

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 30, 2022

Mrs. Jane M. Miller Agent for In2Care BV c/o Biologic Regulatory Consulting, Inc. 10529 Heritage Bay Blvd. Naples, FL 34120

Subject: PRIA Label Amendment – Addition of *Culex* Mosquito Claims as well as Changes to

Precautionary Statements, First Aid Statements, and Efficacy Duration Claims

Product Name: In2Mix

EPA Registration Number: 91720-1 Application Date: June 28, 2021 Decision Number: 576885

Dear Mrs. Miller:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is 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.

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.

Page 2 of 2 EPA Reg. No. 91720-1 Decision No. 576885

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 Briana Hanlon at (202) 566-2716 or at hanlon.briana@epa.gov.

Sincerely,

Jamica Cair

Tamica Cain, Product Manager 10 Invertebrate & Vertebrate Branch 2

Registration Division (7505T)

Enclosure

Outer Bag/Outer Box Labeling -

PYRIPROXYFEN	GROUP	7C	INSECTICIDE
Beauveria bassiana	GROUP	UN	INSECTICIDE
Strain GHA			

In2Mix®

For Use In The In2Care® Mosquito Station

[For use to control *Aedes* species of Mosquitoes that may transmit Zika, Chikungunya, and Dengue Fever]

THIS PRODUCT IS NOT INTENDED FOR HOMEOWNERS

[ROOM FOR MARKETING STATEMENTS AND ARTWORK]

READ ALL LABEL DIRECTIONS COMPLETELY BEFORE USE

Active Ingredients:	% w/w
Pyriproxyfen (CAS No. 95737-68-1)	74.03%
Beauveria bassiana strain GHA* (CAS No. 63428-82-0)	10.00%
Other Ingredients:	<u>15.97%</u>
Total	100.00%

^{*} Contains not less than 4.5 X 10⁹ viable spores/gm.

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE LABEL BOOKLET FOR [FIRST AID], [ADDITIONAL] PRECAUTIONARY STATEMENTS AND COMPLETE DIRECTIONS FOR USE [INCLUDING STORAGE AND DISPOSAL INSTRUCTIONS]

Manufactured by:

In2Care BV Marijkeweg 22, 6709 PG, Wageningen, The Netherlands

Net Weight: [12.5 g (0.44 [oz.] [ounce])

25 packages x 0.5 g each (0.018 [oz.] [ounce])]

[25 g (0.88 [oz.][ounce]

50 packages x 0.5 g each (0.018 [oz.][ounce])]

[50 g (1.76 [oz.][ounces])

100 packages x 0.5g each (0.018 [oz.][ounce])]



EPA Reg. No.: 91720-1 EPA Est. No.: XXXXX-XXX

06/30/2022

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

91720-1

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

Causes moderate eye irritation. Avoid contact with eyes, or clothing. Wear appropriate protective eyewear. Avoid breathing dust. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

	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 eye. Call a poison control
	center or doctor for treatment advice.

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information concerning this product, call the poison control center at 1-800-222-1222. For non-emergency general information on this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep this product in its tightly closed original container when not in use. Store in a cool, dry, well-ventilated area that is inaccessible to children and animals. For optimal long-term storage, do not store above 73° F (23° C). Store this product in a place away from strong bases, strong acids, sources of ignition and direct sunlight.

During transport and field use, keep **In2Mix**® packages below 110° F (43° C) at all times by avoiding sunlight and heat, and using isolation packaging.

PESTICIDE DISPOSAL: Dispose of used gauze in a sanitary landfill, or by other procedures approved by state and local authorities. Dispose of used water in the **In2Care® Mosquito Station** by pouring onto the ground, and not near a water source. Prevent entry of used water into sewers, gutters, or drains, or any area where drainage to storm sewers, water bodies, or aquatic habitat can occur. Notify authorities if liquid enters sewers or public waters.

CONTAINER HANDLING: Non-refillable container. Completely empty **In2Mix®** package into the **In2Care® Mosquito Station** by shaking and tapping sides and bottom to loosen clinging particles. When completely empty, dispose of empty package in trash or by other procedures approved by state and local authorities.

