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GOVERNOR

STATE OF MAINE DEPARTMENT OF AGRICULTURE, CONSERVATION AND FORESTRY BOARD OF PESTICIDES CONTROL 28 STATE HOUSE STATION AUGUSTA, MAINE 04333-0028

WALTER E. WHITCOMB COMMISSIONER

> HENRY JENNINGS DIRECTOR

To: Board of Pesticides Control Members
From: Mary Tomlinson, Pesticides Registrar/Water Quality Specialist
RE: FIFRA Section 18 request for use of Apivar to control Verroa mites in honey bee colonies
Date: March 1, 2013

This FIFRA Section 18 request for the use of Apivar (amitraz) to control Verroa mites in honey bee colonies is submitted at the request of Tony Jadczak, State Apiarist. Varroa mites are a major pest of honey bees, causing significant colony losses in Maine. Enclosed is the above referenced Section 18 Specific Emergency Exemption request and supporting documents for your consideration.

Varroa mites have developed resistance to two currently registered pesticides and the other registered pesticides cause bee mortality, provide inconsistent mite control, and/or have use limitations making them impractical for large commercial beekeeping operations. Apivar provides miticidal effects via a different mode of action, suggesting it will be a valuable option in resistance management and organic honey production.

Lebelle Hicks, PhD DABT, pesticide toxicologist for the Board, reviewed the background information on exposure potential and toxicity data for the proposed use of amitraz in beehives under this section 18. This use and related residues in the honey will not increase the risks to the general population or the most highly exposure subpopulation, children one to two years of age. In addition, because this product is intended to be applied only to the inside of the beehive; therefore, environmental releases should not be an issue. Lebelle will be at the meeting to address questions.

Please reviewing the following documents and let me know if you have any questions.

- 1. Maine Section 18 request
- 2. Letter of support from Tony Jadczak, Maine State Apiarist
- 3. Letter of support from Toyokazu Matsumoto, Arysta LifeScience America, Inc.
- 4. Apivar container label
- 5. Draft Maine Section 18 label with use directions
- 6. Apivar MSDS
- 7. List of Maine's threatened and endangered species

2013 FIFRA SECTION 18 EMERGENCY SPECIFIC EXEMPTION REQUEST FOR USE OF APIVAR TO CONTROL VARROA MITE IN HONEY BEE COLONIES IN MAINE

Submitted by Maine Board of Pesticides Control Maine Department of Agriculture, Conservation and Forestry

March 1, 2013

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

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 Apivar (amitraz) 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:

Mary Tomlinson, Pesticides Registrar/Water Quality Specialist Maine Board of Pesticides Control Maine Department of Agriculture, Conservation and Forestry State House Station 28 Augusta, ME 04333-0028 mary.e.tomlinson@maine.gov Phone: (207) 287-7544 Fax: (207) 287-7548

(ii) Qualified experts:

The following qualified expert is also available to answer questions:

Anthony Jadczak, Maine State Apiarist Maine Department of Agriculture, Conservation and Forest State House Station 28 Augusta, ME 04333-0028 207-287-7562 anthony.m.jadczak@maine.gov

(a) Technical and scientific aspects:

Dr. Jeff Pettis, Research Leader USDA-ARS Bee Research Laboratory Bldg. 476 BARC-E Beltsville, MD 20705 Telephone: 301-504-7299 Fax: 301-504-8736 Email: jeff.pettis@ars.usda.gov

Toyokazu Matsumoto, President Arysta Life Sciences America, Inc. 1450 Broadway, 7th Floor New York, NY 10018 Telephone: 212-930-5100 Fax: 212-930-5119 Email: toyokazu.matsumoto@arysta-hns-corp.com

b) Economic aspects:

Dr. Jeff Pettis, Research Leader USDA-ARS Bee Research Laboratory Bldg. 476 BARC-East Beltsville, MD 20705 Telephone: 301-504-7299 Fax: 301-504-8736 E-mail: jeff.pettis@ars.usda.gov

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

(ii) Unregistered pesticide product:

Common Chemical Name: (Active Ingredient): Amitraz: N'-(2,4-dimethylphenyl)-N-[[(2,4-dimethylphenyl)imino]methyl]-N-methylmethanimidamide

Trade Name: Apivar

Formulation: Impregnated sustained-release plastic strip impregnated

Amount of active ingredient: 3.33% amitraz

Manufactured by: WyjoLab, SA ZA les Servenilles 36310 Chaillac France

- Manufactured for: Veto-pharma S.A. 14 avenue du Quebec 91140 Villebon-sur-Yvette France
- U.S. Agent: Arysta LifeScience America, Inc. 1450 Broadway, 7th Floor New York, NY 10018

(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 in the request packet.

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

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

Use of Apivar is requested for honey bee colonies located in all Maine counties.

(ii) Method of Application:

To control varroa mite, remove honey supers before application of Apivar. Use two Apivar strips per brood chamber. Separate the double strip and hang each strip between two comb frames inside the brood area or bee cluster, with a minimum distance of two frames between strips. Suspend Apivar strips in the brood chamber in such a way that the bees can walk on both sides of the strips. Leave strips inside the hive for 42 days minimum, and then remove. In case of movement of bees inside the beehive away from the strips, reposition the strips into the bee cluster, and leave strips in place for 14 more days before removal. Strips must be removed after a maximum of 56 days. **DO NOT** re-use the strips.

Hang Apivar strips in the hives in the spring or the fall if Varroa mite infestations have reached treatment threshold. All Apivar strips should be removed two weeks before the honey flow starts.

DO NOT USE APIVAR STRIPS WHEN HONEY SUPERS ARE PRESENT.

Remove honey supers before application of Apivar strips and do not replace supers until 14 days after the strips are removed. Treat all infested colonies within the yard. The treatment is most effective when brood rearing is lowest.

