa then approximately 22,000 of the 65,000 hives used to pollinate Maine blueberries needed replacement ($65,000 \times 45\% \text{ loss} = 29,250 \text{ mortality} \times 75\% \text{ due to varroa} = 21,937 \text{ hives}$).

Assuming the colonies are replaced via the three methods previously stated: hive purchase (\$150/colony), splitting (\$60/colony), and nuclei hives (\$65/colony); the cost of replacement is approximately \$2,010,800. This cost does not include the reduced pollination income for approximately two thirds of the colonies (nuclei and split colonies) that do not develop into premium (above grade) colonies.

The gross revenue from honey production and commercial beekeeping in Maine in 2011 was \$4,535,300, a 24.2% loss equaling \$1,445, 885, from the five-year average (2006-2010) of \$5,981,185 (Appendix 3, Table 2). Additional production costs associated with colony replacement translates into a 57.8% total loss equaling \$3,456,685 in 2011.

REFERENCES

- 21 CFR § 182.20. 2012. Essential oils, oleoresins (solvent- free), and natural extractives (including distillates), Essential oils, oleoresins (solvent free), and natural extractives (including distillates) that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act.
- Ahumada-Segura, F., 2010a. HopGuard Bee Toxicity and Residue Trial-Tucson 2010. USDA-ARS Carl Hayden Bee Research Center. Tucson. AZ.
- Ahumada-Segura, F., 2010b. HopGuard Residue in Honey. USDA-ARS Carl Hayden Bee Research Center. Tucson. AZ.
- Betatech. 2012a. Betatech Hop Products, a Division of John I Haas, Inc. 2012. Hopguard Section 18 submission.
- Betatech. 2012b. Generic Section 18 label for Hopguard.
- Betatech. 2012c. Washington State Section 18 label for Hopguard.
- Chemical Book. 2012. <http://www.chemicalbook.com/>.
- Calderone, N.W. 2009. Evaluation of Mite-Away-II for fall control of *Varroa destructor* (Acari: Varroidae) in colonies of the honey bee *Apis mellifera* (Hymenoptera: apidae) in the northeastern USA. *Experimental and Applied Acarology*. 50:123-132.
- EPA. 2011. Meeting Summary for the Pre-Registration Meeting with BetaTec Hop Products held on August 10, 2011. Hopguard active ingredients Potassium Salt of Hop Beta Acids
- FDA. 2001. US Food and Drug Administration Agency Response Letter. GRAS Notice No. GRN 000063.
- Floris, G., Satta, A., Cabras, P., Garau, V.L., and A. Angioni. 2004. Comparison between two thymol formulations in the control of *Varroa destructor*: effectiveness, persistence, and residues. *Journal of Economic Entomology*. 97(2): 187-191.
- Maine Department of Agriculture, Food & Rural Resources. 2011. Eastern Plant Board Report. Division of Plant & Animal Health.
- Sammataro, D., Finley, J., and R. Underwood. 2008. Comparing oxalic acid and sucroicide treatments for *Varroa destructor* (Acari:Varroidae) control under desert conditions. *Journal of Economic Entomology*. 101(4): 1057-1061.
- Sammataro, D., Untalan, P., Guerrero, F., and J. Finley. 2010. The resistance of *Varroa* mites (Acari: Varroidae) to acaricides and the presence of esterase. *International Journal of Acarology*. 31(1): 67-74.
- Sigma Aldrich. 2012. <http://www.sigmaaldrich.com/united-states.html>.
- Stanton and LeValley. 2010. Feed Composition for Cattle and Sheep Fact Sheet # 1.615. Colorado State University.
- TOXNET. 2012. <http://toxnet.nlm.nih.gov/>.

REFERENCES cont.

vanEnglesdorp, D, Caron, D., Hayes, J., Underwood, R., Henson, M., Rennich, K., Spleen, A., Andree, M., Snyder, R., Lee, K., Roccasacca, K., Wilson, M., Wilkes, J., Lengerich, E., and J. Pettis. 2012. A national survey of managed honey bee 2010-11 winter colony losses in the USA: results from the Bee Informed Partnership. *Journal of Agricultural Research*. 51(1): 115-124.

APPENDIX 1



United States Department of Agriculture

Research, Education and Economics
Agricultural Research Service

July 22, 2010

To: Gene Probasco

From Dr. Gloria DeGrandi-Hoffman Ph.D.
Research Leader

Re: Section 18 for HopGuard

This memo is to provide information on the comparative ease of use for HopGuard relative to other products available for control of Varroa mites in honey bee colonies. Certainly, any product that is delivered in a strip that is placed in the colony will take less time to apply and be less disturbing to the colony than products that are applied on or between all brood frames or that the beekeeper needs to place on paper for dispensing. Commercial beekeepers make applications of Varroa treatments to thousands of colonies, and those products that can be applied in a few seconds per colony are the most desirable.



