



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

EPA Reg. Number:

89668-8

Date of Issuance:

4/16/2024

**NOTICE OF PESTICIDE:**

Registration  
 Reregistration  
 (under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

WB1 Males

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

MosquitoMate, Inc.  
 210 Malabu Drive, Suite 110  
 Lexington, KY 40502

**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.

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency. 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) provided that you:

1. The subject registration will automatically expire at midnight on December 31, 2028.
2. 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.

Signature of Approving Official:

**MICHAEL  
 MENDELSON**

Digitally signed by MICHAEL  
 MENDELSON  
 Date: 2024.04.16 11:18:53 -04'00'

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

Date:

4/16/2024

3. This product may be used in all U.S. States and Territories, and the District of Columbia.
4. The quality control procedures that are part of the manufacturing process must: 1) ensure the released mosquito gender ratio of no more than 1:250,000 (female *wAlbB*-infected mosquitoes to male *wAlbB*-infected mosquitoes), and 2) test for the fitness and viability of the WB1 Males that are maintained in the laboratory colony. As part of the quality control procedures, MosquitoMate must:
  - a. Submit to EPA bi-annual reports on the results of these quality control procedures, due by May 31<sup>st</sup> and November 30<sup>th</sup> each year.
  - b. Report to EPA any incidences where batches of WB1 Males exceed the 1:250,000 mosquito gender ratio and any reduction in WB1 Males fitness and viability, within 30 days of when first detected.
  - c. Halt the distribution of any batches of WB1 Males that do not pass the standards of the approved manufacturing process or the quality control procedures.
5. As part of the procedures to monitor for establishment of the *wAlbB* strain in *Ae. aegypti* in the environment, MosquitoMate must adhere to the following monitoring protocol:
  - a. Monitor for *wAlbB*-infected offspring in the environment on a quarterly basis starting six weeks from initial releases in each of the new climate zones added to this registration as defined by the IECC Climate Zone Map (2012). Monitoring is required only in those zones where WB1 Males are actively being released. (Note some states overlap multiple climate zones).

Zone 1: Hawaii, Guam, Puerto Rico, the U.S. Virgin Islands, Florida, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Republic of the Marshall Islands, and Republic of Palau.

Zone 2: Florida, Louisiana, Texas, and Arizona.

Zone 3: California, Arizona, New Mexico, Texas, Oklahoma, Arkansas, Louisiana, Mississippi, Alabama, Georgia, South Carolina, and North Carolina.

Zone 4: North Carolina, Virginia, District of Columbia, Delaware, West Virginia, Tennessee, Kentucky, Ohio, Indiana, Illinois, Missouri, Kansas, Texas, New Mexico, Colorado, Arizona, Maryland, California, Oregon, and Washington.

Zone 5: Washington, Oregon, Nevada, Montana, Idaho, Colorado, Nebraska, South Dakota, Iowa, Indiana, Illinois, West Virginia, Pennsylvania, New York, New Jersey, Rhode Island, Massachusetts, Connecticut, and New Hampshire.

Zone 6: Maine, New Hampshire, Vermont, New York, Pennsylvania, Michigan, Wisconsin, Minnesota, North Dakota, Montana, Wyoming, Idaho, Washington.

Zone 7: Maine, Michigan, Minnesota, North Dakota, Wyoming, Colorado, Alaska.

Zone 8: Alaska.

- b. Collect a representative sample of 93 *Ae. aegypti* mosquitoes collected in the field as eggs or larvae using ovitraps, larval collection using dippers or suction devices, or adults using BG/CDC traps (or collect all *Ae. aegypti* samples if fewer than 93 are collected across sites). Sampling must occur using a minimum of ten traps within a 10 km radius of the release area.
  - c. Perform PCR or LAMP assays for the *Wolbachia* wAlbB strain in the sampled *Ae. aegypti* mosquitoes as described in the *Wolbachia* infection Quality Control document. If wAlbB-infected *Ae. aegypti* offspring are detected, sampling will be increased to monthly in the detection area.
  - d. If 10% of *Ae. aegypti* eggs or larvae sampled from a site per visit are confirmed positive for the WB1 strain in two consecutive monthly tests, then cessation of releases within 3 km of the positive site must occur. Releases may resume if an additional mosquitoicide is used or once <10% of *Ae. aegypti* eggs or larvae are positive for the WB1 strain during subsequent monthly monitoring. Once no WB1-infected *Ae. aegypti* eggs or larvae are detected at the positive site during monthly monitoring, quarterly monitoring may resume.
  - e. Report the results of such monitoring to EPA bi-annually, due by May 31<sup>st</sup> and November 30<sup>th</sup> each year.
  - f. Report to EPA any occurrence of wAlbB-infected offspring in the environment within 30 days of when they are first detected.
6. Make the following labeling change before you release this product for shipment:
- Revise the EPA Registration Number to read, "EPA Reg. No. 89668-8."
7. 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 FIFRA 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 03/17/2022

If you have any questions, please contact Kara Welch by phone at (202) 566-1510 or via email at [welch.kara@epa.gov](mailto:welch.kara@epa.gov).