Resistance management: This pest scenario is highly susceptible to resistance. Amitraz belongs to Insecticide Resistance Action Committee (IRAC) Group 19. Some individuals in

the Varroa mite population may be naturally resistant to Apivar. Over time, resistant Varroa mites will reproduce and dominate the mite population if Apivar is used repeatedly in the same location. To delay resistance, rotate this product with other Varroa mite control products in different chemical classes so that the potential for Varroa mite populations to develop resistance is minimized. Pesticide use should be based on an integrated pest management (IPM) program that includes, monitoring, record keeping, and considers cultural, biological and other chemical control practices. Using IPM with strict adherence to label directions (specifically the removal of amitraz strips after 56 days) on approved treatments reduces the risks of encouraging the development of resistant Varroa mite populations. Correctly identify the pest and ensure that the treatment thresholds are met prior to use. Monitor treated pest populations for resistance development and incorporate resistance management practices into a control program. Report performance issues due to the development of amitraz resistance in target pest.

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

Strips will be applied at the rate of two strips per brood chamber. Each strip contains approximately 0.5 g of amitraz (a.i.).

(iv) Maximum number of applications:

A maximum of two applications per year (spring and/or 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 Apivar is estimated to be approximately 80,200 beehives (10,180 resident beehives and 70,000 commercial migratory beehives) registered in 2012 (Maine Department of Agriculture, 2012).

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

Assuming that 100% of the 80,200 honey bee colonies in Maine will be treated with four strips (two strips x two brood chambers) up to two times per year (spring and fall); a maximum of 641,600 strips may be used. If 100% of the honey bee colonies in Maine are treated, then the total amount of amitraz applied in Maine will be 320,800 grams (641,600 strips x 0.5 grams of amitraz per strip) or 707 lbs.

(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 Apivar. 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 Apivar will be during the spring and fall of 2013.

(ix) Earliest possible harvest dates:

Honey is typically harvested the end of July and mid-September depending on the amount of honey produced and environmental conditions that influence nectar secretion.

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

There are five pesticides currently approved by the EPA for control of Varroa mites and registered in Maine. In addition, EPA granted FIFRA Section 18 Emergency Specific Exemption for the use of HopGuard (beta acids) on August 3, 2102. None of these pesticides 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).

<u>Apistan (fluvalinate)</u> 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.

<u>Checkmite (coumaphos)</u> 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 contributed to the development of resistance among the Varroa mite population to the chemical. With few exceptions, it is no longer effective against the Varroa mite in Maine (similar to Apistan).

<u>ApiGuard (thymol)</u> is a contact/vapor-action pesticide that is formulated as a gel. It is effective in controlling Varroa mites under certain optimal conditions. 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). Labor is an issue with this pesticide since it requires two successive applications.

<u>Api Life Var (thymol/eucalyptus oil/menthol)</u> is another contact/vapor-action/contact pesticide that is formulated as a tablet. It is dependent on optimum temperatures and requires three successive applications when bees are not producing honey. This pesticide is too labor intensive for the large-scale beekeepers.

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

<u>HopGuard (beta acids)</u> authorized under Section 18 Emergency Exemption is a contact action pesticide formulated on a presoaked cardboard strip. The current formulation requires multiple applications (three) when hives are rearing brood and is too labor intensive for large-scale beekeepers.

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

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

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

<u>Api Life Var (thymol/eucalyptus oil/menthol)</u> is labor intensive since three applications are necessary for Varroa control. In addition, bee mortality has been reported (similar to ApiGuard) under certain environmental conditions.

<u>Mite-Away Quick Strips</u> (formic acid) is also hazardous to the applicator unless it is handled very carefully. It is associated with queen loss, adult bee/brood mortality, and absconding when used during hot temperatures. The product's efficacy is inconsistent and influenced by the amount of brood present and size of the hive being treated.

<u>Sucrose octanoate esters (Sucrocide)</u> 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 (Sammataro et al., 2008).

<u>HopGuard (beta acids)</u>, authorized under Section 18 Emergency Exemption, performs well when hives have minimal-no brood. This pesticide provides Varroa control for approximately three days (while the strips remain wet). The current formulation necessitates multiple applications when hives are actively rearing brood which increases labor and associated costs for large scale beekeeping operations.

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

Data from the USDA-ARS laboratory in Beltsville, MD, has demonstrated the efficacy of Apivar against Varroa mite. Apivar was first authorized in France in 1995 and there have been no complaints regarding the use of Apivar and sale of more than 10 million strips in France. In addition, there have been no complaints concerning Apivar with more than five million strips sold over a ten year period in Spain, one million strips sold in New Zealand over a six year period and more recently one million strips sold in Canada since 2008. Apivar has also been sold in the European Union, Japan, and Middle East with no complaints.

Pesticide application via strips as a control for Varroa is compatible with commercial beekeeping because the strip delivery is a practice known to beekeepers and involves minimal labor.

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

Amitraz (CAS# 33089-61-1) (TOXNET, 2013) is an acaricide currently registered by EPA for use on cattle and hogs as a dermal ectoparasite treatment. There are tolerances for cattle: fat, meat and meat byproducts, and milk. The hog tolerances include fat, kidney, liver, meat, and meat byproducts. Amitraz is used on cotton in foreign countries and there is an import tolerance for cotton (EPA, 2010). The existing tolerances include the parent compound, metabolites, and degradates (40 CFR 180.287, 2013) and range from 0.01 to 1 ppm.

