

# PERMIT TO ALLOW SUPPLY AND EMERGENCY USE OF AN UNREGISTERED AGVET CHEMICAL PRODUCT FOR CONTROL OF VARROA MITES IN HONEYBEE COLONIES

## **PERMIT NUMBER – PER94153**

This permit is issued to the Permit Holder in response to an application granted by the APVMA under section 112 of the Agvet Codes of the jurisdictions set out below. This permit allows a Supplier (as indicated) to possess the product for the purposes of supply and to supply the product to a person who can use the product under permit. This permit also allows a person, as stipulated below, to use the product in the manner specified in this permit in the designated jurisdictions. This permit also allows the Permit Holder, the Supplier (if not one and the same) and any person stipulated below to claim that the product can be used in the manner specified in this permit.

## THIS PERMIT IS IN FORCE FROM 1 NOVEMBER 2023 TO 30 NOVEMBER 2024

## **Permit Holder:**

NSW DEPARTMENT OF PRIMARY INDUSTRIES 105 Prince Street ORANGE NSW 2800

## **Supplier:**

NSW DEPARTMENT OF PRIMARY INDUSTRIES 105 Prince Street ORANGE NSW 2800

ACT ENVIRONMENT, PLANNING AND SUSTAINABLE DEVELOPMENT DIRECTORATE – ENVIRONMENT 480 Northbourne Avenue DICKSON ACT 2602

AGRICULTURE VICTORIA 475 Mickleham Road ATTWOOD VIC 3049

Commercial suppliers, with head office names and addresses as listed in **Attachment 5**.

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## Persons who can use the product under this permit:

Persons generally, within the designated jurisdictions.

## **CONDITIONS OF USE**

## **Products to be used:**

**APIVAR** 

AN UNREGISTERED PRODUCT

Containing: 33 g/kg (500 mg/strip) AMITRAZ as the only active constituent.

**APIVAR** 

AN UNREGISTERED PRODUCT

Containing: 3.33% (500 mg/strip) AMITRAZ as the only active constituent.

**APITRAZ** 

AN UNREGISTERED PRODUCT

Containing: 500 mg/strip AMITRAZ as the only active constituent.

## **RESTRAINT:**

DO NOT use the Product when honey supers are present.

DO NOT harvest honey when the treatment is in place. Honey if produced or harvested while the treatment is in place must not be made available for human consumption.

DO NOT extract honey from the brood chamber.

DO NOT recycle brood frames as honey frames in treated hives.

HONEYCOMB/PROPOLIS/ROYAL JELLY: DO NOT make honeycomb, propolis, royal jelly from treated bees or hives available for human consumption.

DO NOT USE the Product over two consecutive treatment periods. The Product must only be used once a year.

## **Directions for Use:**

Situation	Pest	Rate
Control and surveillance of	Varroa mite	Apivar:
Varroa mite in beehives	(Varroa destructor)	Use 2 Apivar strips per brood chamber
- during a surveillance period in response to an		or
outbreak, during eradication, or for ongoing control.		1 Apivar strip per nuclei.
control.		The strips must remain in place in the hive for the full $6 - 10$ week treatment period.
		Refer to <b>Attachment 1</b> .
		Apitraz:
		Use 1 Apitraz strip per 4 frames of bees. Do not exceed 2 strips per brood chamber.
		Use 1 Apitraz strip per nuclei.
		The strips must remain in place in the hive for the full 6 week treatment period.
		Refer to <b>Attachment 4</b> .

## **Critical Use Comments:**

- The Supplier must only purchase the Product for control or surveillance of Varroa mites while the registered product, Apivar 500 MG Bee Hive Strips for Honey Bees (APVMA 88615), is not available.
- Compatibility of this product with any other product has not been studied, therefore using this product concurrently with any other product should be avoided.
- Where possible, rotate the use of amitraz strips with other products with different modes of action. Note that Apivar and Apitraz strips contain the same active constituent, and that the actives tau-fluvalinate (e.g. Apistan) and flumethrin (e.g. Bayvarol Strips) have the same mode of action as each other.

## **Apivar**

- Hang each strip within two frames from the edge of the cluster e.g. between frames 3 and 4 and between frames 7 and 8.
- APIVAR strips are suspended in the brood chamber in such a way that the bees can walk on both sides of the strips. Dose must not exceed the stated dose rate in a fully populated hive
- **Storage**: Store below 30°C (room temperature). Store in the original closed package. Protect from light. Use the contents within 24 hours of opening. Discard any unused portion.

