



U.S. ENVIRONMENTAL PROTECTION AGENCY  
 Office of Pesticide Programs  
 Biopesticides and Pollution Prevention Division (7511P)  
 1200 Pennsylvania Ave., N.W.  
 Washington, D.C. 20460

**EPA Reg. Number:**

89668-4

**Date of Issuance:**

11/3/2017

**NOTICE OF PESTICIDE:**

Registration  
 Reregistration  
 (under FIFRA, as amended)

**Term of Issuance:**

Unconditional

**Name of Pesticide Product:**

ZAP Males®

**Name and Address of Registrant (include ZIP Code):**

MosquitoMate, Inc.  
 2520 Regency Rd. Suite B  
 Lexington, KY 40503

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention 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 or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her 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 the 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), subject to the following terms:

1. The subject registration will automatically expire at midnight on December 31, 2022.
2. This product may only be used in the following States and the District of Columbia: California, Connecticut, Delaware, Illinois, Indiana, Kentucky, Massachusetts, Maine, Maryland, Missouri, New Hampshire, New Jersey, Nevada, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Vermont, and West Virginia.

**Signature of Approving Official:**

Michael Mendelsohn, Chief  
 Emerging Technologies Branch  
 Biopesticides and Pollution Prevention Division (7511P)  
 Office of Pesticide Programs

**Date:**

11/3/2017

3. You must submit a one-year storage stability study (OPPTS Guideline 830.6317), starting at the time of first product shipment to one of the destinations located in each of the following three geographic regions (Region 1: California and Nevada; Region 2: Illinois, Indiana, Kentucky, Missouri, Ohio, Tennessee, and West Virginia; Region 3: Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont). Data points shall be taken four times per year in scientifically justifiable intervals and cover the seasonal temperature extremes. You must provide these data to EPA within 3 months after completion of the study. The following criteria must be met:
  - a. Shipment must occur through product distribution channels that will be used after registration.
  - b. Viability of ZAP Males<sup>®</sup>, reported as mosquito survivability, must be recorded at the 1) time of delivery and 2) the day of product expiration. Temperature in the container at both time points as well as the distance shipped must be recorded.
4. Within 60 days of issuance of this registration, you must submit to EPA information which details the quality control procedures you will use in your manufacturing process in order to: 1) ensure the released mosquito gender ratio of no more than 1:250,000 (female ZAP-infected mosquitoes to male ZAP-infected mosquitoes), and 2) test for the fitness and viability of the ZAP Males<sup>®</sup> that are maintained in the laboratory colony. As part of the quality control procedures you must:
  - a. Submit to EPA bi-annual reports on the results of these quality control procedures. The first report is due May 31, 2018.
  - b. Report to EPA any incidences where batches of ZAP Males<sup>®</sup> exceed the 1:250,000 mosquito gender ratio and any reduction in ZAP Males<sup>®</sup> fitness and viability, within 30 days of when they are first detected.
  - c. Halt the distribution of any batches of ZAP Males<sup>®</sup> that do not pass the standards of the approved manufacturing process or the quality control procedures.
5. Within 60 days of issuance of this registration, you must submit to EPA a protocol for the monitoring of ZAP-infected female mosquitoes in the environment. As part of this protocol you must:
  - a. Monitor for ZAP-infected females in the environment on a monthly basis within each of the geographic regions indicated in term 3, above.
  - b. Report the results of such monitoring to EPA bi-annually. The first report is due May 31, 2018.
  - c. Report to EPA any occurrence of ZAP-infected females in the environment within 30 days of when they are first detected.
  - d. Include in your monitoring plan a provision for remediation, including halting additional ZAP Males<sup>®</sup> releases, if mosquito populations within the treated area(s) are not reduced (or increase) from pre-treatment levels.
6. You must submit and/or cite all data required for registration or registration review of your product when the EPA requires all registrants of similar products to submit such data.

7. You must make the following labeling change before you release this product for shipment:
  - Revise the EPA Registration Number to read, “EPA Reg. No. 89668-4.”
8. You must submit one (1) copy of the final printed labeling for the record before you release this product for shipment.