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Agricultural Research - Investing in Your Future

APPENDIX 2



United States Department of Agriculture

Research, Education, and Economics
Agricultural Research Service

June 13, 2010

Mr. Lloyd Schantz
Vice President
J. I. Haas, Inc.

Dear Lloyd,

I write in support of Hopguard® as a varroa mite control product and your company's efforts to get it to beekeepers under a section 18 exception. The parasitic varroa mite is considered the number one pest of bees worldwide and its control is necessary for successful beekeeping. Our control options are limited. Further the mite has developed resistance to the two synthetic products used in the U.S., fluvalinate and coumaphos. Thus a real need exist for alternatives.

As you know the beekeeping industry has been suffering extensive losses over the past few years. Our four years of survey of U.S. beekeepers has indicated a greater than 30% loss of bee colonies over the fall and winter; a rate of loss that puts many beekeepers at risk of economic collapse. Colony Collapse Disorder (CCD) has been one of the leading causes of these recent losses but is by no means the only reason. Additionally, we suspect that varroa mites are a likely primary stress factor on bees that allows for pathogens like virus to take hold. I expect that Varroa mites could account for as much as 75% of the bee losses in any particular year. The collapse of colonies that we call CCD could be initiated by the stress caused by the feeding of Varroa. CCD remains unresolved but if we had better varroa control products it is certain that bee health would improve.

The beekeeping industry is in real and immediate need of varroa control alternatives. My experience to date with Hopguard® has been positive and I feel this product will offer a safe and effective alternative to the hard chemicals we have been relying upon but which the mites have developed resistance to. Please let me know if you need additional information or if I can be of further assistance.

Sincerely,

A handwritten signature in cursive script that reads "Jeff Pettis".

Dr. Jeff Pettis
Research Leader
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Bee Research Laboratory
Building 476, Beltsville, MD 20705
An Equal Opportunity Employer

APPENDIX 3

Table 1. Maine honey production and value 2006-2011.

	Honey Producing Colonies	Yield per Colony (lbs)	Production (lbs)	Ave. Price per Pound (dollars)	Value of Production (dollars)
2006	11,000	23	253,000	1.60	405,000
2007	9000	26	234,000	1.32	309,000
2008	7000	42	294,000	1.57	462,000
2009	6000	50	300,000	1.95	585,000
2010	6000	41	246,000	2.11	519,000
5 Year Ave.	7,800	36	265,400	1.71	456,000
2011	4000	30	120,000	1.91	229,000

Source: USDA-NASS 2010

Table 2. Tier 2 Analysis of Honey Production and Commercial Beekeeping Operations in Maine

	Baseline Em	ergency	Change	% Change
	\$	\$		
Pollination income	5,525,000	4,306,300	-\$1,218,700	
Honey production (lbs)	265,400	120,000	-145,400	-54.8
Honey income	\$456,185	\$229,000	-\$227,185	-49.8
Gross revenue	\$5,981,185	\$4,535,300	-\$1,445,885	-24.2
Replacement colony cost (\$150/colony)		\$1,096,800	-\$1,096,800	
Nucleus colony cost (\$65/colony)		\$475,280	-\$475,280	
Split existing parent colony cost (\$60/colony)		\$438,720	-\$438,720	
Total additional costs		\$2,010,800	-\$2,010,800	-33.6
Total losses (% change compared with gross revenue)			-\$3,456,685	-57.8



EMERGENCY EXEMPTION USE DIRECTIONS

EPA FILE SYMBOL 12-ME-01

STATE: Maine
CHEMICAL: Potassium Salt of Hop Beta Acids (HopGuard™)
CROP / SITE: Honey Bees / All counties in the state of Maine
PEST: *Varroa destructor*
EFFECTIVE: August 1, 2012 to December 31, 2012

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 four weeks. Retreat, as necessary, up to three times per year.

A maximum of six (6) applications per year (12 strips or approximately 23.0 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 (usually during spring, summer or fall) 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 when little to no brood is present in the colony.

The use directions must be in the possession of the user at the time of application.

Any adverse effects resulting from the use of HopGuard™ under this emergency exemption must be immediately reported to the Maine Board of Pesticides Control at 207-287-2731.

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 4 weeks remove.

Manufactured by: BetaTec Hop Products, Inc., A Division of John I. Haas, Inc., P.O. Box 1441, Yakima, WA 98907

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HOPGUARD™

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 EXEMPTIONS EXPIRE ON DECEMBER 31, 2012.

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 four weeks. Retreat, as necessary, up to three times per year.

A maximum of three applications per year (six strips or approximately 11.52 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 (usually during spring, summer or fall) 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 when little to no brood is present in the hive.

Any adverse effects resulting from the use of HopGuard™ 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 4 weeks 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™ kit contains 50 cardboard strips. Each strip is folded in half and contains 1.92 grams of potassium salt of hop beta acids, and the kit contains 96 grams (3.4 ounces) of potassium salt of hop beta acids.

