

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 26, 2018

Mrs. Jane M. Miller Agent for In2Care BV c/o Biologic Consulting, Inc. 115 Obtuse Hill Road Brookfield, CT 06804-3223

Subject: Label Amendment – Addition of User Manual to Master Labeling

Product Name: IN2MIX®

EPA Registration Number: 91720-1 Application Date: October 23, 2018

Decision Number: 545428

Dear Mrs. Miller:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, 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 the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. 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.

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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 Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327, or via email at <u>Rodia.Carmen@epa.gov</u>.

Sincerely,

Richard Gebken

Product Manager 10

Invertebrate & Vertebrate Branch 2

Registration Division (7505P)

Office of Pesticide Programs

Enclosure: Stamped "Accepted" Master Label, dated October 26, 2018

Outer Bag Labeling -

ACCEPTED

10/26/2018

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 91720-1

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

IN2MIX®

Refills for Use in the IN2CARE® Trap THIS PRODUCT IS NOT FOR RETAIL SALE.

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

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

READ ALL LABEL DIRECTIONS COMPLETELY BEFORE USE

FIRST	AID
If Inhaled	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by 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 a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
If on Skin	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 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.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or going For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call the National Pesticide Information Center at 1-800-858-7378, from 8:00 a.m. to 12:00 p.m. PST, Monday through Friday. After 12:00 p.m. PST on weekdays, and during the weekend, you may call the poison control center at 1-800-222-1222.

Net Weight: 50 g (1.76 ounces)

100 refills x 0.5g each (0.018 ounces)

PRECAUTIONARY STATEMENTS

HAZARD TO HUMAN AND DOMESTIC ANIMALS

Harmful if inhaled, swallowed, or absorbed through skin. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Remove and wash contaminated clothing before reuse. Obtain medical attention if irritation persists. Avoid contamination of food or feedstuffs.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

All applicators and handlers must wear:

- Long-sleeved shirt and long pants;
- Waterproof gloves; and
- Shoes plus socks

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.

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).

USER SAFETY RECOMMENDATIONS

Users 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.

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 (preferably locked) area that is inaccessible to children and animals. Store this product in a place away from strong bases, strong acids, sources of ignition and direct sunlight. **PESTICIDE DISPOSAL:** For waste materials following 4-week treatment interval (e.g., disposal of used netting with actives/used water with attractants at time of IN2MIX® refill replacement): Dispose of used netting in a sanitary landfill, or by other procedures approved by state and local authorities. Dispose of used water with attractants by pouring out of IN2CARE® trap 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: Shake unopened IN2MIX® packet to assure that actives stick to netting. Open packet and place one IN2MIX® pesticide-treated netting on the floater. Completely empty remaining contents (powder and odor tablets) into IN2CARE® trap by shaking and tapping sides and bottom to loosen clinging particles. When completely empty, dispose of empty packets in trash or in a sanitary landfill, or by other procedures approved by state and local authorities.

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

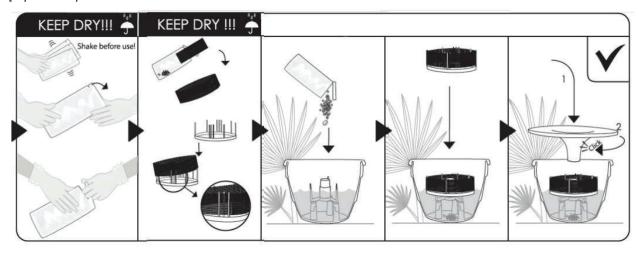
FOR OUTDOOR USE ONLY

ASSEMBLY

Assemble the plastic IN2CARE® trap as directed in the enclosed user manual. Fill the base with 4 to 5 quarts (3.5–4.5 liters) of clean tap water. Place one IN2MIX® pesticide-treated netting on the floater [as indicated below]. Empty the remaining contents (powder and odor tablets) of the packet into the water.

Use one IN2MIX® packet per trap every 4 weeks when adult mosquitoes are active. DO NOT allow people or pets to contact the pesticide.