## Apitraz

- Hang each strip between two frames with full bee coverage. Hang the strips in such a way as to provide bees with free access to both sides, whilst maintaining bee space.
- Place strips within two frames of the edge of the cluster. For example, place one strip between the third and the fourth and the other between the seventh and eighth brood comb.
- Strips must remain in the hive for 6 weeks. Apitraz treatment must not exceed 6 weeks.
- All colonies in the same apiary should be treated simultaneously. The safety profile for the product has not been established in weak colonies.
- The strips should not be cut.
- **Storage**: Do not store above 25°C. Protect from light. Use immediately after opening. Do not use if you see signs of deterioration.

## **Signal Heading:**

**POISON** 

## **Safety Directions:**

Avoid contact with skin. When opening the container, preparing the product for use and if applying by hand, wear gauntlet-length chemical resistant gloves. Wash hands after use.

### **First Aid Instructions:**

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.

**Re-entry/Rehandling Statement**: The use of gauntlet-length chemical resistant gloves is recommended any time the miticide strips are handled, including on removal of the strips from the beehives.

**Additional User Safety**: DO NOT open inner pouch until ready for use. DO NOT allow children to play with plastic strips. Take particular care in people suffering from diabetes or under MAOI-containing medication or in case of concomitant hypertensive treatment.

## **Environmental Protection**

Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.

## **Disposal**

Dispose of container by wrapping with paper and putting in garbage.

## Withholding Periods:

**Apivar**: Honey: Zero (0) days after the removal of the strips.

DO NOT harvest honey when the treatment is in place.

Apitraz: Honey: Honey collected from hives within 14 days following removal of treatment

must not be used or processed for human consumption.

### **Jurisdiction:**

NSW, ACT and VIC only.

## **Additional Conditions:**

This permit allows for the use of a product in a manner specified on the permit. Persons who wish to prepare for use and/or use products for the purposes specified in this permit must read, or have read to them, the details and conditions of this permit. Unless otherwise stated, the use of the product must be in accordance with the appropriate product label at **Attachment 1** for Apivar, or **Attachment 4** for Apitraz.

The holder of the permit must notify the APVMA of new information, including relevant information in accordance with section 161 of the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, in accordance with the obligation imposed by that section.

## Supply

The supplier must supply the product in a container that complies with the requirements of section 18 of the Agricultural and Veterinary Chemicals Code Regulations. Attached to this container must be a label which is identical in content and format to the relevant product label at **Attachment 2**, 3 or 4.

As shown in the attachments, for all product manufactured after the date of the start of this permit, the product label must carry the appropriate signal heading. The signal heading may be applied as an oversticker, and must be applied without obscuring any other label text. The signal heading must be applied in accordance with the APVMA Veterinary Labelling Code.

A copy of this permit must be supplied with the product.

## Record keeping

Maintain records of all treatments performed under this permit. Details must include the date and locations where treatments occurred, the total amount of product used, and the names and addresses of the persons undertaking the use. These details must be maintained for a minimum period of two years from the date of expiry of this permit, and must be made available to the APVMA upon request.

## Export of treated produce

## Apivar:

Apiarists should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for honey and other bee products treated with APIVAR. If you are collecting honey for export, please check with Findex (Aust) Pty Limited on +61 2 9619 1955 for the latest information on MRLs and import tolerances before using APIVAR.

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## Apitraz:

Apiarists should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for honey and other bee products treated with APITRAZ. If you are collecting honey for export, please check with Ecrotek Australia Limited Partnership +61 1800 905 687 for the latest information on MRLs and import tolerances before using APITRAZ. The holder of the permit must notify the APVMA of new information, including relevant information in accordance with section 161 of the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, in accordance with the obligation imposed by that section.

Issued by the Australian Pesticides and Veterinary Medicines Authority

Note: 29/04/2024 – Permit updated to add commercial suppliers. Permit expiry extended to 31/07/2024. Permit issued as Version 2.

22/07/2024 – Permit updated to add commercial suppliers and use in VIC. Permit expiry extended to 30/11/2024. Permit issued as Version 3.

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## $Attachment\ 1-Australian\ Registered\ Product\ Label\ -\ Apivar\ 500\ MG\ Bee\ Hive\ Strips$ for Honey Bees $-\ APVMA\ No.\ 88615\ /\ 121827$

