



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 15, 2021

Micah Reynolds
Regulatory Consultant to Veto-Pharma S.A.S.
Technology Sciences Group, Inc.
1150 18th Street, N.W.
Washington, D.C. 20036

Subject: PRIA Label and CSF Amendment – Revised Group A data; Revising Basic and Alternate CSFs; adding marketing claims to the label.
Product Name: Apivar
EPA Registration Number: 87243-1
Application Date: 09/08/2020
Decision Number: 566021

Dear Mr. Reynolds:

The amended label and CSF(s) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Please note that the record for this product currently contains the following CSF(s):

- Basic CSF dated August 11, 2020
- Alternate CSF dated August 11, 2020

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process.

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Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Dee Colby by phone at 703-347-8657, or via email at colby.deanna@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Gene Benbow".

Gene Benbow, Product Manager 7
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Apivar®

ACCEPTED

07/15/2021

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 87243-1

Strips for the in-hive control of Varroa mites (varroatosis) on honey bees

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

**KEEP OUT OF REACH OF CHILDREN
WARNING**

FIRST AID	
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none">• 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 IN EYES:	<ul style="list-style-type: none">• 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:	<ul style="list-style-type: none">• 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 container or label with you when calling a poison control center or doctor or going for treatment. For TRANSPORTATION EMERGENCIES, call 24 hours a day CHEMTREC 1-800-424-9300. For MEDICAL EMERGENCY, call 24 hours a day ProPharma Group 1-866-257-2596. For PRODUCT USE Information, Call US Phone Number 212-930-5101.	

EPA Reg. No. 87243-1
EPA Est. No. 87243-FRA-001**Manufactured [by] [for]:**Véto-pharma S.A.S.
12/14 rue de la Croix-Martre
91120 Palaiseau - FRANCE
US PHONE NUMBER: 212-930-5101
[www.apivar.net]

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:

⚠ WARNING: This product can expose you to Amitraz, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

ENVIRONMENTAL HAZARDS

For terrestrial uses: This product is toxic to fish and aquatic invertebrates. Do not contaminate water when disposing of used strips or packaging.

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.

For varroa treatment - Remove honey supers before application of Apivar[®]. Use 2 Apivar[®] strips per brood chamber (*i.e.*, one strip per 5 Frames of Bees - FoB).

# FoB	≤5	6 - 10	11 - 15	≥16
# strips	1	2	3	4

Install Apivar strips in the hive immediately after opening package. 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, and then remove. In case of movement inside the beehive far from the strips, reposition the strips into the bee cluster, and leave the strips in place for 14 more days. Strips must be removed after a maximum of 56 days. **DO NOT** re-use the strips.

Timing:

Hang Apivar[®] strips in the hives in the spring and/or the fall if varroa mite infestations have reached treatment threshold. Remove all Apivar[®] strips 2 weeks before the honey flow starts.

DO NOT USE APIVAR® STRIPS WHEN HONEY SUPERS ARE PRESENT.

If mite infestation reaches treatment thresholds in fall, remove surplus honey supers before using Apivar®.

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:

Any mite population may contain individuals naturally resistant to Apivar® and other similar miticides. The resistant individuals may dominate the mite population if this group of miticides is used repeatedly in the same location. Other resistance mechanisms that are not linked to site of action but are specific for individual chemicals, such as enhanced metabolism, may also exist. Appropriate resistance management strategies should be followed.

To delay miticide resistance:

- Where possible, rotate the use of Apivar® or other similar miticides with different groups that control the same pests.
- Miticide use should be based on an Integrated Pest Management (IPM) program that includes scouting, record keeping, and considers cultural, biological and other chemical control practices.
- Correctly identify the pest and ensure economic and agronomic thresholds are met before treatment.
- Monitor treated pest populations for resistance development.
- Contact your local extension specialist or certified crop advisors for any additional pesticide resistance management and/or IPM recommendations for the specific site and pest problems in your area.
- For further information or to report suspected resistance contact your local extension specialist.
- Do not leave strips in colonies for greater than the designated 56 day maximum.

RESTRICTIONS:

- For in-hive use only.
- Do not use Apivar® strips when honey supers are present.
- Maximum rate = 2 strips per brood chamber per application (*i.e.*, one strip per 5 Frames of Bees - FoB).
- Remove honey supers before application of Apivar®.
- Remove Apivar® strips 14 days before placing honey supers.
- Strips must be removed after a maximum of 56 days.
- Do not re-use strips.
- Do not use Apivar® more than 2 times a year, *i.e.* no more than once in spring and once in fall.

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 unused product in the original container and away from food or feed.
PESTICIDE DISPOSAL:	To avoid waste, use all strips in this container by application according to label directions. Wrap used strips in newspaper and place in the trash.
CONTAINER HANDLING:	Nonrefillable container. Do not reuse or refill this container. Dispose of in a sanitary landfill or by incineration. Do not burn unless allowed by state and local ordinances.

Warranty and Disclaimer: This product is to be used only in accordance with the directions on the label. To the extent consistent with applicable law, 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.