[Optional picture and text -



Page 3 of 8

MASTER LABEL
Bracketed [] text is optional

[PLACEMENT

Place the activated IN2CARE® trap outside on the ground in a level, shaded location. Avoid locations with continuous direct sunlight. For optimal coverage, place at least 1 trap

every 4,300 sq. feet (400 sq. meters), or at least 10 traps per acre. Do not exceed 15 traps per acre.

[TO REFILL

Re-visit each IN2CARE® trap every 4 weeks. Remove the lid and take out the floater. Dispose of the waste materials (netting and water) as indicated in the Storage and Disposal section of this label. Refill with 4 to 5 quarts (3.5 - 4.5 liters) of clean tap water. Take a new IN2MIX® refill packet and

repeat the assembly steps as described [in the User Manual] [above].]

[HOW IT WORKS

 ${\sf IN2MIX}^{\circledast} \text{ slowly kills adult } \textit{Aedes } \text{spp. mosquitoes. Therefore, dead adult mosquitoes may not be found}$

in the trap.

The Aedes spp. larvae that emerge from eggs laid inside the trap are killed by the growth regulator prior to transforming into adults. This means that it is normal to see small living larvae in the trap that will

eventually die.

After laying eggs, the adult female should be contaminated with a growth regulator and slow acting adulticide so she can carry the growth regulator to other nearby breeding sites and should die within a

few days following exposure to the adulticide.

For best results, remove/empty artificial water containers (e.g., flower pots, plastic cups, car tires, etc.) that serve as other breeding sites, and use a registered mosquito larvicide to treat breeding sites that cannot

be removed or emptied.

Aedes spp. mosquitoes can have very specific breeding preferences within certain locations. Check for the presence of live and dead mosquito larvae inside the traps every 4 weeks. When a trap continuously has zero or much fewer larvae when compared to other nearby traps, the unattractive trap should be

relocated to another nearby shaded location.

NOTICE: Buyer and user assume all risks and liability of use, storage and/or handling of this product not in

EPA Reg. No.: 91720-1

EPA Est. No.: XXXXX-XX-XXX

accordance with the terms of this label.

BUYER GUARANTEE LIMITED TO LABEL CLAIMS

Manufactured by: In2Care BV

Marijkeweg 22, 6709 PG,

Wageningen,

The Netherlands

Individual refill packets labeling -

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

IN2MIX®

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

READ ENCLOSED MANUAL FOR COMPLETE DIRECTIONS FOR USE

FIRST AID

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by 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 a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If on Skin: 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 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.

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

Net Weight: 0.5g (0.018 ounces)

Manufactured by: In2Care BV Marijkeweg 22, 6709 PG, Wageningen, The Netherlands

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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.

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.

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).

USER SAFETY RECOMMENDATIONS

Users should:

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- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
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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.

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 (preferably locked) area that is inaccessible to children and animals. Store this product in a place away from strong bases, strong acids, sources of ignition and direct sunlight.

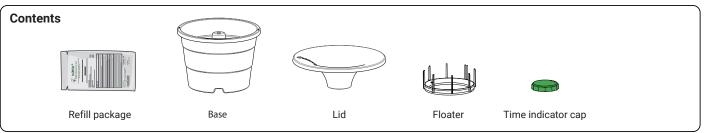
PESTICIDE DISPOSAL: For waste materials following 4-week treatment interval (e.g., disposal of used netting with actives/used water with attractants at time of IN2MIX® refill replacement): Dispose of used netting in a sanitary landfill, or by other procedures approved by state and local authorities. Dispose of used water with attractants by pouring out of IN2CARE® trap 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.

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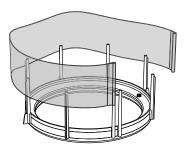
Installation



Assembly



Fill the base with 4 to 5 quarts (3.5 - 4.5 liters) of clean tap water. For placement details see other side of this sheet.



Slide the loop at the ending of the gauze over the pin as shown.