Historically, there have been beehive uses for a 10% amitraz strip (Hoechst-Roussel Agri-Vet Company, 1992) at three strips per brood chamber during non-honey producing times. This is a much higher application rate than 3.33% amitraz strips with two per brood chamber. The previous tolerances were 1 ppm in honey and 6 ppm in beeswax (EPA, 2004). The honey beehive use and the honey beeswax tolerances were revoked in 2007 (EPA, 2007; EPA, 2010). It should be noted that while amitraz is not commonly found in acidic media including honey, its degradates are (Wallner, 1999; Floris et al., 2001; Korta et al., 2001; EPA, 2004; Martel et al., 2007; EPA, 2011; EPA, 2012). EPA considered and denied a petition to exempt amitraz from a tolerance in honey (EPA, 2012).

EPA is reviewing the data supporting re-establishment of the tolerance of 1.0 ppm in honey in support of the section 3 registration of Avipar strips (EPA, 2010; South Dakota, 2013). New tolerance for beeswax is not currently under discussion (EPA, 2011).

SECTION 166.20(a)(7): RISK ASSESSMENT

<u>Human Health</u>

Risks from dietary exposure to amitraz have been evaluated by EPA in 2004 and 2011. Other than the livestock-cotton uses mentioned above, the other uses of amitraz include two existing technical products, EPA# 65331-6 (Merial Limited, 2010) and EPA# 2382-190 (Virbac Animal Health, 2012), that limit the uses of the formulated products to domestic animals. There is one animal drug product for use on dogs regulated by FDA containing amitraz, Mitoban Liquid Concentrate, a 19.9 % amitraz in an organic solvent product (FDA, 2013).

The current EPA risk assessment is based on reversible central nervous system (CNS) effects found in a study using human volunteers. Amitraz acts as an alpha adrenergic agonist causing symptoms of CNS depression. Because the rapid onset and resolution of the symptoms, EPA views amitraz exposures of all durations as a series of short term exposures. The no observable adverse effect level (NOAEL) for amitraz in humans is 0.125 mg/kg, which is much lower than the NOAELs in other species (EPA, 2011). When evaluating pesticide risks from dietary exposures, the reference dose (RfD) is the lowest NOAEL/uncertainty factors (UF) and the population adjusted dose (PAD) is the RfD/ Food Quality Protection Act Safety Factor (FQPA SF).

The UFs for amitraz, used by EPA in their 2011 dietary evaluation, were a factor of 10X for human variability and 10X combined Database UF-FQPA SF of 10X due to the lack of adequate reproductive and developmental studies. This results in a total of the UFs of 100 and the acute reference dose (aRfD) is 0.00125 mg/kg/day. The acute population adjusted dose (aPAD) is equal to the RfD/FQPA SF. The FQPA SF for amitraz is 1X, therefore the aPAD is equal to the aRfD, 0.00125 mg/kg/day (EPA, 2011). Earlier EPA dietary risk assessments were based on the NOAEL of 0.25 from the chronic oral study in dogs with UF of 10X for extrapolating from animal to humans, 10X for variability in humans, and 10X database uncertainty resulting in a total of 1000. The earlier aRfD was 0.25/1000 = 0.00025 mg/kg/day because the FQPA SF was 1X, the aPAD was 0.00025 mg/kg/day (EPA, 2004).

In both the 2004 and 2011 EPA dietary risk assessments for amitraz, the most highly exposed subpopulation is children ages 1 to 2 years of age. This was because of the use of amitraz on cattle and residues in milk. At the 99.9 percentile, in 2004, for children ages 1 to 2 years, the estimated dietary intake of amitraz was 0.000349 mg/kg/day and, in 2011, the intake was estimated at 0.000344 mg/kg/day. The 2004 dietary exposure calculation included residues in cattle, including milk, and swine. Honey was not included in this analysis because the registrant had voluntarily canceled the use (EPA, 2004). The 2011 assessment was for cattle, including milk, swine, and honey (EPA, 2011).

Because of the differences in residue in the commodities and the calculation of the aPAD, the resulting percent of the aPAD were 140% in 2004 and 27.6% in 2011. Recently, EPA published a notice of intent to cancel the uses on cattle and swine in the technical product, EPA# 85904-1, made by Arysta (EPA, 2013). The other two registered technical products, EPA# 65331-6 (Merial Limited, 2010) and EPA# 2382-190 (VirBac Animal Health, 2012), do not have cattle or swine uses on their labels. This means that the total residues of amitraz in the diet will be decreasing over the next few years.

In the 2004 dietary risk assessment, EPA evaluated the cancer risks from dietary exposure to amitraz using the EPA standard risk assessment procedure for carcinogens. The lifetime dietary exposure was < 0.000001 mg/kg/day and the resulting cancer risk was 2.8 X 10⁻⁸. EPA's acceptable cancer risk is 1 X 10⁻⁶. The risk from chronic exposure to amitraz in the diet is below the acceptable risk level.

Conclusion

The proposed Section 18 use of amitraz in beehives and related residues in the honey will not increase the risks to the general population or the most highly exposure subpopulation, children 1 to 2 years of age.

Environmental Fate and Risks

The proposed use of this product is intended to be applied only to the inside of the beehive (Arysta, 2013); therefore, environmental releases should not be an issue (Arysta, 2012b).

Threatened and Endangered Species

The proposed use of this product is intended to be applied only to the inside of the beehive (Arysta, 2013); therefore, the use is expected to have no adverse effects on the threatened and endangered species or their habitats in Maine (Arysta, 2012b). A list of Maine's endangered and threatened species is included in the request packet.

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

Arysta Life Sciences America, Inc., has been notified of this agency's intent regarding this application. The letter of support from Toyokazu Matsumoto, President, is included in the request packet.

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

Please refer to the Section 18 request for South Dakota.

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 meliffera* colonies. The mites live within the colony, and reproduce in the bee's brood cells. Mites feed 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). 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, Conservation and Forestry (ACF) 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 ANTICPATED 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 honey bee colonies has added significant 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). 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 (Pettis, 2010 letter, Appendix). 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:

Data for 2012 is not yet available; therefore, the following is based on 2010-2011 data. 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 2007 with 23 lbs per colony through 2009 with yields of 50 lbs per colony (Table 1).

