NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):
Veto-pharma S.A.S, c/o
Wendy McCombie
12/14 rue de la Croix-Martre
91120 Palaiseau, France

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

Continues page 2

Signature of Approving Official:

Melissa Bridges
Product Manager (acting) 07
Invertebrate &Vertebrate Branch 3

Date:
3/31/23
2. Make the following label changes before you release the product for shipment:
   
   • Revise the EPA Registration Number to read, “EPA Reg. No. 87243-4.”

3. Submit one copy of the final printed label for the record before you release the product for shipment.

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 FIFRA 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) lists 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. 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.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

The record for this product currently contains the following CSF(s):

   • Basic CSF dated 10/27/2021

If you have any questions, please contact Andrés Garzón at (202) 566-2690 or at GarzonMoreno.Andres@epa.gov.

Enclosure
RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
For retail sale to and use only by certified applicators or persons under their direct supervision, and only for those uses covered by the certified applicator’s certification

Amiflex®
Amiflex® by Veto-Pharma
Veto-Pharma committed to Apiculture
Gel formulation for the in-hive control of varroa mites on honey bees

ACTIVE INGREDIENT:
Amitraz: N’-(2,4-dimethylphenyl)-N-[(2,4-dimethylphenyl)imino]methyl]-N-methylmethanimidamide  2.0 %
OTHER INGREDIENTS:  98.0 %
TOTAL:  100.0 %

KEEP OUT OF REACH OF CHILDREN
DANGER  PELIGRO

FIRST AID

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 ON SKIN OR CLOTHING
• 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 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.

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.

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.

Refer to [back] [side] [other] [panel] [peel back] [package insert] for [first aid and additional precautionary statements] and [Directions for Use]

EPA Reg. No. 87243-U
EPA Est. No. 87242-FRA-001

Veto-Pharma SAS
12/14 rue de la Croix Martre
91120 Palaiseau- France

AMIFLEX (EPA Reg. No. 87243-U)
Master Label, version dated 2023 March 29
PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Harmful if inhaled. Avoid breathing vapor when applying the product.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:
- Coveralls worn over long-sleeved shirt and long pants
- Socks and chemical-resistant footwear
- Waterproof or chemical-resistant gloves made of barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride (PVC), or viton ≥ 14 mils
- Protective eyewear such as goggles, face shield, or safety glasses

USER SAFETY REQUIREMENTS

Follow the manufacturer’s instructions for cleaning/maintaining PPE. If no such instructions for washables exists, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:
- Wash hands thoroughly with soap and water after handling before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

California warning:
ATTENTION: This product contains a chemical known to the state of California to cause birth defects or other reproductive harm. For more information go to www.65Warnings.ca.gov.

ENVIRONMENTAL HAZARDS

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

GENERAL INFORMATION

Amiflex® is a product specifically designed for use in beehives. The easy-to-use dosing gun ensures correct dosage of the active ingredient amitraz. Amiflex® has no harmful effect on the honeybee colony, neither on brood nor on adults, when used according to directions. It ensures no residues in honey beyond the maximum limits when used according to directions.
DIRECTIONS FOR USE

Restricted Use Pesticide

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

Read entire label, use strictly in accordance with precautionary statements and directions, and with applicable state and federal regulations.

Amiflex® is a gel formulation designed for use in beehives to control the parasitic mite (Varroa destructor) sensible to amitraz on honeybees.

Loading of Dosing gun – Load and secure Amiflex® syringe into dosing gun [see pictures 1, 2, 3]. Remove the cap of the syringe [see picture 4]. Gently and briefly depress trigger several times to prime tool ready for application of product to hives [picture 5]. Each pull of the trigger delivers a standard dose of 3 ml of product. Apply 2 doses of 3 ml per brood chamber/brood box. When product syringe is empty, replace with new product syringe. Retain dosing gun for future applications of Amiflex®.