Should you wish to add/retain a reference to your company’s website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the 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 EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a Section 3 registration, the website will be referred to the EPA’s Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6. A stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF):

- Basic CSF dated 04/25/2017

Any CSFs other than that listed above are superseded.

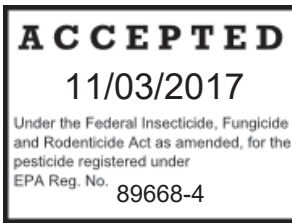
If you have any questions, please contact Wiebke Striegel by phone at (703) 347-0556 or via email at [striegel.wiebke@epa.gov](mailto:striegel.wiebke@epa.gov).

Sincerely,



Michael Mendelsohn, Chief  
Emerging Technologies Branch  
Biopesticides and Pollution  
Prevention Division (7511P)  
Office of Pesticide Programs

Enclosure



Single Property Release (Sub-label A)

# Wolbachia pipientis, ZAP Strain

# ZAP Males®

The *Wolbachia* bacterium prevents the development of Asian Tiger (*Aedes albopictus*) mosquito eggs

**ACTIVE INGREDIENT:**

*Wolbachia pipientis*, ZAP Strain\*..... 0.001 %

**OTHER INGREDIENTS:**..... 99.999 %

**TOTAL:**..... **100.0 %**

\*The Active Ingredient is *Wolbachia pipientis*, ZAP Strain, contained in live adult *Aedes albopictus* mosquitoes.

**KEEP OUT OF REACH OF CHILDREN**

***Contains live male mosquitoes***

**NET UNIT CONTENTS:** A minimum of 0.002 milligrams (mg) *Wolbachia pipientis*, ZAP strain, contained in a minimum of 1,000 adult *Aedes albopictus* mosquitoes. Contains X units. Net weight X ounces (X - X oz. packets).

**EXPIRATION DATE:**

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For use only by MosquitoMate, Inc.; persons under direct contract with MosquitoMate, Inc., for the purpose of application of this pesticide; or by federal, state, tribal, or local government officials responsible for public health or vector control; or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform mosquito control applications.

**INSECTS SUPPRESSED**

ZAP Males® selectively suppress populations of *Aedes albopictus* (Asian tiger mosquito). If used in accordance with this label, ZAP Males® have shown to suppress female tiger mosquito populations between 60% and 65%.

**RESTRICTIONS**

- For use only in the following states: CA, CT, DC, DE, IL, IN, KY, MA, ME, MD, MO, NH, NJ, NV, NY, OH, PA, RI, TN, VT, and WV.
- For outdoor use only.
- Use by expiration date.
- Do not apply in winds exceeding 15 mph.
- Do not use aerial mosquito adulticide sprays for mosquito control at the same time as ZAP Males®.

## WHEN TO USE

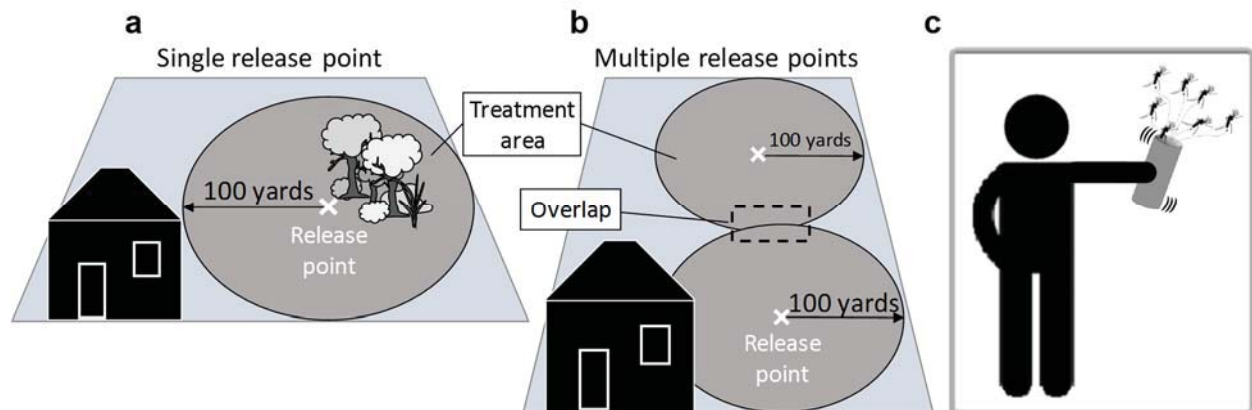
Start releases of *ZAP Males*<sup>®</sup> at the beginning of the tiger mosquito season, which helps ensure highest possible efficacy (greatest population suppression). If the initial release of *ZAP Males*<sup>®</sup> is delayed, efficacy may be reduced. In this case it is highly advisable to first reduce the existing tiger mosquito population prior to releasing *ZAP Males*<sup>®</sup> by using other pesticides registered for mosquito control. Contact MosquitoMate, Inc. at +1-859-488-1125 to determine the start and end of the tiger mosquito season in your area. Additional information on tiger mosquito biology can be found in the *ZAP Males*<sup>®</sup> product manual or by visiting [www.mosquitomate.com](http://www.mosquitomate.com).