Manufactured by: BetaTec Hop Products, Inc., A Division of John I. Haas, Inc., P.O. Box 1441, Yakima, WA 98907

Material Safety Data Sheet

1. Identification of the Preparation and the Manufacturers			
Product name:	HopGuard™		
Intended Use:	Mite Control		
Manufacturers:	Barth-Haas Group / John I. Haas, Inc. Address: 5185 MacArthur Blvd., N. W., Suite 300 Washington, D. C. 20016, USA Emergency phone: +1 202 777 4800 (office hours) Email: info@johnihaas.com		
2. Composition/Information on Ingredients			
Components:	Proprietary blend of an extract of hops and food grade excipients.		
	Extract of hops	Polysorbate 60 (Tween 60)	Propylene glycol
CAS number:	Not established	9005-67-8	57-55-6
Einecs number:	Not established	Not established	200-338-0
3. Hazards Identification			
Main hazards:	May cause irritation		
Oral ingestion:	No hazards anticipated from ingestion. However it is an extremely bitter substance. Ingestion of large amounts may cause irritation to mouth, throat or stomach		
Eye contact:	May cause minor eye irritation		
Skin contact:	Not likely to cause skin irritation		
4. First Aid Measures			
Skin contact:	Wash skin with soap and water		
Eye contact:	Flood the eye with plenty of water. Obtain medical attention if irritation persists.		
Inhalation:	Remove from exposure		
Oral ingestion:	Treat symptomatically and supportively		
5. Fire-Fighting Measures			
Extinguishing media:	Use any means suitable to extinguish surrounding fire including dry chemical, foam, CO ₂ or water spray		
Special fire fighting procedures:	None		
Unusual fire and explosion:	Slight fire hazard when exposed to heat or flame. Heat from fire can generate flammable vapor.		
6. Accidental Release Measures			
Personal protection:	Wear appropriate protective clothing		
Environmental Precautions:	Prevent material from entering drains or water courses		
Methods for cleaning up:	Absorb spill with absorbent material such as paper towel, fly ash, sand or dirt. Scoop/shovel into disposal container. Wash hard surfaces with hot water and/or detergent to remove completely.		

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BetaTec Hop Products, 5185 MacArthur Blvd, N.W., Suite 300, Washington DC, 20016
Phone: +1 (202) 777-4800, Fax: +1 (202) 777-4895

Material Safety Data Sheet

7. Handling and Storage	
Handling:	Avoid excessive contact with product
Storage:	Store at or below room temperature away from direct sunlight.
8. Exposure Controls/Personal Protection	
Respirator:	Not required unless handling creates potential for inhalation.
Hand protection:	PVC or rubber gloves
Eye protection:	Safety goggles should be worn during handling
Skin protection:	Normal working clothes. Launder contaminated clothing before reuse. If potential of splashing, wear PVC or rubber apron.
9. Physical and Chemical Properties	
Form:	Liquid
Color:	Amber/brown
Odor:	Resinous
pH	8.0 – 9.0
Flashpoint:	Not applicable
Flammability:	Non-flammable
Explosive properties:	None known
Vapor pressure:	<0.1 mg Hg @ 20 °C
Vapor density:	> 1 (Air = 1)
Density (g/ml):	Approximately 1.0
Solubility in water:	sparingly
Evaporation rate:	Not known
10. Stability and Reactivity	
Conditions to avoid	No hazardous conditions known
Materials to avoid:	Avoid strong oxidizing agents.
Hazardous decomposition products:	Combustion produces carbon monoxide, carbon dioxide along with thick smoke.
11. Toxicology Information	
Acute toxicity:	Relatively non-toxic by dermal absorption and ingestion
12. Ecological Information	
Ecotoxicity:	Not known
Mobility:	Product will dissolve in water
Persistence and degradability:	Not known
Bioaccumulation potential:	Product is not expected to bioaccumulate
Other adverse effects:	Not known

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Material Safety Data Sheet

13. Disposal Considerations	
Product disposal:	Contaminated absorbent material may be disposed of in an approved land fill. Comply with all applicable federal, state and local regulations concerning waste disposal
Container disposal:	Labels should not be removed from containers until they have been cleaned. Contaminated containers should be cleaned using appropriate methods and then re-used, recycled or disposed of in accordance with applicable local or national regulations.
14. Transport Information	
UN-No: Not listed	Not listed
Class:	Not listed
Shipping name:	HopGuard™
Packing Group:	Not listed
Marine pollutant:	Not known
15. Regulatory Information	
This product is not classified in Annex 1 Directive 67/548/EEC on the classification, packaging and labeling of dangerous substances. We are unaware of any regulations which regard this product as dangerous.	
16. Other Information	
The information in this safety sheet is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information is based on our present knowledge and should be used only as a supplement to information already in your possession concerning this product. The determination of whether and under what conditions the product should be used is yours to make. We do not accept any liability for loss, injury or damage that may result from its use.	

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