Year	Honey Producing Colonies	Yield per Colony (lbs)	Production (lbs)	Ave. Price per Pound (dollars)	Value of Production (dollars)
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
2011	4000	30	120,000	1.91	229,000
5 Year Ave.	6,400	38	238,800	1.77	420,800

 Table 1. Baseline yield of Maine honey production and value 2007-2011.

Source: USDA-NASS 2011

However, 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. 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 49.7% loss in honey production from the five-year baseline prior to the emergency was experienced by the industry (Table 2).

	Baseline	Emergency	Change	% Change
Pollination income (\$90/hive ave.)	\$6,248,520	\$5,222,160	\$1,026,360	
Honey production (lbs)	238,800	120,000	-118,800	-49.7
Honey income	\$420,800	\$229,000	-\$191,800	-45.6
Gross revenue	\$6,908,120	\$5,571,160	-\$1,336,960	-19.4
Replacement colony cost (\$150/colony		\$570,195	-\$570,195	
Nucleus colony cost (\$65/colony)		\$247,085	-\$247,085	
Split existing parent colony cost (\$60/colony		\$228,078	-\$228,078	
Total additional costs		\$1,045,358	-\$1,045,358	15.1
Total losses (% change compared with gross revenue)			-\$2,382,318	34.5

 Table 2. Tier 2 Analysis of Honey Production and Commercial Beekeeping Operations in Maine 2011.

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

According to USDA-NASS 2011, honey production was valued at \$519,000 in 2010 (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 45.6% when compared to the five year average value of \$420,800 (Tables 1, 2).

The primary income for commercial beekeepers in Maine is derived from crop pollination. In 2012, approximately 69,428 colonies were used to pollinate the state's wild blueberry and apple crops. The state's processed wild blueberry crop was valued at \$69.1 million in 2012 and the apple crop at \$ 15.4 million in 2012. 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.

The primary income for commercial beekeepers in Maine is derived from crop pollination. In 2012, approximately 69,428 colonies were used to pollinate the state's wild blueberry and apple crops. The state's processed wild blueberry crop was valued at \$69.1 million in 2012 and the apple crop at \$ 15.4 million in 2012. 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. In 2012, beekeepers were compensated \$90/hive on average.

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 bees and brood frames from an existing parent colony. Over time, a split colony and parent 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 \$95 to \$135, package bees at \$96, 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 2011-12 was approximately 21.9%. If 75% of these losses are attributed to Varroa then approximately 11,404 of the 69,428 hives used to pollinate Maine blueberries needed replacement (69,428 x 21.9% loss = 15,205 mortality x 75% due to varroa =11,404 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 \$1,045,358. 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 2012 honey production data is not available at this time, however, gross revenue from honey production and commercial beekeeping in Maine in 2011 was \$5,571,160, a 19.4% loss equaling \$1,3368,960 from the five-year average (2007-2011) of \$6,908,120 (Table 2). When the additional costs of replacing colonies are considered, a 34.5% total loss equaling \$2,382,318 is realized.

REFERENCES

40 CFR § 180.287. 2013. Amitraz; tolerances for residues.

- Arysta. 2009. Amitraz Insecticide for Manufacturing Use Only (EPA# 85904-1).
- Arysta. 2012a. Section 18 label for ApiVar Strips South Dakota.
- Arysta. 2012b. Environmental Fate of Amitraz. Arysta Lifescience America. unpublished study TGS/Arysta 2012/1.
- Arysta. 2013. Proposed Section 18 label for AviPar Strips Maine 2013.
- 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. 2004. Amitraz Acute Probabilistic, Chronic, and Cancer Dietary Exposure Assessment for the Tolerance Reassessment Eligibility Decision (TRED) Document.
- EPA. 2007. Amitraz, Atrazine, Ethephon, Ferbam, Lindane, Propachlor and Simazine; Proposed Tolerance Actions. *Federal Register*. **72** (113): 32570- 32582.
- EPA. 2011. Amitraz Acute Probabilistic (Food only), Dietary Exposure Assessment for Section 3 Registration Action that was requested for use of Amitraz in AviPar Strips in Bee Hives.
- EPA. 2012. Amitraz. Response to the Submission: "Discussion of Residues of Amitraz in Honey and Beeswax for ApiVar strips."
- EPA. 2013. Notice of Receipt of Request for Amendments to Delete Uses in Certain Pesticide Registrations. *Federal Register*. 78(1): 95-97.
- FDA. 2013. Animal Drugs Description of Mitoban Liquid Concentrate for Dogs.
- Floris, I., Satta, A., Garau, V.L., Melis, M., Cabras, P., and N. Aloul. 2001. Effectiveness, Persistence and Residue of Amitraz Plastic Strips in Apiary Control of *Varroa destructor*. *Apidologie*. 32: 577-585.
- 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.

Hoechst-Roussel Agri-Vet. 1992. Miticur Bee Mite Strip (EPA Reg. No. 54382-5) label.

- Korta, E., Bakkali, A., Berruetta, A., Gallo, B., Vicente, F., Kilchenmann, V., Bogdanov, S. 2001. *Journal of Agricultural Food Chemistry*. 49: 5835-5842.
- Martel, A. C., Zeggane, S., Aurieres, C., Drajnudel, P., Faucon, J. P., and M. Aubert. 2007. Acaricide Residues in Honey and Wax after Treatment of Honey Bee Colonies with Apivar or Asuntol 50. *Apidologie*. 38: 534-544.
- Maine Department of Agriculture, Food & Rural Resources. 2011. Eastern Plant Board Report. Division of Plant & Animal Health.
- Merial Limited. 2010. Amitraz Technical For Manufacturing Use Only (EPA Reg. No. 65331-6) label.
- Sammataro, D., Finley, J., and R. Underwood. 2008. Comparing oxalic acid and sucrocide 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.