Try not to touch the gauze extensively to avoid removal of the active powders.

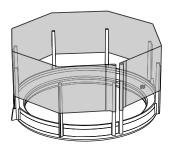


Put the gauze-carrying floater inside the trap by gently placing it over the central tube flat onto the water.

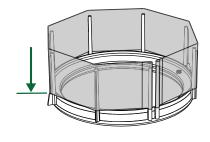
Prevent the gauze from getting wet as water will degrade the powder.



Shake the refill package thoroughly and open it by tearing at the notches. Gently take out the powder-coated piece of gauze.



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.

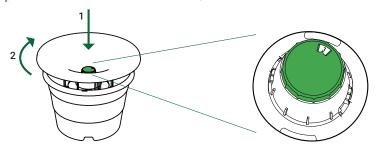


Empty the remaining contents (powder and odor tablets) of the refill package

into the water of the trap. Avoiding the

gauze from getting wet.

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 too far.



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

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



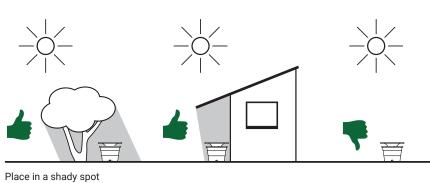
Note: The In2Care Mosquito Trap slowly kills adult *Aedas* spp. mosquitoes. The contents of the trap therefore may not contain high numbers of dead mosquitoes. However, the trap kills the mosquito larvae that emerge from the eggs that are laid inside the trap, prior to larvae transforming into adult mosquitoes. This means that small living larvae may be encountered in the trap that will eventually die.. The exiting adult female *Aedes* spp. mosquito itself is contaminated with a growth regulator and slow acting adulticide, so that she can carry the growth regulator to other nearby breeding sites (in the vicinity of the trap). She will be killed by the growth regulator within a few days.





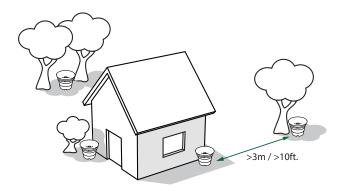
Maintenance

Placement





Recommendations



For an optimal efficacy of the activated In2Care Mosquito Trap, ensure high trap coverage (1 trap per 400m²/10-15 per acre) in the selected treatment area and remove other mosquito breeding sites as much as possible. Do not exceed 15 traps per acre.

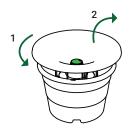
Place on a level surface

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

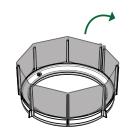
We recommend outdoor trap placement on the ground in a level, shaded location, close to human habitation/houses. In dry areas, check the water level inside the trap regularly and add more water when needed.

Re-visit each trap every 4 weeks.

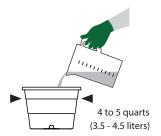
Evenly distribute traps over available space



Remove the lid by turning it counter clockwise until the stop and lift it.



Take out the floater and dispose of the used netting and used water as indicated in the Storage and Disposal section of the label on the refill package.



Remove leaves or other debris that may have fallen into the water and refill the trap with 4 to 5 quarts (3.5-4.5 liters) of clean tap water.

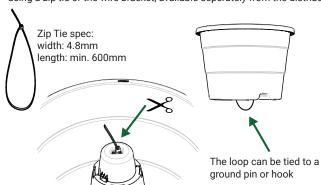
Maintenance

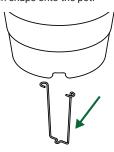


Take a new refill package and repeat the assembly steps as described on the other side of this manual.

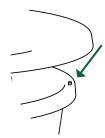
Fixating

When traps are disturbed by animals, stability can be improved by fixating the trap to the ground using a zip tie or the wire bracket, available seperately from the distributor, which snaps onto the pot.





The wire bracket can be screwed onto a surface or fixed with a ground pin.



Another fixation option is to use the holes in the rim of the pot and tie the pot to a pole or tree using a zip tie or a small rope.