For varroa treatment - Amiflex® can be used both in brood free colonies and when brood is present. Amiflex® cannot be used in presence of honey supers. Scrape frames clear of all wax and propolis that could prevent the bees from coming into contact with the gel, for example, clean top feeders, top bars, or for a double brood chamber/brood box hive, below the frames for the top brood chamber/brood box. Set two [wooden] supports [included] per brood chamber/brood box on the top bars of frames in the center of the brood area or in the center of the bee cluster. Avoid end frames for application. For a better distribution of the active ingredient in the colony, leave a minimum of one frame free of gel between two frames with gel. Use the dosing gun to apply 2 doses of 3 ml of Amiflex® by applying a line of gel on each support [See picture 6]. For a double brood chamber/brood box hive, the total dosage will be 4 lines of 3 ml (i.e a total of 12 ml) of gel.
Timing:
This product is designed to reduce the load of phoretic mites with quick knockdown action.
Amiflex® does not replace a long action product, especially for a late-summer treatment.
The product can be used any time when honey supers are not present and as long as the bees are actively foraging. Avoid treatment during times of the year when bees are not actively foraging (e.g. winter). Do not use during honey flow.

Due to its quick action, the product can be used several times during the year in order to limit the mite exponential growth. Do not exceed 4 Amiflex® treatments per year.

If varroa infestation is high: apply a second application 7 days after removing the first one in order to cover new emerging bees. Do not apply Amiflex® more than two times in a row before one honey flow.

Amiflex® can also be applied 7 days before applying a long action treatment, to obtain a knockdown effect before such treatment.

**Withholding period for honey collection:**
DO NOT USE AMIFLEX® WHEN HONEY SUPERS ARE PRESENT.
The treatment period is 7 days. After the 7 days, remove the potential treatment leftover and support. The honey supers can now be set-up.

**Resistance-management:**
Any mite population may contain individuals naturally resistant to Amiflex® and other similar miticides. The resistant individuals may dominate the mite population if this amitraz-based 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 Amiflex® or other amitraz-containing miticides with miticides containing a different active ingredient registered for use in hives.
- 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.

RESTRICTIONS:

• For in-hive use only.
• Do not use Amiflex® on sparsely populated and inactive colonies.
• Do not use Amiflex® when honey supers are present.
• Remove honey supers before application of Amiflex®.
• Maximum rate per treatment = 2 x 3 ml (6 ml) per brood chamber/brood box per treatment
• Remove the treatment leftover and supports before placing honey supers
• Do not use Amiflex® more than 4 times a year
• Do not use Amiflex® more than 2 times in a row before one honey flow.

<table>
<thead>
<tr>
<th><strong>STORAGE AND DISPOSAL</strong></th>
</tr>
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<td>Do not contaminate water, food or feed by storage or disposal.</td>
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| **PESTICIDE STORAGE:** | Store unopened syringes in a cool, dry area, out of direct sunlight, and away from other pesticides that may contaminate the product. To prevent contamination, store unused product in the original container and away from food or feed. Use the syringe immediately after its first opening and discard any unused product. |
| **PESTICIDE DISPOSAL:** | To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product and used [wooden] supports to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry). |
| **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 syringes each containing 120 mL of Amiflex® [one dosing gun] [and XX supports]
[Expiration date: 24 months]
(NOTE TO REVIEWER: Batch number and Date of manufacture will be printed directly on the container.)
Amiflex®

Amiflex by Veto-Pharma
Veto-Pharma committed to Apiculture

Gel formulation for the in-hive control of varroa mites on honey bees

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**KEEP OUT OF REACH OF CHILDREN**
**DANGER**
**PELIGRO**

**FIRST AID**

**IF IN EYES:**
- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
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- Take off contaminated clothing.
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- 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.
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Refer to [back] [side] [other] [panel] [peel back] [package insert] for [first aid and additional precautionary statements] and [Directions for Use]

EPA Reg. No. 87243-U
EPA Est. No. 87242-FRA-001

Veto-Pharma SAS
12/14 rue de la Croix Martre
91120 Palaiseau- France

AMIFLEX (EPA Reg. No. 87243-U)
Master Label, version dated 2023 March 29
PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER:** Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Harmful if inhaled. Avoid breathing vapor when applying the product.

PERSONAL PROTECTIVE EQUIPMENT (PPE)
Applicators and other handlers must wear:
- Coveralls worn over long-sleeved shirt and long pants
- Socks and chemical-resistant footwear
- Waterproof or chemical-resistant gloves made of barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride (PVC), or viton ≥ 14 mils
- Protective eyewear such as goggles, face shield, or safety glasses

USER SAFETY REQUIREMENTS
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ENVIRONMENTAL HAZARDS
For terrestrial uses: This product is toxic to fish and aquatic invertebrates. Do not contaminate water when disposing of used packaging.