Technical Sciences Group Inc. 2012. Memo to Meredith Laws, EPA, re: Apivar Strips.

TOXNET. 2013. http://toxnet.nlm.nih.gov/.

- vanEnglesdorp, D, Caron, D., Hayes, J., Underwood, R., Henson, M., Rennich, K., Spleen, A.,
 Andree, M., Snyder, R., Lee, K., Roccasecca, 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.
- Virbac Animal Health. 2012. Amitraz Technical For Manufacturing Use Only (EPA Reg. No. 2382-190) label.

Wallner. 1999. Varroacides and Their Residues in Bee Products. Apidologie. 30: 235-248



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,

All Petti

Dr. Jeff Pettis Research Leader USDA-ARS Bee Research Laboratory Bldg. 476 BARC-E Beltsville, MD 20705 USA 301-504-7299 jeff.pettis@ars.usda.gov



Bee Research Laboratory Building 476, Beltsville, MD 20705 An Equal Opportunity Employer

Attachment 2



STATE OF MAINE DEPARTMENT OF AGRICULTURE, CONSERVATION AND FORESTRY DIVISION OF ANIMAL AND PLANT HEALTH 28 STATE HOUSE STATION AUGUSTA, MAINE 04333-0028

WALTER E. WHITCOMB COMMISSIONER

> ELLIS B. ADDITON DIRECTOR

PAUL R. LEPAGE GOVERNOR

February 7, 2013

John Jemison, Chairman Maine Board of Pesticides Control 28 State House Station Augusta, ME 04333

Dear Dr. Jemison,

I support the FIFRA Section 18 Emergency Exemption request for Apivar (amitraz) manufactured by Veto-pharma to control Varroa in honey bee colonies. Varroa and the viral complex the mite vectors to immature and adult honey bees are the primary cause for honey bee mortality in Maine, the US and countries where the mite is established.

Apivar will provide beekeepers with an effective Varroa treatment alternative to the two other registered synthetic acaricides, Apistan (fluvalinate) and CheckMite (coumaphos) since it has a different mode of action. Varroa is resistant to both Apistan and CheckMite due to repeated usage over many years. Apivar is superior to the thymol based Varroa controls because it is formulated as a strip and provides control over a period of two brood cycles. It is effective in a wide range of temperatures and does not cause queen loss, brood mortality, absconding and/or robbing behavior.

The EPA granted a section 18 exemption for Apivar to South Dakota on October 19, 2012 and subsequently to: OR, ND, CO, MS, MN, CA, FL, MI, AR and KY. In addition, HI, TX, NB, WY, GA, LA, ID, OH, DE, VT, WA, WI, and NY are petitioning EPA for section 18 approvals.

Honey bees are vital for blueberry production in Maine and the demand for honey bees has increased seven fold over the last three decades (1981-9,454 hives, 2012-69,428 hives). Honey bees are also used to pollinate Maine's apple, cranberry, small fruit and vegetable crops.

If you or any board members have questions regarding this request or the status of beekeeping, please contact me at 207-287-7562 desk, 207-441-5822 cell. I plan to attend the Board of Pesticides Control meeting in Augusta on March 1, 2013 and will answer any questions the board may have. Thank you for considering this matter.

Sincerely, Anthony M. Jadegall Anthony M. Jadezak State Apiarist



January 21, 2013

Ms. Mary E. Tomlinson Pesticide Registrar/Water Quality Specialist Maine Board of Pesticides Control 28 State House Station Augusta, ME 04333

Subject: Application for an Emergency Exemption Amitraz to Control Varroa Mites in Honeybee Hives

Dear : Ms. Mary E. Tomlinson:

Arysta LifeScience America Inc. (Arysta) is the manufacturer of Amitraz Technical, EPA Reg. No. 85904-1. Veto-pharma SA (Veto-pharma), our affiliated company in France, for whom we are the agent, has submitted a Section 3 registration application dated December 23, 2009 for Apivar, a plastic strip impregnated with Amitraz to be used in honeybee hives to control varroa mites. Amitraz had been used in the U.S. in impregnated strips (Miticure, EPA Reg. No. 54382-5) to control mites in honeybee hives in the past and tolerances were established for honey and beeswax. Veto-pharma's new strip, Apivar, has one-third the amount of amitraz that was in the previous registered product and, since both products call for the use of 2 strips per hive, Apivar will deliver much less amitraz to the hive.

Apivar is approved for use in beehives in Europe and other countries and is in active production. Arysta and Veto-pharma understand that Maine will be requesting an Emergency Exemption. Veto-pharma will make available sufficient Apivar strips should the Emergency Exemption be approved.

If you have any questions regarding our commitment, please contact me at 212-930-5101.

Sincerely

Toyokazu Matsumoto President Arysta Lifescience America Inc.

c.c. Vito-pharma SA, France

0410

Arysta LifeScience America Inc. 1450 Broadway, 7th Floor, New York, NY 10018 Telephone: 212-930-5100 Fax: 212-930-5119 www.arystalifescience.com

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Apivar[™] is a sustained-release plastic strip designed for use in beehives to control the parasitic mite (*Varroa destructor*) on honey bees.

pivar

тм

strips

For varroa treatment

To control varroa mite, remove honey supers before application of Apivar[™]. Use 2 Apivar[™] strips per brood chamber. Separate the double strip and hang each strip between two comb frames inside the brood area or the bee cluster, with a minimum distance of 2 frames between strips. Suspend Apivar[™] strips in the brood chamber in such a way that the bees can walk on both sides of the strips. Leave strips inside the hive for 42 days minimum, and then remove. In case of movement inside the beehive far from the strips, a repositioning of the strips should be done into the bee cluster, and the strips left in place for 14 more days before removal. Strips must be removed after a maximum of 56 days. **DO NOT re-use the strips**.