Label Booklet -

PYRIPROXYFEN	GROUP	7C	INSECTICIDE
Beauveria bassiana	GROUP	UN	INSECTICIDE
Strain GHA			

In2Mix®

For Use In The In2Care® Mosquito Station

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[ROOM FOR MARKETING STATEMENTS AND ARTWORK]

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Other Ingredients:	<u>15.97%</u>
Total	100.00%

^{*} Contains not less than 4.5 X 10⁹ viable spores/gm.

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE INSIDE LABEL BOOKLET FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND COMPLETE DIRECTIONS FOR USE.

Manufactured by:

In2Care BV
Marijkeweg 22, 6709 PG,
Wageningen, The Netherlands

EPA Reg. No.: 91720-1

EPA Est. No.: XXXXX-XX-XXX

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

Causes moderate eye irritation. Avoid contact with eyes, or clothing. Wear appropriate protective eyewear. Avoid breathing dust. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

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HOTLINE NUMBER

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PERSONAL PROTECTIVE EQUIPMENT (PPE)

All applicators and handlers must wear:

- Long-sleeved shirt and long pants;
- Waterproof gloves; and
- Shoes plus socks
- In addition, all applicators and handlers must wear a NIOSH-approved particulate respirator with any N, R, or P filter (NIOSH approval number prefix TC-84A); or a NIOSH-approved powered air purifying respirator with an HE filter (NIOSH approval number prefix TC-21C).

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

USER SAFETY RECOMMENDATIONS

Applicators and other handlers should:

- Wash hands 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.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic invertebrates. Do not apply directly to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water by cleaning of equipment or disposal of equipment wash-waters. Application of this product is prohibited directly into sewers or drains, or to any area like a gutter where drainage to storm sewers, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application.

This product is highly toxic and may be pathogenic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

DIRECTIONS FOR USE

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

READ ALL LABEL DIRECTIONS COMPLETELY BEFORE USE.

SHAKE In2Mix® PACKAGE BEFORE USE.

FOR OUTDOOR USE ONLY.

DO NOT allow people or pets to contact the pesticide.

HOW IT WORKS

In2Mix® powder contains a growth regulator and slow acting adulticide.

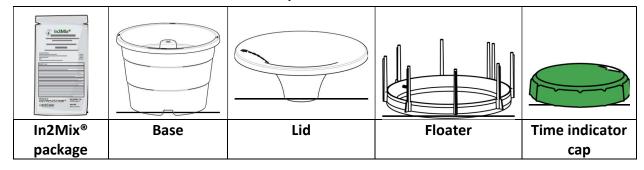
The growth regulator kills the *Aedes* and *Culex* spp. larvae that emerge from eggs laid inside the In2Care® Mosquito Station prior to transforming into adults. This means that it is normal to see small living larvae in the In2Care® Mosquito Station that will eventually die.

After laying eggs, the adult *Aedes* and *Culex* spp. mosquitoes are contaminated with the In**2Mix**® powder. When they fly out of the **In2Care**® **Mosquito Station** to lay more eggs elsewhere, they disseminate the growth regulator and kill larvae in breeding sites around the **In2Care**® **Mosquito Station**.

The adulticide contained in the In2Mix® powder slowly kills adult Aedes and Culex spp. Mosquitoes. Contaminated mosquitoes will die within 9 days following exposure to In2Mix® powder. Therefore, dead adult mosquitoes may not be found in the In2Care® Mosquito Station.

In2Care® Mosquito Stations prevent the emergence of *Aedes* adults for up to [4] [6] [8] weeks per sachet and prevent *Culex* adult emergence for up to 4 weeks.

HOW TO ASSEMBLE THE IN2CARE® MOSQUITO STATION



STEP 1:

1. Fill the base of the In2Care® Mosquito Station with 5 quarts (4.7 liters) of clean tap water.



2. **SHAKE THE In2Mix® PACKAGE THOROUGHLY**. Open by tearing at the notches and gently take out the powder-coated gauze strip.

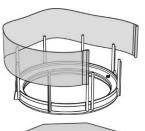


 Empty the remaining contents (powder and odor tablets) of the In2Mix®package into the water in the base of the In2Care® Mosquito Station. Do not allow the gauze to get wet.

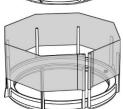


STEP 2:

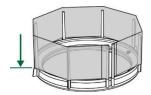
1. To attach the In2Mix® gauze strip to the floater, slide the loop at the end of the gauze over the pin as shown. Handle the gauze carefully to avoid removal of the active powders.