Label Name:	APIVAR 500 MG BEE HIVE STRIPS FOR HONEY BEES	
Label Name.	Name. AFTVAIX 300 MIG BLE THVE STRIFST ORTHORET BLES	
Signal Headings:	POISON	
	KEEP OUT OF REACH OF CHILDREN	
	FOR ANIMAL TREATMENT ONLY	
	READ SAFETY DIRECTIONS BEFORE OPENING OR USING	
Constituent Statements:	500 mg amitraz per strip.	
Claims:	For the control of mites (Varroa destructor) on European honey bees (Apis mellifera).	
Cidinis.	Tor the control of filles (varioa destructor) on European noney bees (Apis fileilliera).	
	This product must only be supplied in the event an outbreak of varroa mite (Varroa destructor) is declared in accordance with the Emergency Plant Pest Response Deed by the Australian Chief Plant Protection Officer of the Commonwealth (after referral from PLANTPLAN).	
	This product must only be used under the direction of the Australian Chief Plant Protection Officer of the Commonwealth.	
	APIVAR 500 MG BEE HIVE STRIPS FOR HONEY BEES contains amitraz, a member of the formamidine family. It is effective against sensitive strains of varroa mites (Varroa destructor). Resistance may develop to any chemical.	
Net Contents:	10 strips 12 strips 60 strips	
Directions for Use:		
Restraints:	DO NOT USE during honey flow or while honey supers are present.  DO NOT harvest honey when the treatment is in place. Honey if produced or harvested while the treatment is in place must not be made available for human consumption.  DO NOT extract honey from the brood chamber.  DO NOT recycle brood frames as honey frames in treated hives.  HONEYCOMB/PROPOLIS/ROYAL JELLY: DO NOT make honeycomb, propolis, royal jelly from treated bees or hives available for human consumption.	

## Attachment 1 – Australian Registered Product Label - Apivar 500 MG Bee Hive Strips for Honey Bees – APVMA No. 88615 / 121827

DO NOT USE APIVAR over two consecutive	e treatment periods.	The product must only be
used once a year.		

Contraindications	j.
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### Precautions:

Compatibility of this product with any other product has not been studied, therefore using this product concurrently with any other product should be avoided.

#### Side Effects:

Overdose: At five times the recommended dosage applied for six weeks, the colonies clustered on very hot days. No other sign was observed. At 1.5 times the recommended dosage applied for ten weeks, no apparent side effects were observed in bees.

#### Dosage and Administration:

Use the contents within 24 hours of opening. Discard any unused portion.

#### DOSAGE RATE:

Use 2 APIVAR strips per brood chamber or 1 APIVAR strip per nuclei. Hang each strip within two frames from the edge of the cluster e.g. between frames 3 and 4 and between frames 7 and 8. APIVAR strips are suspended in the brood chamber in such a way that the bees can walk on both sides of the strips. Dose must not exceed the stated dose rate in a fully populated hive.

If possible, strips should be checked halfway through the treatment interval. If it is noted that the bee cluster has moved away from the strips, reposition the strips into the bee cluster.

#### TIMING:

APIVAR is an effective treatment in both the spring and the autumn. Start the treatment in early spring before the first honey flow. If APIVAR is used in the autumn, strips are not to be placed until after all supers containing honey for human consumption have been removed. DO NOT USE APIVAR while honey supers are present. Recycling of brood frames and honey frames is not advised.

## DURATION:

The strips must remain in the hive for the full 6 - 10 week treatment period (in the situation where brood is forming). Treatment strips must be removed after a maximum of 10 weeks of use. DO NOT re-use the strips.

The strips can remain in the hive for 6 weeks. After checking, its use can be extended to 10 weeks if brood is forming.

## General Directions:

Amitraz is delivered at the surface of the strips and acts by contact with the bees.

Use before honey flow or after honey harvest.

Do not cut the strips.

Apply the product in all colonies of the same apiary at the same time.

Do not re-use the strips.

Do not exceed or decrease the recommended dose and recommended duration of use. Remove the strips at the end of treatment.

Inappropriate use of the product could result in an increased risk of resistance development and could ultimately result in ineffective therapy.

In case of suspicion of amitraz resistance, the use of the product should ideally be based on the results of sensitivity tests.

## $Attachment\ 1-Australian\ Registered\ Product\ Label\ -\ Apivar\ 500\ MG\ Bee\ Hive\ Strips$ for Honey Bees $-\ APVMA\ No.\ 88615\ /\ 121827$