Timing:

Hang Apivar[™] strips in the hives one treatment in the spring or one treatment in the fall if varroa mite infestations have reached treatment threshold. All Apivar[™] strips should be removed 2 weeks before the honey flow starts.

If mite infestation reaches treatment thresholds in autumn, remove surplus honey supers before using Apivar $^{\mbox{\tiny M}}.$

Withholding period for honey collection:

DO NOT USE APIVAR[™] STRIPS WHEN HONEY SUPERS ARE PRESENT. Wait 14 days after removing strips before placing honey supers on hive.

Resistance management:

This pest scenario is highly susceptible to resistance. Amitraz belongs to Insecticide Resistance Action Committee (IRAC) Group 19. Some individuals in the Varroa mite population may be naturally resistant to Apivar¹¹⁴. Over time, resistant Varroa mites will reproduce and dominate the mite population if Apivar if used repeatedly in the same location. To delay resistance, rotate this product with other Varroa mite control products in different chemical classes so that the potential for Varroa mite populations to develop resistance is minimized. Pesticide use should be based on an integrated pest management (IPM) program that includes monitoring, record keeping, and considers cultural, biological and other chemical control practices. Using IPM with strict adherence to label directions (specifically the removal of amitraz strips after 56 days) on approved treatments reduces the risks of encouraging the development of resistant Varroa mite populations. Correctly identify the pest and ensure that treatment thresholds are met prior to use. Monitor treated pest populations for resistance development and incorporate resistance management practices into a control program. Report performance issues due to the development of amitraz resistance in target pest.

Storage and disposal:

Do not contaminate water, food or feed by storage or disposal.

Pesticide storage:

Store in a cool, dry area, out of direct sunlight, and away from other pesticides that may contaminate the strips. To prevent contamination, store this product in the original container and away from food or feed.

Pesticide disposal:

To avoid wastes, use all strips in this container by application according to label directions. Offer remaining product to an approved waste disposal facility or pesticide disposal program.

Container disposal: Unused strips should be stored in a cool, dark area. Any unused, unregistered product must either be returned to the manufacturer or distributor in unopened packaging or disposed of in accordance with the Resource Conservation Recovery Act following the expiration of this emergency exemption.

Warranty and Disclaimer: To the extent consist with applicable law, this product is to be used only in accordance with the directions on the label. The user assumes the risk to persons or property that arises from any use of the product in a way that is inconsistent with the label.

See Supplemental Label for State and File Symbol

EPA Est. No. 87242-FRA-001

Manufactured for: Véto-pharma S.A. 14 avenue du Québec 91140 Villebon-sur-Yvette - FRANCE U.S. Agent: Arysta LifeScience America Inc. 1450 Broadway - New York, NY 10018 Tel: 212-930-5101



For use only as authorized in the State in which the U.S. Environmental Protection Agency (EPA) has granted a FIFRA Section 18 emergency exemption. This Labeling must be in the possession of the user at the time of application.

Emergency exemption use direction APIVAR™ STRIPS - SUPPLEMENTAL LABEL EPA File Symbol: XX-SS-YY

STATE: MAINE For the control of mites (varroatosis) on honey bees

EXPIRATION DATE:

EPA Est. No. 87242-FRA-001

ACTIVE INGREDIENT: Amitraz: N'-(2,4-dimethylphenyl)-N-[[(2,4-dimethylphenyl)imino]methyl]-N-methylmethanimidamide	3.33%	
INERT INGREDIENTS	96.67%	
TOTAL:	100.00%	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

ApivarTM is a sustained-release plastic strip designed for use in beehives to control the parasitic mite (*Varroa destructor*) on honey bees. For varroa treatment - To control varroa mites, remove honey supers before application of ApivarTM. Use 2 ApivarTM strips per brood chamber. Separate the double strip and hang each strip between two comb frames inside the brood area or the bee cluster, with a minimum distance of 2 frames between strips. Suspend ApivarTM strips in the brood chamber in such a way that the bees can walk on both sides of the strips. Leave strips inside the hive for 42 days, and then remove. In case of movement of bees inside the beehive away from the strips, reposition the strips into the bee cluster, and leave strips in place for 14 more days before removal. Strips must be removed after a maximum of 56 days. DO NOT re-use the strips.

Timing:

A maximum of two treatments, one in the spring and/or one in the fall may be made per year if varroa mite infestations reach treatment threshold. All Apivar[™] strips should be removed 2 weeks before the honey flow starts. If mite infestation reaches treatment thresholds in autumn, remove surplus honey supers before using Apivar[™].

Withholding period for honey collection:

DO NOT USE WHEN HONEY SUPERS ARE PRESENT. Wait 14 days after removing strips before placing honey supers on hive.

Resistance-management: This pest scenario is highly susceptible to resistance. Amitraz belongs to Insecticide Resistance Action Committee (IRAC) Group 19. Some individuals in the Varroa mite population may be naturally resistant to Apivar[®]. Over time, resistant Varroa mites will reproduce and dominate the mite population if Apivar is used repeatedly in the same location. To delay resistance, rotate this product with other Varroa mite control products in different chemical classes so that the potential for Varroa mite populations to develop resistance is minimized. Pesticide use should be based on an integrated pest management (IPM) program that includes monitoring, record keeping, and considers cultural, biological and other chemical control practices. Using IPM with strict adherence to label directions (specifically the removal of amitraz strips after 56 days) on approved treatments reduces the risks of encouraging the development of resistant Varroa mite populations. Correctly identify the pest and ensure that treatment thresholds are met prior to use. Monitor treated pest populations for resistance development and incorporate resistance management practices into a control program. Report performance issues due to the development of amitraz resistance in target pest.