GENERAL INFORMATION

Amiflex® is a product specifically designed for use in beehives. The easy-to-use dosing gun ensures correct dosage of the active ingredient amitraz. Amiflex® has no harmful effect on the honeybee colony, neither on brood nor on adults, when used according to directions. It ensures no residues in honey beyond the maximum limits when used according to directions.
DIRECTIONS FOR USE
Restricted Use Pesticide

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**Loading of Dosing gun** – Load and secure Amiflex® syringe into dosing gun [see pictures 1, 2, 3]. Remove the cap of the syringe [see picture 4]. Gently and briefly depress trigger several times to prime tool ready for application of product to hives [picture 5]. Each pull of the trigger delivers a standard dose of 3 ml of product. Apply 2 doses of 3 ml per brood chamber/brood box. When product syringe is empty, replace with new product syringe. Retain dosing gun for future applications of Amiflex®.

**For varroa treatment** - Amiflex® can be used both in brood free colonies and when brood is present. Amiflex® cannot be used in presence of honey supers. Scrape frames clear of all wax and propolis that could prevent the bees from coming into contact with the gel, for example, clean top feeders, top bars, or for a double brood chamber/brood box hive, below the frames for the top brood chamber/brood box. Set two [wooden] supports [included] per brood chamber/brood box on the top bars of frames in the center of the brood area or in the center of the bee cluster. Avoid end frames for application. For a better distribution of the active ingredient in the colony, leave a minimum of one frame free of gel between two frames with gel. Use the dosing gun to apply 2 doses of 3 ml of Amiflex® by applying a line of gel on each support [See picture 6]. For a double brood chamber/brood box hive, the total dosage will be 4 lines of 3 ml (i.e a total of 12 ml) of gel.
**Timing:**
This product is designed to reduce the load of phoretic mites with quick knockdown action.
Amiflex® does not replace a long action product, especially for a late-summer treatment.

AMIFLEX (EPA Reg. No. 87243-U)
Master Label, version dated 2023 March 29
The product can be used any time when honey supers are not present and as long as the bees are actively foraging. Avoid treatment during times of the year when bees are not actively foraging (e.g. winter).
Do not use during honey flow.
Due to its quick action, the product can be used several times during the year in order to limit the mite exponential growth. Do not exceed 4 Amiflex® treatments per year.
If varroa infestation is high: apply a second application 7 days after removing the first one in order to cover new emerging bees. Do not apply Amiflex® more than two times in a row before one honey flow.
Amiflex® can also be applied 7 days before applying a long action treatment, to obtain a knockdown effect before such treatment.

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DO NOT USE AMIFLEX® WHEN HONEY SUPERS ARE PRESENT.
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To delay miticide resistance:
- Where possible, rotate the use of Amiflex® or other amitraz-containing miticides with miticides containing a different active ingredient registered for use in hives.
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• For further information or to report suspected resistance contact your local extension specialist.

RESTRICTIONS:

• For in-hive use only.
• Do not use Amiflex® on sparsely populated and inactive colonies.
• Do not use Amiflex® when honey supers are present.
• Remove honey supers before application of Amiflex®.
• Maximum rate per treatment = 2 x 3 ml (6 ml) per brood chamber/brood box per treatment
• Remove the treatment leftover and supports before placing honey supers
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STORAGE AND DISPOSAL

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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 syringes each containing 120 mL of Amiflex® [and XX supports]
Expiration date: 24 months

(Note to reviewer: Batch number and Date of manufacture: will be printed directly on the container.)
RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
For retail sale to and use only by certified applicators or persons under their direct supervision, and only for those uses covered by the certified applicator’s certification

Amiflex®

Amitraz……2.0%

KEEP OUT OF REACH OF CHILDREN
DANGER       PELEGO

Refer to [outer packaging] [outer label] [package insert] for full Directions for Use