	Amitraz has been available for use against varroa mite in bees for many years, but availability varies between different countries over time. Nevertheless, bees and mites across the world have been exposed to amitraz and resistance in mites may have developed to the point that it could limit the efficacy of amitraz in the field. This is relevant because mite populations arriving in Australia in the future may be resistant to amitraz due to previous drug exposure in the country of origin.
Withholding Periods:	Honey: Zero (0) days after the removal of the strips. DO NOT harvest honey when the treatment is in place.
Trade Advice:	Apiarists should note that maximum residue limits (MRLs) or import tolerances may not exist in all markets for honey and other bee products treated with APIVAR 500 MG BEE HIVE STRIPS FOR HONEY BEES. If you are collecting honey for export, please check with Findex (Aust) Pty Limited on +61 2 9619 1955 for the latest information on MRLs and import tolerances before using APIVAR 500 MG BEE HIVE STRIPS FOR HONEY BEES.
Safety Directions:	When opening the container, preparing the product for use and if applying by hand, wear gauntlet-length chemical resistant gloves. Wash hands after use.
First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.
First Aid Warnings:	
Additional User Safety:	DO NOT open inner pouch until ready for use. DO NOT allow children to play with plastic strips. Take particular care in people suffering from diabetes or under MAOI-containing medication or in case of concomitant hypertensive treatment.
Environmental Statements:	ENVIRONMENTAL PROTECTION: Very toxic to aquatic life. DO NOT contaminate wetlands or watercourses with this product or used containers.
Disposal:	Dispose of container by wrapping with paper and putting in garbage.
Storage:	Store below 30°C (room temperature). Store in the original closed package. Protect from light. Use the contents within 24 hours of opening. Discard any unused portion.

## Attachment 2 - New Zealand Apivar Product Label



ACTIVE INGREDIENT: Contains 33g/kg amitraz in the form of an impregnated plastic strip. (Contains 500mg amitraz per strip.)

WARNING - May cause skin sensitisation. ECOTOXIC

PRECAUTIONS: Keep out of reach of children. Read label before use. If medical advice is needed, have product container or label at hand. If skin irritation or rash occurs: Get medical advice/attention. Collect Spillage. Keep strips in original, unopened packaging, away from foodstuffs. Avoid inhalation of product vapour when opening the sealed packet of strips. Avoid contact with skin and eyes and wear latex gloves when handling the strips. Wash hands thoroughly with soap and water after use. Do not eat, drink or smoke whilst using. Very toxic to fish and other aquatic organisms. Avoid contamination of any water supply with strips or empty container. Take all reasonable steps to ensure that the substance does not cause any significant adverse effects to the environment beyond the application area.

GENERAL: Apivar® is a sustained-release impregnated plastic strip designed for use in beehives to control the parasitic mite (*Varroa destructor*) on honey bees. It is an offence to use this product on animals other than bees.

STORAGE AND DISPOSAL: Store at ambient room temperature, out of direct sunlight. Strips must be disposed of as directed.

#### Registered pursuant to the ACVM Act 1997 No. P05702.

See www.foodsafety.govt.nz for registration conditions. Approved pursuant to the HSNO Act 1996,

Approval Code: HSR000799

NZ Agent: New Zealand Beeswax Ltd, 44 Gladstone Street Sth, RD 22, Geraldine 7992

Registrant in NZ and owner of the product and trademark Apivar®: Véto-pharma S.A.

14 avenue du Québec - Z.A. Courtabœuf 91140 Villebon sur Yvette - FRANCE

APV-60-NZ-N01-04/18

Lot/EXP : see on the back of the packaging



For the control of mites (varroatosis) on honey bees

Net contents 60 plastic strips

#### **DIRECTIONS FOR USE**

#### DOSAGE RATE:

Use 2 Apivar® strips per brood chamber or 1 Apivar strip per nuclei. Hang each strip within two frames from the edge of the cluster e.g. between frames 3 and 4 and between frames 7 and 8. Apivar® strips are suspended in the brood chamber in such a way that the bees can walk on both sides of the strips. Dose must not exceed the stated dose rate in a fully populated hive.



	Nuc	Single	Double
#Frames	≤5	6-10	11-20
# Strips	1	2	4



If possible, strips should be checked halfway through the treatment interval. If it is noted that the bee cluster has moved away from the strips, reposition the strips into the bee cluster.

TIMING: Apivar® is an effective treatment in both the Spring and the Autumn. Start the treatment in early Spring before the first honey flow; if Apivar is used in the autumn, strips are not to be placed until after all supers containing honey intended for human consumption have been removed. Do NOT use Apivar® while honey supers are present. Recycling of brood frames as honey frames is not advised.

**DURATION:** The strips must remain in the hive for the full 6-10 week treatment period. Treatment strips must be removed after a maximum of 10 weeks of use. Do NOT re-use the strips.

WITHHOLDING PERIOD FOR HONEY COLLECTION: All strips must be removed prior to honey flow. Brood frames treated with Apivar should not be moved into honey supers. Apivar must not be used while honey supers are present.

It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels of Agricultural Compounds.

Honey produced for human consumption must not be collected during treatment or within 14 days of the removal of treatment strips.