NET CONTENTS: oz. (g.)
 Contains XX [plastic] strips
 Expiration date: 24 months
 Batch number/Date of manufacture: See [edge] [back] [front] of pack

[Note to Reviewer: Optional Logos and Statements below]

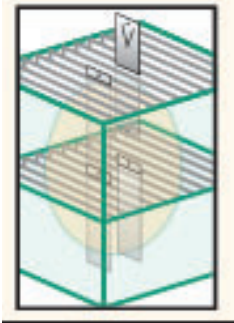
[Committed to apiculture]



[Image of honeybee – image below]



[Image of instruction to user on placement of strips – image below]



Optional Marketing claims – Note to Reviewer – [bracketed] text is optional or alternate phrasing of statements

Manufacturing Claims

- 1) A unique amitraz based product for bees
- 2) Apivar is manufactured in France to the highest quality standards
- 3) The Apivar strip provides consistent results, is not harmful for the bees, and meets or exceeds stringent [manufacturing] quality standards.
- 4) Formulated by beekeeping experts for beekeepers
- 5) Vêto-pharma controls the entire Apivar production chain from the supply of primary materials to release on the market. This means that Vêto-pharma is able to guarantee the high quality of Apivar, in accordance with regulations in the different countries where the product is registered.
- 6) Apivar is manufactured in a GMP facility
- 7) High quality product
- 8) Strict analysis and Quality Control process of each batch before marketing.
- 9) Apivar strips are vacuum-packed to preserve the[ir] active ingredient.

Preservation Claims

- 10) We recommend you install Apivar strips in the hive immediately after opening the package.

Mode of Action Claims

- 11) Apivar is an amitraz-based apiary product that treats not just one generation of Varroa mites, but several successive generations, reducing mite populations in the hive in [1] [one] [a single] application.
- 12) The plastic polymer of Apivar strips has been developed to continuously release amitraz over 6-8 weeks, killing several successive generations of Varroa mites.
- 13) Apivar works by slow-release technology. Varroa mite population fall through the duration of the treatment.

- 14) Mite reduction at the beginning of an Apivar treatment may be lower than in a flash treatment. This is normal, and does not mean the treatment isn't working.
- 15) No knock-down effect: it is normal not to always see a [high fall] [large decrease in mite population] in the first days of the treatment.
- 16) A long-acting treatment like Apivar kills several successive generations of Varroa mites during the 6-8 weeks treatment period. As a result, the colony remains clean for longer than with a flash treatment.
- 17) Amitraz is a miticide that paralyzes Varroa mites. Varroa can no longer hold on to the bees and fall to the bottom of the hive, leading to their starvation.
- 18) The plastic polymer strip of Apivar is specifically designed to ensure a regular release of amitraz on the surface of the strip during the duration of treatment.
- 19) Amitraz migrates from the inside of the strip to the surface upon contact with bees.
- 20) The polymer strip was chosen for its rigidity and its ability to continuously release the active ingredient over a 6-8-week period.
- 21) Apivar works by contact: the active ingredient is continuously delivered over time. As bees [get] [move] in contact with the strip's surface, they pick up molecules of the active ingredient and then distribute them throughout the colony.
- 22) The active ingredient is delivered continuously during the treatment period.

Application Claims

- 23) Effective in [One] single application
- 24) [Provides] Long period of protection : 6 to 8 weeks of treatment with only one application
- 25) Convenient and easy to use
- 26) Apivar can be used in the presence of queen cells or non-mated young queens.
- 27) Quick and easy to use
- 28) Easy way to treat your colonies against varroa mites
- 29) No temperature constraint when using Apivar
- 30) Apivar can be used in any season when the supers are not placed on the hive

- 31) Apivar can be used as a spring treatment (before spring honey production) and as a late summer / autumn treatment.
- 32) Strips can [remain] [be left] in the hive between 6 to 8 weeks depending on the size of the brood area.
- 33) Apivar can be introduced as soon as hive activity resumes in the spring, or after the withdrawal of supers, even when outside temperatures are high, without risk to the colony.
- 34) The larger the area of brood is, the longer the strips should be left in the hive within a maximum treatment period of 8 weeks.
- 35) Hang Apivar strips in the hives in the spring and/or the fall if Varroa mite infestations have reached treatment threshold.
- 36) The strips should be placed in such a way that the bees can have free access to both sides.
- 37) Effectiveness is tied to contact between bees and strips
- 38) Promote as much contact as possible

- 39) More contact = better distribution of amitraz in the colony
- 40) There are no counter-indications for feeding colonies at the same time as Apivar strips are inserted into the hives, as the system does not disturb feeding activity.
- 41) Treat all of your colonies at the same time to avoid re-infestation.
- 42) Do not apply at a rate lower than that specified on the label.
- 43) Check the position of the strips in the brood nest during the treatment and, readjust it. Scrape the strip to remove wax or propolis
- 44) If you discover that the brood area has moved away from the Apivar strips, relocate the strips to the brood area and lengthen the treatment period up to 56 days maximum to ensure maximum efficiency.
- 45) Reposition and scratch the strips if necessary.
- 46) Repositioning and scratching of the strips improves the efficacy of the treatment.

Resistance Management Statements

- 47) Leave strips inside the hive for 42-56 days, and then remove.
- 48) At the end of treatment, remove the strips in order to prevent the presence of low quantities of amitraz in the hive and prevent the development of possible resistance.
- 49) To avoid encouraging the development of resistance, do not leave the strips in place throughout the winter season.
- 50) Apivar strips are not biodegradable and should be disposed of after treatment in accordance with local regulations.

Additional Claims

- 51) Specifically formulated for bee hives.
- 52) Simple composition of two ingredients
- 53) Apivar is not harmful to bees and hive products thanks to the quality of its components and its controlled-release technology.
- 54) Apivar is composed of only 2 ingredients, the amitraz and the plastic strip. No other ingredients.
- 55) Not harmful to brood and bees
- 56) No brood mortality induced by Apivar at recommended dose.
- 57) No negative effect to brood or queens
- 58) No negative effect for brood or bees

Distribution Statements

- 59) Available from your US beekeeping supplier