EPA Reg. No. 87243-X
EPA Est. No. 87242-FRA-001

Veto-Pharma SAS
12/14 rue de la Croix Martre
91120 Palaiseau- France

NET CONTENTS: oz. (g.)
[Lot] [Batch] No.:
(Note to Reviewer; Optional Logos and Marketing Statements below)

[committed to apiculture]
Manufacturing Claims
1) An innovative amitraz based product [specifically designed] for honey bees
2) First amitraz flash treatment for honey bees [for commercial beekeepers]
3) First [registered] amitraz flash treatment for honey bees [for commercial beekeepers]
4) A [registered] flash treatment for honey bees [for commercial beekeepers]
5) A [registered] product to flash-treat your hives with amitraz
6) Amiflex® provides consistent results, is not harmful to bees, and meets or exceeds stringent [manufacturing] quality standards.
7) Formulated by beekeeping experts for beekeepers
8) Véto-pharma controls the entire Amiflex production chain from the supply of primary materials to release on the market. This means that Véto-pharma can guarantee the high quality of Amiflex, in accordance with regulations in the different countries where the product is registered.
9) High-quality product
10) Strict analysis and Quality Control process of each batch before marketing.

Mode of Action Claims
11) A flash treatment like Amiflex® kills [phoretic] varroa mites during the treatment period. As a result, the mite infestation of the colony quickly decreases.
12) [Knockdown] [flash action]
13) Amiflex® is effective to control mite infestation
14) Amiflex® effectively reduces the mite infestation pressure during the season.
15) “Knockdown effect” to [quickly reduce the mite load of a colony] [reduce the mite pressure below the infestation threshold].
16) Amiflex® reduces the mite infestation level during the season to prevent an excessive infestation before the late-summer or fall treatment.
17) Amiflex® can be applied 7 days before applying a long action treatment (such as Apivar) to obtain a knockdown effect before the long action treatment.
18) Amitraz is a miticide that paralyzes Varroa mites. Varroa can no longer hold on to the bees and fall to the hive’s bottom, leading to their starvation.
19) Amiflex® works by contact: As bees [get] [move] in contact with the gel, they pick up molecules of the active ingredient and then distribute them throughout the colony.

Application Claims
20) Easy and fast to apply
21) Labor-saving [thanks to a quick in-hive application] [due to a ready-to-use formulation and dosing gun]
22) Ready-to-use formulation: no mixing of product required.
23) Fast application thanks to the dosing gun delivering the exact dose required (3 ml)
24) Designed to prevent direct contact with [the active ingredient] [amitraz]
25) No direct exposure to [the active ingredient] [amitraz]
26) Specially designed for commercial beekeepers
27) Amiflex® can be used in the presence of queen cells or non-mated young queens.
28) Easy way to treat your colonies against varroa mites
29) No temperature constraint when using Amiflex®, as long as bees are actively foraging.
30) Amiflex® can be used in any season when the supers are not placed on the hive and as long as bees are actively foraging.
31) Amiflex® can be introduced as soon as foraging activity resumes in the spring, or after the withdrawal of supers, with no temperature constraint, without risk to the colony.
32) Leave the product inside the hive for 7 days, and then remove.
33) Can be used 7 days before a long action treatment [like ApiVar®] to optimize the effectiveness of the long-action treatment.
34) There are no counter-indications for feeding colonies simultaneously as treating with Amiflex®, as the product does not disturb feeding activity.
35) Treat all your colonies at the same time to avoid re-infestation.
36) Respect the dosage. Do not apply at a rate lower than that specified on the label.
37) Due to its quick action, the product can be used several times (4 times per year maximum) during the year to limit the exponential growth of mites.
38) When treatment is completed, remove product.
39) Reduced waste
40) Unique packaging specially designed for commercial beekeepers

Additional claims
41) Amiflex® does not harm the bees, beekeepers, or hive products thanks to its components’ quality and specific dosage.
42) Specifically formulated for beehives.
43) [Not harmful] [No negative effect] to brood, bees, and queens.
44) No brood mortality induced by Amiflex® at the recommended dose.
45) Allows high flexibility in timing varroa treatments during the season due to a short treatment period and flash action [knockdown effect].

Distribution Statements
46) Available from your US beekeeping supplier
47) Convenient and economical
48) Ideal for [commercial beekeepers] [large apiaries]