**RESISTANCE MANAGEMENT:** Intensive use of Apivar® could result in the development of resistant strains of mites. To minimise this risk use Apivar® strictly in accordance with the label directions. DO NOT use Apivar for two consecutive treatment periods. It is recommended to alternate the use of Apivar® with products from other chemical groups.

STRIP DISPOSAL: Dispose of strips and empty packaging in a suitable landfill. Strips must not be discarded where they may come in contact with, or be consumed by, food-producing animals.

Véto-pharma

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## Attachment 2 – New Zealand Apivar Product Label



## For the control of mites (varroatosis) on honey bees



France

## Net contents 12 plastic strips

ACTIVE INGREDIENT: Contains 33g/kg amitraz in the form of an impregnated plastic strip. (Contains 500mg amitraz per strip.)

WARNING - May cause skin sensitisation. ECOTOXIC

PRECAUTIONS: Keep out of reach of children. Read label before use. If medical advice is needed, have product container or label at hand. If skin irritation or rash occurs: Get medical advice/attention. Collect Spillage. Keep strips in original, unopened packaging, away from foodstuffs. Avoid inhalation of product vapour when opening the sealed packet of strips. Avoid contact with skin and eyes and wear latex gloves when handling the strips. Wash hands thoroughly with soap and water after use. Do not eat, drink or smoke whilst using. Very toxic to fish and other aquatic organisms. Avoid contamination of any water supply with strips or empty container. Take all reasonable steps to ensure that the substance does not cause any significant adverse effects to the environment beyond the application area

GENERAL: Apivar® is a sustained-release impregnated plastic strip designed for use in beehives to control the parasitic mite (Varroa destructor) on honey bees. It is an offence to use this product on animals other than bees.

STORAGE AND DISPOSAL: Store at ambient room temperature, out of direct sunlight. Strips must be disposed of as directed.

#### Registered pursuant to the ACVM Act 1997 No. P05702. See www.foodsafety.govt.nz for registration conditions.

Approved pursuant to the HSNO Act 1996, Approval Code: HSR000799

NZ Agent: New Zealand Beeswax Ltd, 44 Gladstone Street Sth, RD 22, Geraldine 7992

Registrant in NZ and owner of the product and trademark Apivar<sup>a</sup>: Véto-pharma S.A.S. 12/14 rue de la Croix-Martre 91120 PALAISEAU - FRANCE



APV-65-NZ-N01-02/20



Lot/EXP: see on the packaging



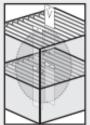
#### DIRECTIONS FOR USE

#### DOSAGE RATE:

Use 2 Apivar<sup>®</sup> strips per brood chamber or 1 Apivar strip per nuclei. Hang each strip within two frames from the edge of the cluster e.g. between frames 3 and 4 and between frames 7 and 8. Apivar<sup>®</sup> strips are suspended in the brood chamber in such a way that the bees can walk on both sides of the strips. Dose must not exceed the stated dose rate in a fully populated hive.



	Nuc	Single	Double
# Frames	≤5	6-10	11-20
# Strips	1	2	4



If possible, strips should be checked halfway through the treatment interval. If it is noted that the bee cluster has moved away from the strips, reposition the strips into the bee cluster.

#### TIMING:

Apivare is an effective treatment in both the Spring and the Autumn. Start the treatment in early Spring before the first honey flow; if Apivar is used in the autumn, strips are not to be placed until after all supers containing honey intended for human consumption have been removed. Do NOT use Apivare while honey supers are present. Recycling of brood frames as honey frames is not advised.

#### DURATION

The strips must remain in the hive for the full 6-10 week treatment period. Treatment strips must be removed after a maximum of 10 weeks of use. Do NOT re-use the strips.

#### WITHHOLDING PERIOD FOR HONEY COLLECTION:

All strips must be removed prior to honey flow. Brood frames treated with Apivar should not be moved into honey supers. Apivar must not be used while honey supers are present.

It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels for Agricultural Compounds.

Honey produced for human consumption must not be collected during treatment or within 14 days of the removal of treatment strips.

#### RESISTANCE MANAGEMENT:

Intensive use of Apivar® could result in the development of resistant strains of mites. To minimise this risk use Apivar® strictly in accordance with the label directions. DO NOT use Apivar for two consecutive treatment periods. It is recommended to alternate the use of Apivar® with products from other chemical groups.

#### STRIP DISPOSAL:

Dispose of strips and empty packaging in a suitable landfill. Strips must not be discarded where they may come in contact with, or be consumed by, food-producing animals.