## APPLICATION RATE

- Estimate peak male tiger mosquito population density based on typical monthly population density for male tiger mosquitoes encountered in the treatment area.
- Release *ZAP Males*<sup>®</sup> at a minimum rate of 10 *ZAP Males*<sup>®</sup> per 1 wild-type adult male tiger mosquito per week, based on estimated peak male tiger mosquito population density, by releasing *ZAP Males*<sup>®</sup> twice a week at a rate of 5:1.
- Adhere to this regimen until the end of the mosquito season to ensure highest possible efficacy.

## METHOD OF APPLICATION

- Keep container closed until ready to release the *ZAP Males*<sup>®</sup>.
- A single release point treats an area with a radius of about 100 yards centered around the release point (**Figure a**).
- To cover larger areas, multiple release points are required and user must ensure that treatment areas overlap (**Figure b**).
- Determine and adhere to the release point(s) for the entire tiger mosquito season.
- *ZAP Males*<sup>®</sup> should be released in shaded areas, e.g., in close proximity to trees or shrubs.
- When ready to release (**Figure c**):
  1. Carry the container to the pre-determined release site.
  2. Point opening of container away from face and open lid.
  3. Gently shake container to facilitate release of the *ZAP Males*<sup>®</sup>.



## USE IN INTEGRATED VECTOR MANAGEMENT PROGRAMS

*ZAP Males*<sup>®</sup> can be used as part of an integrated vector management program. This includes the use of source reduction, larvicides, and adulticides. Any integration of mosquito adulticiding must be timed to minimize potential negative effects on the *ZAP Males*<sup>®</sup> that are released into the treatment area. Consult the pesticide label of the adulticide to determine the most appropriate timing of release of *ZAP Males*<sup>®</sup> between pesticide treatments.

## STORAGE AND DISPOSAL

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

### STORAGE

Keep container closed until ready to use. Keep in original container. Store *ZAP Males*<sup>®</sup> out of direct sunlight and at moderate temperatures 59 °F - 77 °F (15 °C - 25 °C).

### PESTICIDE DISPOSAL

Release all living *ZAP Males*<sup>®</sup> present in container. Discard dead individuals in trash. If *ZAP Males*<sup>®</sup> are not released by the expiration date, kill males by freezing or allow them to die by keeping inside closed container for a minimum of 7 days, then discard dead mosquitoes in trash.

### CONTAINER HANDLING

**Nonrefillable container.** Do not reuse or refill this container. Offer for recycling if available or dispose of in trash, or in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

**Refillable container.** Refill this container with *ZAP Males* (*Wolbachia pipientis*, *ZAP* strain in *Aedes albopictus*) only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Offer for recycling if available or dispose of in trash, or in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. Cleaning before refilling is the responsibility of the refiller. For cleaning, remove the cap from both ends of the tube, and then use a dry brush to remove any mosquitoes stuck to the inside of the container. Call +1-859-488-1125 for instructions on returning the empty container.

## WARRANTY STATEMENT CONDITIONS

The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of MosquitoMate, Inc. All such risks shall be assumed by the user or buyer.