2. Wrap the gauze around the floater and slide the other gauze loop on the last pin as shown. Work your way around moving the gauze down at each pin.

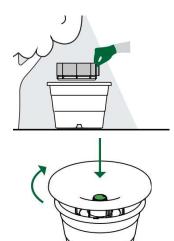


3. Push the gauze down the pins until it will go no further (where the bottom of the pin hits the circular rib). The rib will prevent the gauze from sliding down too far.

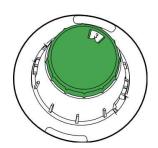


STEP 3:

Place the assembled floater inside the base of the In2Care®
 Mosquito Station by gently placing it over the central tube
 flat onto the water. Do not allow the gauze to get wet as
 water will degrade the powder.



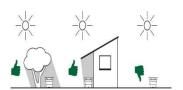
2. Place the lid on the central tube, push it down and turn it clockwise.



3. Turn the time indicator to the number of the current month as a service reminder.

WHERE TO PLACE

 Place the water filled In2Care® Mosquito Station outside on the ground in a level, shaded location near human habitation. Avoid locations with direct sunlight; continuous shade is needed.

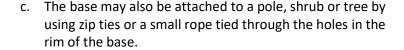


For best results, remove and/or empty artificial water containers (e.g., flowerpots, plastic cups, car tires, etc.) and natural breeding sites (e.g., puddles, tree holes, etc.). Larger water bodies that cannot be removed or emptied should be (frequently) treated with appropriate mosquito larvicides.

 For optimal coverage, place at least 1 In2Care® Mosquito Station every 4,300 sq. feet (400 sq. meters), or at least 10 stations per acre in areas where Aedes and/or Culex spp. Mosquitoes breeding can be expected. Do not exceed 15 stations per acre.



- 3. When necessary, stability can be improved by securing the In2Care® Mosquito Station to the ground with the following:
 - a. Wire bracket, available separately from the distributor, which snaps onto the base. The wire bracket can be screwed onto a surface or fixed with a ground pin.
 - b. Zip tie (not included). Zip Tie spec: width: 4.8mm length: 600mm. The loop can be tied to a pin or hook.





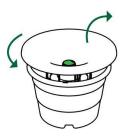
NOTE: Aedes and Culex spp. Mosquitoes can have very specific breeding preferences within certain locations. Check for the presence of live and dead mosquito larvae inside the **In2Care® Mosquito Station** every 4 to 8 weeks. When a station continuously has zero or much fewer larvae when compared to other nearby stations, the unattractive station should be relocated to another nearby shaded location.

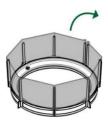
MAINTAINING THE IN2CARE® MOSQUITO STATION

 Re-visit each In2Care® Mosquito Station every 4 to 8 weeks for Aedes mosquitoes. For optimal control of Culex mosquitoes, service the stations every 4 weeks. Remove the lid by turning it counterclockwise until it stops and lift up.

NOTE: In hot and dry climates the water level must be checked more frequently. Add water as necessary to maintain the correct amount (5 quarts; 4.7 liters) in the base of the **In2Care® Mosquito Station**.

Take out the floater and dispose of the used gauze and water as indicated in the STORAGE AND DISPOSAL section of this label.





3. Remove leaves or other debris that may have fallen into the base of the In2Care® Mosquito Station. Refill the station with 5 quarts (4.7 liters) of clean tap water.



4. Take a new In2Mix® package and repeat Steps 1 & 2 in HOW TO ASSEMBLE.



STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep this product in its tightly closed original container when not in use. Store in a cool, dry, well-ventilated area that is inaccessible to children and animals. For optimal long-term storage, do not store above 73° F (23° C). Store this product in a place away from strong bases, strong acids, sources of ignition and direct sunlight.

During transport and field use, keep **In2Mix**® packages below 110° F (43° C) at all times by avoiding sunlight and heat, and using isolation packaging.

PESTICIDE DISPOSAL: Dispose of used gauze in a sanitary landfill, or by other procedures approved by state and local authorities. Dispose of used water in the **In2Care® Mosquito Station** by pouring onto the ground, and not near a water source. Prevent entry of used water into sewers, gutters, or drains, or any area where drainage to storm sewers, water bodies, or aquatic habitat can occur. Notify authorities if liquid enters sewers or public waters.