Under the Federal Insecucide, Fungic and Rodenticide Act as amended, for 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	Take off contaminated clothing.	
CLOTHING:	<ul> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>	
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
IF SWALLOWED:	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> </ul>	
	<ul> <li>Have person sip a glass of water if able to swallow.</li> </ul>	
	<ul> <li>Do not induce vomiting unless told to by a poison control center or doctor.</li> </ul>	
	<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>	
IF IN EYES:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> </ul>	
	<ul> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> </ul>	
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
IF INHALED:	<ul> <li>Move person to fresh air.</li> </ul>	
	<ul> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> </ul>	
	<ul> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>	

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<sup>®</sup>. Use 2 Apivar<sup>®</sup> 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.

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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<sup>®</sup>.

## 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<sup>®</sup> 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<sup>®</sup>.
- Remove Apivar<sup>®</sup> 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<sup>®</sup> 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:	IDE 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	Nonrefillable container. Do not reuse or refill this	
HANDLING:	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]

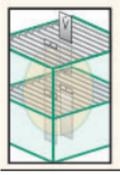
[Committed to apiculture]



[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
- 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) Véto-pharma controls the entire Apivar production chain from the supply of primary materials to release on the market. This means that Véto-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.
- 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.
- 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.
- 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

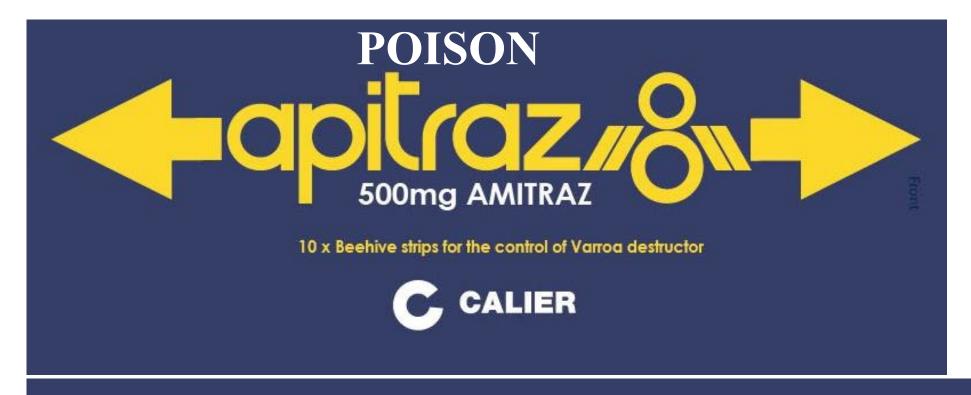
- 47) Leave strips inside the hive for 42-56 days, and then remove.
- 48) At the end of treatment, remove the strips in order to prevent the presence of low quantities of amitraz in the hive and prevent the development of possible resistance.
- 49) To avoid encouraging the development of resistance, 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



Resistance Management: Intensive and exclusive use of Apitraz could result in the development of resistant mite strains. To minimise this risk follow all label instructions correctly. Do NOT use Apitraz for two consecutive treatments. Alternate the use of Apitraz with a product from a different chemical class. For example if treating in the Autumn and Spring use Apitraz for one treatment and an alternate chemical class treatment for the other. If treating once a year, use Apitraz in alternating years. To ensure correct administration strips should be checked halfway through the application period. If the bee population has moved away from the strips, reposition the strips to give contact with the bee colony. Special warnings: All colonies in the same apiary should be treated simultaneously. The safety profile for the product has not been established in weak colonies. Storage: Store at room temperature out of direct sunlight. Store unopened in a dry location. Precautions: Handle and open container with care to minimise the potential for

inhalation. Avoid contact with skin and eyes. This product may cause skin sensitisation, allergic reactions and eye imitation. Personal protective equipment consisting of leather gloves and the usual beekeeping protective clothing should be worn while handling this product. In case of contamination, wash thoroughly with soap and water. In case of contact, rinsewith plenty of water immediately. If irritation occurs, seek immediate medical advice. Do not eat, drink or smokewhile administering this product. Keep children well away during application of product. Approved pursuant to the ACVM Act 1997 No. ACVM P009498 see foodsafety govt.rz for registration conditions. Approved pursuant to the HSNO ACT 1996. Approval code: HSR101246 For any information about this veterinary medicinal product in New Zealand, please contact Ecrotek Ltd. Marketing authorisation holder and manufacturer responsible for batch release: LABORATORIOS CALIER, S.A. C/Barcelonès, 26 (B. Ramassar) 08530 Les Franqueses del Vallès, (Barcelona)

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## Attachment 4 – New Zealand Apitraz Product Label

▶ Indication: For the treatment of Varroa destructor. Target species: Honey bees – Apis mellifera. Not for human consumption. It is an offence to use this product on animals other than bees. Safety precautions: Keep out of reach of children. Avoid inhalation and skin contact. Do not store above 25°C. Use immediately after opening. Do not use if you see signs of deterioration. Active ingredient: Amitraz 500 mg per strip [33g/kg] impregnated in a white rectangular plastic strip with two tabs and a marker fold line. Harmful – May cause skin sensitisation.