## DISCLAIMER OF WARRANTIES

To the extent consistent with applicable law, MosquitoMate, Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of MosquitoMate, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, MosquitoMate, Inc. disclaims any liability whatsoever for special, incidental, or consequential damages resulting from the use or handling of this product.

## LIMITATIONS OF LIABILITY

To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries, or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at MosquitoMate, Inc.'s election, the replacement of product.

Manufactured by:



MosquitoMate, Inc.  
2520 Regency Road, Suite B  
Lexington, KY 40503

<http://www.mosquitomate.com>  
Phone: (859) 488-1125

EPA Registration No. 89668-  
EPA Est. No.: 89668-KY-001  
Batch Code: XXXX

Sub-label B: Wide-area treatment sub-label

## *Wolbachia pipientis*, ZAP Strain

# ZAP Males®

The *Wolbachia* bacterium prevents the development of Asian Tiger (*Aedes albopictus*) mosquito eggs

**ACTIVE INGREDIENT:**

*Wolbachia pipientis*, ZAP Strain\*.....0.001 %

**OTHER INGREDIENTS:**.....99.999 %

**TOTAL:**.....**100.0 %**

\*The Active Ingredient is *Wolbachia pipientis*, ZAP Strain, contained in live adult *Aedes albopictus* mosquitoes.

**KEEP OUT OF REACH OF CHILDREN**

***Contains live male mosquitoes***

**NET UNIT CONTENTS:** A minimum of 0.002 milligrams (mg) *Wolbachia pipientis*, ZAP strain, contained in a minimum of 1,000 adult *Aedes albopictus* mosquitoes. Contains X units. Net weight X ounces (X - X oz. packets).

**EXPIRATION DATE:**

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### INSECTS SUPPRESSED

ZAP Males® selectively suppress populations of *Aedes albopictus* (Asian tiger mosquito). If used in accordance with this label, ZAP Males have shown to suppress female tiger mosquito populations between >40% and <90%.

### RESTRICTIONS

- For use only in the following states: CA, CT, DC, DE, IL, IN, KY, MA, ME, MD, MO, NH, NJ, NV, NY, OH, PA, RI, TN, VT, and WV.
- For outdoor use only.
- Use by expiration date.
- Do not apply in winds exceeding 15 mph.
- Do not use aerial mosquito adulticide sprays for mosquito control at the same time as ZAP Males®.



## WHEN TO USE

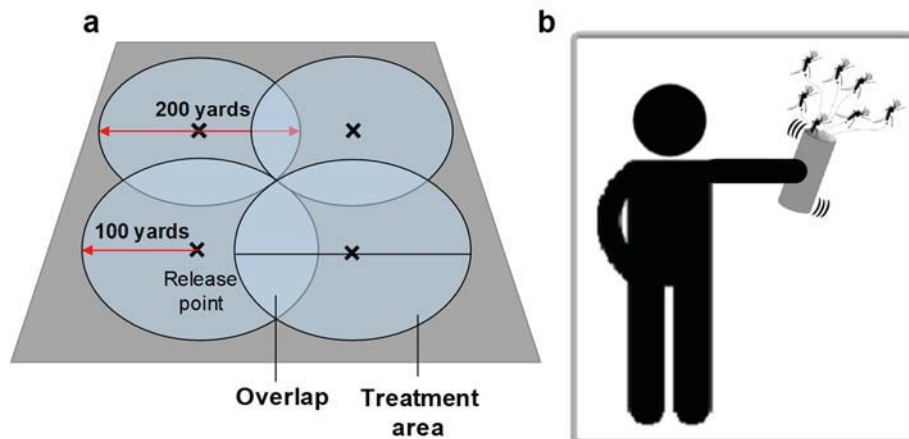
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- When ready to release (**Figure c**):
  1. Carry the container to the pre-determined release site.
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## DISCLAIMER OF WARRANTIES

To the extent consistent with applicable law, MosquitoMate, Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of MosquitoMate, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, MosquitoMate, Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

## LIMITATIONS OF LIABILITY

To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at MosquitoMate, Inc.'s election, the replacement of product.

Manufactured by:



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2520 Regency Road, Suite B  
Lexington, KY 40503  
<http://www.mosquitomate.com>

**Phone: (859) 488-1125**

**EPA Registration No. 89668-  
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