Warranty and Disclaimer: To the extent consist with applicable law, this product is to be used only in accordance with the directions on the label. The user assumes the risk to persons or property that arises from any use of the product in a way that is inconsistent with the label.



STORAGE AND DISPOSAL		
	Do not contaminate water, food or feed by storage or disposal.	
PESTICIDE STORAGE:	Store in a cool, dry area, out of direct sunlight, and away from other pesticides that may contaminate the strips. To prevent contamination, store this product in the original container and away from food or feed.	
PESTICIDE DISPOSAL:	To avoid wastes, use all strips in this container by application according to label directions. Offer remaining product to an approved waste disposal facility or pesticide disposal program.	
CONTAINER DISPOSAL:	Unused strips should be stored in a cool, dark area. Any unused, unregistered product must either be returned to the manufacturer or distributor in unopened packaging or disposed of in accordance with the Resource Conservation Recovery Act following the expiration of this emergency exemption.	

KEEP OUT OF REACH OF CHILDREN WARNING

	WANNING
FIRST AID	
IF SWALLOWED:	Call a poison control center or doctor immediately for treatment advice.
	Have person sip a glass of water if able to swallow.
	 Do not induce vomiting unless told to by a poison control center or doctor.
	• Do not give anything by mouth to an unconscious person.
IF ON SKIN OR	Take off contaminated clothing.
CLOTHING:	Rinse skin immediately with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes.
	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
	Call a poison control center or doctor for treatment advice.
IF INHALED:	Move person to fresh air.
	• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-
	to-mouth if possible.
	Call a poison control center or doctor for further treatment advice.
Have the product cor	ntainer or label with you when calling a poison control center or doctor or going for treatment. For
TRANSPORTATION E	MERGENCIES, call 24 hours a day CHEMTREC 1-800-424-9300. For MEDICAL EMERGENCY, call 24 hours a day
PROSAR 1-866-257-2	596. For PRODUCT USE Information Call 1-212-930-5101.

PRECAUTIONARY STATEMENTS

HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS

WARNING: May be fatal if absorbed through the skin. Harmful if swallowed or inhaled. Do not get in eyes, on skin, or on clothing. Avoid inhalation of product vapor when opening the sealed packet of strips. Avoid contact with skin and eyes and wear chemical-resistant gloves when handling the strips. Wash thoroughly with soap and water after handling and before eating, drinking, chewing-gum, using tobacco or using the toilet. Wear coveralls worn over short-sleeved shirt and short pants, socks, footwear and chemical-resistant gloves. Remove and wash contaminated clothing before reuse.

CALIFORNIA WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to birds, fish and aquatic invertebrates. Do not apply directly to any body of water. Do not contaminate water when disposing of used strips.

Authorization holder: Véto-pharma S.A. 14 avenue du Québec 91140 Villebon-sur-Yvette – France U.S. Agent: Arysta LifeScience America Inc. New York, NY 10018 1450 Broadway Tel: <u>212-930-5101</u>

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Safety Data Sheet

Véto-pharma

acc. to ISO/DIS 11014 Reviewed on 12/19/2012 Printing date 12/19/2012 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: APIVAR® · 1.2 Relevant identified uses of the substance or mixture and uses advised against For use only as authorized in the State in which the U.S. Environmental Protection Agency (EPA) has granted a FIFRA Section 18 emergency exemption. · Application of the substance / the preparation Preparation Pharma Active ingredients \cdot 1.3 Details of the supplier of the safety data sheet · Manufacturer/Supplier: Véto-pharma 14, avenue du Québec Z-A. de Courtaboeuf 91 140 VILLEBON SUR YVETTE FRANCE Tél: +33 (0)1 69 18 84 80 Fax: +33 (0)1 69 28 12 93 info@vetopharma.com www.vetopharma.com · 1.4 Emergency telephone number: NHS Direct: 0845 46 47 / Textphone: 0845 606 46 47 CHEMTREC: 1-800-424-9300 (North America) 2: Hazards identification · 2.1 Classification of the substance or mixture · Classification according to Regulation (EC) No 1272/2008 The product is not classified according to the CLP regulation. · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable. · Information concerning particular hazards for human and environment: The product does not have to be labelled due to the calculation procedure of international guidelines. · Classification system: The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data. · 2.2 Label elements · Labelling according to EU guidelines: Observe the general safety regulations when handling chemicals. The product has not been classified and marked in accordance respective national laws. 2008/58/CE (30eme ATP); 2009/2/CE (31eme ATP); 2006/8/CE · Safety phrases: 2 Keep out of the reach of children. · Special labelling of certain preparations: Contains amitraz (ISO). May produce an allergic reaction. · Classification system: · NFPA ratings (scale 0 - 4) Health = 0Fire = 0Reactivity = 0(Contd. on page 2) USA

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Safety Data Sheet acc. to ISO/DIS 11014

Printing date 12/19/2012

Trade name: APIVAR®

Véto-pharma

Reviewed on 12/19/2012



- · Protective equipment:
- Do not inhale explosion gases or combustion gases.
- No special measures required.

6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up: Pick up mechanically.

(Contd. on page 3)

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Safety Data Sheet acc. to ISO/DIS 11014

Printing date 12/19/2012

Trade name: APIVAR®

Véto-pharma

Reviewed on 12/19/2012

(Contd. of page 2)

· 6.4 Reference to other sections

No dangerous substances are released. See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

7: Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- Information about protection against explosions and fires: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

- · Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

8: Exposure controls/personal protection

• Additional information about design of technical systems: No further data; see item 7.