Directions for use and Dosage rate: In-hive use. Use two Apitraz strips per brood box. Hang each strip between two frames with full bee coverage. Hang the strips in such a way as to provide bees with free access to both sides, whilst maintaining bee space. Place strips within two frames of the edge of the cluster. For example place one strip between the third and the fourth and the other between the seventh and eighth brood comb. Double brood box colories would require four strips administered, two per brood chamber. For nucleus colories one strip should be used. Maximum dosage must not exceed one strip per five fully covered frames of bees. Timing of treatment: Treatment should be started early spring prior to honey flow. If using in the autumn strips must not be administered until all honey supers intended for human consumption have been removed. Do NOT use Apitraz when honey supers are present.

Duration of treatment: Strips must remain in the hive for between 6-10 weeks. Apitraz treatment must not exceed 10 weeks. Do NOT reuse strips. Withholding period: Honey produced for human consumption must not be collected during treatment or within 14 days of the removal of treatment strips. It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels of Agricultural Compounds. Brood frames treated with Apitraz must not be moved into honey supers. Usage precautions: The strips should not be cut. The product should be applied when the bees are still active, the exact timing of which can vary between climatic zones. Disposal: Wrap strips and packaging in paper and dispose of in a suitable landfill. Strips must not be discarded where they may come in contact with, or be consumed by, food-producing animals. Avoid contamination of waterways with strips or packaging. Very toxic to fish and other aquatic organisms.

Registered in New Zealand to Laboratorios Calier, S.A.

Distributed in New Zealand by Ecrotek Limited, 15 Kerwyn Avenue, East Tamaki, Auckland 2013 www.ecrotek.co.rz 0800 11 77 66

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## Attachment 5 – Head office addresses of approved commercial suppliers for use in the designated jurisdictions

ACE OHLSSON

Stores 7 and 8, Warehouse J

SYDNEY MARKETS NSW 2129,

(Note: all VIC, NSW and ACT businesses that trade

as Ace Ohlsson are approved suppliers.)

ALL ABOUT BEEKEEPING

21B Station Street

**DIAMOND CREEK VIC 3089** 

ARIANWEN'S HONEY

238 Cowper street

**GOULBURN NSW 2580** 

**AUSTRALIAN HONEYBEE** 

**ENTERPRISES** 

187 Punch Street

**GUNDAGAI NSW 2722** 

AUSTRALIAN QUEEN BEE LINE PTY

LTD

21 Leewood Drive

**ORANGE NSW 2800** 

AUSTWIDE BEEKEEPING SUPPLIES

557 Cabbage Tree Road

**WILLIAMTOWN NSW 2318** 

**B&W RURAL** 

Unit 4/46-50 Bourke Street DUBBO, NSW, 2830

(Note: all NSW and ACT businesses that trade as

B&W Rural are approved suppliers.)

**BECS BEEHIVE** 

53 Gembrooke Road

**GEMBROOKE VIC 3783** 

BEEKEEPING IN AUSTRALIA

41 Hoddle Avenue

**BRADBURY NSW 2560** 

BEEKEEPING SUPPLIES AUSTRALIA

164 Cobalt St

CAROLE PARK QLD 4300

BEES R US HONEY AND BEEKEEPING

**SUPPLIES** 

69 Duncan Street

**BRAIDWOOD NSW 2622** 

BINDAREE BEEKEEPING SUPPLIES

18 East Street

**MURRUMBATEMAN NSW 2582** 

**BOBS BEEKEEPING SUPPLIES** 

54 Gills Road

**WATSONS CREEK VIC 3097** 

BOROUGH ONLINE PTY LTD

(Trading as "The Bee Store")

21 Lara Way

**CAMPBELLFIELD VIC 3061** 

BROWNS BEES AUSTRALIA PTY LTD

1560 Collombatti Road

**COLLOMBATTI NSW 2440** 

**BUZZ BEE** 

21 Rozelle Avenue

**RINGWOOD EAST VIC 3135** 

CARE PACKAGING PTY LTD

3 Olympic Place

KELSO NSW 2795

CENTRAL COAST BEE SUPPLIES

207/12 Pioneer Avenue

**TUGGERAH NSW 2261** 

CENTRAL COAST HONEY

32 Palmers Lane

**BENSVILLE NSW 2251** 

CERACELL PTY LTD

41 Business Drive

NARANGBA QLD 4504

CERACELL BEEKEEPING SUPPLIES

(NZ) LTD

23 Ra Ora Drive

East Tamaki

**AUCKLAND 2013 NEW ZEALAND** 

**COFFS BEEKEEPING SUPPLIES** 

23 Hawkes Drive

**WOOLGOOLGA NSW 2456** 

DEBZZZ BEEKEEPING

68 Back Creek Road

YACKANDANDAH VIC 3749

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## Attachment 5 – Head office addresses of approved commercial suppliers for use in the designated jurisdictions