CONTAINER HANDLING: Non-refillable container. Completely empty **In2Mix®** package into the **In2Care® Mosquito Station** by shaking and tapping sides and bottom to loosen clinging particles. When completely empty, dispose of empty package in trash or by other procedures approved by state and local authorities.

NOTICE: To the extent consistent with applicable law, buyer and user assume all risks and liability of use, storage and/or handling of this product not in accordance with the terms of this label.

Individual package labeling -

PYRIPROXYFEN	GROUP	7C	INSECTICIDE
Beauveria bassiana	GROUP	UN	INSECTICIDE
Strain GHA			

In2Mix®

For Use In The In2Care® Mosquito Station

[ROOM FOR MARKETING STATEMENTS AND ARTWORK]

SHAKE WELL BEFORE USE

Active Ingredients:	% w/w
Pyriproxyfen (CAS No. 95737-68-1)	74.03%
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Other Ingredients:	<u>15.97%</u>
Total	100.00%

^{*} Contains not less than 4.5 X 10⁹ viable spores/gm.

CAUTION

SEE LABEL BOOKLET FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND COMPLETE DIRECTIONS FOR USE

Manufactured by:

In2Care BV
Marijkeweg 22, 6709 PG,
Wageningen,
The Netherlands

Net Weight: 0.5g (0.018 [oz.] [ounce])

EPA Reg. No.: 91720-1 EPA Est. No.: XXXXX-XXX

PRECAUTIONARY STATEMENTS

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	FIRST AID		
If in Eyes	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 eye. Call a poison control		
	center or doctor for treatment advice.		

HOTLINE NUMBER

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Optional Marketing Claims to be used on any of the included sublabels

Note to PM: Any combination of approved claims may be inserted.

INSECTICIDAL/EFFICACY CLAIMS

- 1. Controls Aedes species of mosquitoes that may transmit Zika, Chikungunya, and Dengue Fever
- 2. Controls container-breeding [Aedes] [Culex] [mosquito] larvae that could develop into adults that may transmit Zika virus and West Nile virus [and Dengue Fever].
- 3. Kills [disease carrying] mosquitoes that may transmit [Zika virus] [and] [West Nile Virus] [Dengue Fever]
- 4. Attracts [Aedes] [Culex] mosquitoes during their breeding cycle
- 5. Kills [Aedes] [Culex] adult mosquitoes within 9 days
- 6. [Aedes] [Culex] Larvae in the In2Care® Mosquito Station will not develop into adult mosquitoes
- 7. [Aedes] [Culex] Mosquitoes [auto-disseminate] [spread] larvicide from the station to their breeding sites
- 8. [Kills] [Controls] [Aedes] [Culex] mosquito larvae in surrounding breeding places
- 9. Prevents [Aedes] [Culex] mosquitoes from [emerging] [breeding] [multiplying] [reproducing]
- 10. Prevents emergence of adult *Aedes* mosquitoes for up to 8 weeks before replacement of sachet is needed
- 11. Prevents emergence of adult *Culex* mosquitoes for up to 4 weeks before replacement of sachet is needed
- 12. Kills [Aedes] [Culex] mosquito [larvae] [pupae] [offspring] [immature stages] [aquatic life stages] in the trap container before they become [breeding] [biting] adults
- 13. Sachets can be stored at least one year [at room temperature] [at 77 \pm 3 ° Fahrenheit] [at 25 \pm 2 ° Celsius]

PACKAGE/EASE OF USE/LOCATION CLAIMS

- 1. For outdoor use
- 2. [Ideal] [Great] [Use] for mosquito control in yards
- 3. Ideal for use [in yards] [in gardens] [in parks] [near ponds][on lawns] [on outdoor patios] [on outdoor decks]
- 4. Does not release unpleasant odors
- 5. No noises/ sounds [coming from the station]
- 6. Easy to [set up] [assemble] [use] [install]
- 7. Quick/Easy to [maintain] [service]
- 10. Convenient floater/sachet replacement timer
- 12. No batteries or electricity required
- 13. Two active ingredients in one product
- 14. Dual action
- 15. Can be used [in combination] with other mosquito control tools
- 19. Patented technology

Optional Artwork to be used on any of the included sublabels



Picture of Aedes mosquito



Picture of Culex mosquito



are deployed

Picture of In2Care Mosquito Station in which the In2Mix packets



"Mosquito Control Solutions"