- · 8.1 Control parameters
- · Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists that were valid during the creation were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- \cdot General protective and hygienic measures:
- The usual precautionary measures for handling chemicals should be followed.
- · Breathing equipment: Not required.
- · Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. • Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Eye protection: Not required.

(Contd. on page 4)

USA

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Safety Data Sheet acc. to ISO/DIS 11014

Printing date 12/19/2012

Véto-pharma

Reviewed on 12/19/2012

Trade name: APIVAR®

(Contd. of page 3)

9. I hysical and chemical pro	speries
9.1 Information on basic physical a	and chemical properties
General Information	
· Appearance:	
Form:	Solid
Color:	Opaque
Odor:	Characteristic
Gaour inresnoia:	Not determined.
pH-value:	Not applicable.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not determined.
Ignition temperature:	Not applicable.
Decomposition temperature:	Not determined.
Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not applicable.
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water:	Insoluble.
Partition coefficient (n-octanol/wat	ter): Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Solvent content:	
Organic solvents:	0.0 %
Solids content:	3.3 %
9.2 Other information	No further relevant information available.

10: Stability and reactivity

- · 10.1 Reactivity
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: To avoid thermal decomposition do not overheat.
- · Stable until: 2 ans

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Safety Data Sheet acc. to ISO/DIS 11014

Printing date 12/19/2012

Véto-pharma

Reviewed on 12/19/2012

Trade name: APIVAR®

(Contd. of page 4)

- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known.

11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity:
- Primary irritant effect:
- on the skin: No irritant effect.
- \cdot on the eye: No irritating effect.
- Sensitization: No sensitizing effects known.
- Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

12: Ecological information

- · 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 3 (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.

• vPvB: Not applicable.

· 12.6 Other adverse effects No further relevant information available.

13: Disposal considerations

- · 13.1 Waste treatment methods
- Recommendation: Smaller quantities can be disposed of with household waste.

(Contd. on page 6)

USA

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Safety Data Sheet acc. to ISO/DIS 11014

Printing date 12/19/2012

Trade name: APIVAR®

Véto-pharma

Reviewed on 12/19/2012

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· Uncleaned packagings:

· Recommendation: Disposal must be made according to official regulations.

14.1 UN-Number		
ADR, ADN, IMDG, IATA	not regulated	
14.2 UN proper shipping name		
ADR	non regulated	
ADN, IMDG, IATA	not regulated	
14.3 Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
Class	not regulated	
14.4 Packing group		
ADR, IMDG, IATA	not regulated	
14.5 Environmental hazards:		
Marine pollutant:	No	
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Anne	ex II of	
MARPOL73/78 and the IBC Code	Not applicable.	
Transport/Additional information:	D.O.T : Not regulated	
UN "Model Regulation".		

15: Regulatory information

 \cdot 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture \cdot Sara

· Section 355 (extremely hazardous substances):

None of the ingredient is listed.

· Section 313 (Specific toxic chemical listings):

33089-61-1 amitraz (ISO)

• TSCA (Toxic Substances Control Act):

24937-78-8 ethylene vinyl acetate copolymer

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

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• Chemicals known to cause developmental toxicity:

33089-61-1 amitraz (ISO)

· Cancerogenity categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

·NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA) Maine Department of Inland Fisheries and Wildlife - Maine Endangered Species Program... Page 1 of 3 Attachment 7



Maine Department of Inland Fisheries and Wildlife - Maine Endangered Species Program... Page 2 of 3 Attachment 7

	Rapids Clubtail (Gomphus quadricolor)
	Mayflies
	<u>Flat-Headed Mayfly (Roaring Brook</u> <u>Mayfly)</u> (Epeorus frisoni)
Mami	mals
	New England Cottontail (Sylvilagus transitionalis)
Repti	les
-	Snakes
	Black Racer (Coluber constrictor)
	Turtles
	Blanding's Turtle (Emys blandingii)
	Box Turtle (Terrapene carolina)
Maine Thr	eatened Species
Birds	
	Arctic Tern (Sterna paradisaea)
	Atlantic Puffin (Fratercula arctica)
	Barrow's Goldeneye (<i>Bucephala islandica</i>)
	Black-crowned Night Heron (Nycticorax nycticorax)
	Common Moorhen (<i>Gallinula chloropus</i>)
	Great Cormorant (<i>Phalacrocorax carbo</i>) (Breeding population only)
	Harlequin Duck (Histrionicus histrionicus)
	Razorbill (Alca torda)
	Short-eared Owl (Asio flammeus) (Breeding population only)
	Upland Sandpiper (Bartramia longicauda)
Fish	
	Swamp Darter (Etheostoma fusiforme)
Inver	tebrates
	Butterflies and Moths
	Purple Lesser Fritillary (<i>Boloria</i> <i>chariclea grandis</i>)
	Sleepy Duskywing (<i>Erynnis brizo</i>)
	Dragonflies and Damselflies
	Boreal Snaketail (<i>Ophiogomphus</i> <i>colubrinus</i>)
	<u>Ringed Boghaunter</u> (<i>Williamsonia</i> <i>lintneri</i>)
	Freshwater Mussels

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	Brook Floater (<i>Alasmidonta varicosa</i>) <u>Tidewater Mucket</u> (<i>Leptodea ochracea</i>) <u>Yellow Lampmussel</u> (<i>Lampsilis cariosa</i>)	
	Mayflies	
	Tomah Mayfly (Siphlonisca aerodromia)	
	Moths	
	Pine Barrens Zanclognatha (<i>Aanclognatha martha</i>)	
	Twilight Moth (<i>Lucia rachalae</i>)	
	Mammals	
	Northern Bog Lemming (Synaptomys borealis)	
	Reptiles	
	Turtles	
	Spotted Turtle (Clemmys guttata)	
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