DENWOOD ENTERPRISES 13 Ninnis Street LEUMEAH NSW 2560

EC TOBIN & SONS BEEKEEPING SUPPLIES 43 Christie St RAGLAN NSW 2795

ECROTEK 15E Kerwyn Ave East Tamaki AUCKLAND 2013 NEW ZEALAND

ECROTEK: BEEKEEPING SUPPLIES AUSTRALIA 51 Marshalls Lane BLAYNEY NSW 2799

EDMONDS HONEY/GEELONG HONEY 5 Lower Duneed Road MOUNT DUNEED VIC 3217

ELDERS RURAL SERVICES
Unit 4/46-50 Bourke Street
DUBBO, NSW, 2830
(Note: all VIC, NSW and ACT businesses that trade as Elders Rural Services are approved suppliers.)

FASE GLOBAL ENTERPRISE 2 Factory Street GRANVILLE NSW 2142

GUILFOYLE BEEKEEPING SUPPLIES 38 Begonia Street INALA QLD 4077

GUILFOYLE BEEKEEPING SUPPLIES Shop 6/82 Victoria Street WERRINGTON NSW 2747

HIVE IQ 4/62 Dacre Street MITCHELL ACT 2911

HORNSBY BEEKEEPING SUPPLIES Hornsby and Mount Druitt Unit 8, 47-51 Jersey street HORNSBY NSW 2077 HUNTER VALLEY APIARIES 71 Bakers Lane KURRI KURRI NSW 2327

IN BEES WE TRUST SYDNEY BEE SHOP U2 39 Lower Bent Street NEUTRAL BAY NSW 2089

IWOOHOO PTY LTD Unit 1A 1 Swaffham Rd MINTO NSW 2566

J.P. & J.K MAGILL – WILLOWGLEN 33 Ballengara Bransdon Rd COOPERABUNG NSW 2441

JEERALANG APIARY SUPPLIES Koala Drive JEERALANG JUNCTION VIC

KELVIN TRADING 31/830-850 Princes Highway SPRINGVALE VIC 3171

LOCKWOOD BEEKEEPING SUPPLIES 2319 Mitchell Hwy VITTORIA NSW 2799

LYSON BEEKEEPING SUPPLIES AUSTRALIA 18B Industrial Avenue MUDGEE NSW 2850

MCCAHONS BEE MATERIAL Jubilee Lake Road DAYLESFORD VIC 3460

MCDONALD HONEY 5 Melissa Court MCKENZIES HILL VIC 3451

NEW ZEALAND BEESWAX LTD 44 Gladstone St South Orari, RD22 GERALDINE 7992, NEW ZEALAND

NUPLAS GROUP 2 Westbrook Road SWAN HILL VIC 3585

## Attachment 5 – Head office addresses of approved commercial suppliers for use in the designated jurisdictions

PARKER BEEKEEPING SUPPLIES

21 Dunmore Rd

Unit 21/19 McCauley Street

DUNMORE NSW 2529

MATRAVILLE NSW 2036

PENDER BEEKEEPING SUPPLIES

2/72 Munibung Road

CARDIFF NSW 2285

V'S BEES QLD

Unit 11/229 Brisbane Road

BIGGERA WATERS QLD 4216

REDPATH BEEKEEPING SUPPLIES

193 Como Parade

EAST PARKDALE VIC 3195

VALLEY BEES
70 Whitbread Street
TAREE NSW 2430

TAMWORTH BEEKEEPING SUPPLIES
397 Armidale Road
TAMWORTH NSW 2340

VICTORIAN APIRARISTS' ASSOC
11-15 Haystack Court
NARRE WARREN NORTH VIC 3804

THE GOLD COAST AMATEUR
BEEKEEPERS SOCIETY INC.
WHIRRAKEE WOODWARE
74 BillaBirra Cres
NERANG QLD 4211
MARYBOROUGH VIC 3465

**Notes**: As these products are unregistered, an import consent must be requested, and must be in place with the APVMA for each supplier or user importing product from any overseas country, including New Zealand. This is in addition to any other relevant import permits from other Australian Government Departments.

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