Sincerely,

**MICHAEL  
MENDELSON** Digitally signed by  
MICHAEL MENDELSON  
Date: 2024.04.16  
11:19:58 -04'00'

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

Enclosure: Stamped Label

{Note to reviewer: [Bracketed text] is optional or alternate wording and (parenthetical text) is informational.}

# *Wolbachia pipientis, wAlbB Strain*

# **WB1 Males**

**The *Wolbachia* bacterium prevents the development of Yellow Fever (*Aedes aegypti*) mosquito eggs**

**ACTIVE INGREDIENT:** The Active Ingredient is *Wolbachia pipientis, wAlbB Strain*\*, contained in live adult *Aedes aegypti* mosquitoes ..... < 0.001% \*\*

\* Cytoplasmic Incompatibility (CI) confirmation: egg hatch from incompatible matings < 0.2%

\*\* Percent (w/w) of adult male mosquitoes

**KEEP OUT OF REACH OF CHILDREN**

***Contains live male mosquitoes***

(Note to reviewer: One of the following options for net contents will be displayed on the commercial label.)

**[600C] NET UNIT CONTENTS:** *Wolbachia pipientis, wAlbB strain*, contained in 600 ± 60 adult male *Aedes aegypti* mosquitoes.

Contains X units. Net weight X ounces (X - X oz. packets).

**[1200C] NET UNIT CONTENTS:** *Wolbachia pipientis, wAlbB strain*, contained in 1,200 ± 120 adult male *Aedes aegypti* mosquitoes.

Contains X units. Net weight X ounces (X - X oz. packets).

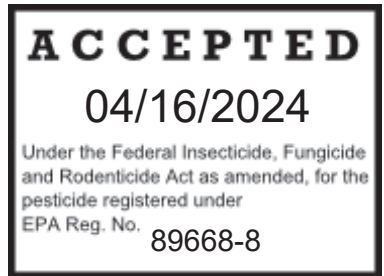
**[1200T] NET UNIT CONTENTS:** *Wolbachia pipientis, wAlbB strain*, contained in 1,200 ± 900 adult male *Aedes aegypti* mosquitoes.

Contains X units. Net weight X ounces (X - X oz. packets).

**[8400C] NET UNIT CONTENTS:** *Wolbachia pipientis, wAlbB strain*, contained in 8,400 (5,000 – 14,000) adult male *Aedes aegypti* mosquitoes.

Contains X units. Net weight X ounces (X - X oz. packets).

**Use as soon as possible and within 72 hours of receipt.**



## **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

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by the state or tribal lead pesticide regulatory agency to perform mosquito control applications.

## **INSECTS SUPPRESSED**

*WB1 Males* reduce populations of *Aedes aegypti* (Yellow Fever mosquito). If used in accordance with this label, *WB1 Males* have shown to reduce female yellow fever mosquito populations. Reduced suppression levels will be observed in release areas that are within 100 meters of a non-release area, e.g., along the outside edge of the release area, due to the immigration of females from outside the release area.

## **RESTRICTIONS**

- For use only in locations with *Ae. aegypti* (Yellow Fever mosquito)
- For outdoor use only.
- To be applied at contiguous areas that are 20 acres or larger in size.
- Use as soon as possible and within 72 hours of receipt.
- Do not apply in wind speeds exceeding 15 mph.
- Do not use at a time when aerial mosquito adulticides are actively being applied in the WB1 Male treatment area.

## **WHEN TO USE**

Start releases of *WB1 Males* at the beginning of the yellow fever mosquito season, which helps ensure highest possible efficacy (greatest population suppression). If the initial release of *WB1 Males* is delayed, efficacy may be reduced. In case of delay, it is highly advisable to first reduce the existing yellow fever mosquito population prior to releasing *WB1 Males* by using other pesticides registered for mosquito control.

Contact MosquitoMate, Inc. at +1-859-429-0501 to determine the start and end of the yellow fever mosquito season in your area.

## **APPLICATION RATE**

Application rates are based on area. Apply a minimum of 1,200 males per acre per week across a contiguous area that is 20 acres or larger. For multiple units, divide the number of WB1 males by 1,200 to determine the number of acres to be treated. If multiple units are used, distribute mosquito releases evenly over the area to be treated. Adhere to this regimen until the end of the mosquito season to ensure highest possible efficacy.

(Note to reviewer: One of the following sets of application rate instructions will appear on the commercial label depending on container net contents size.)

- *(For the 600C unit):* Two [600C units] (1,200 WB1 Males) are adequate WB1 males for one acre of the total treatment area, which is 1/20<sup>th</sup> of the minimum 20 contiguous acre treatment area.
- *(For the 1200C unit):* Each [1200C unit] (1,200 WB1 Males) is adequate WB1 males for one acre of the total treatment area, which is 1/20<sup>th</sup> of the minimum 20 contiguous acre treatment area.
- *(For the 1200T unit):* This container may be used in refilling the 8400C unit, refer to the loading device instructions on proper use and transfer of this container. If the WB1 male number is not displayed on the container, then the user may optionally confirm the number of WB1 males in the 1200T unit by following the instructions provided with the loading device and adjust the treated area appropriately to apply a minimum of 1,200 males per acre per week. Apply only at contiguous areas that are 20 acres or larger in size.
- *(For the 8400C unit):* The user may optionally confirm the number of WB1 males in the 8400C unit by following the instructions provided with the loading device, and adjust the treated area appropriately to apply a minimum of 1,200 males per acre per week. The user may refill the 8400C unit with WB1 Males using multiple 1200T units. Refer to the loading device instruction manual for refilling and loading instructions. Apply only at contiguous areas that are 20 acres or larger in size.

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- (Only for the 8400C unit) **Instructions for refilling the 8400C unit:** Following instructions provided with the 8400C container loading device (“loading device”), load a clean, empty 8400C container into the loading device, ensuring that the 8400C container is fully sealed in the loading device. Load the 1200T containers into the loading device, ensuring that the 1200T containers are fully sealed in the loading device. Activate the loading device following the instructions that are provided with the loading device. Run loading device until the mosquitoes are transferred. Unload the (filled) 8400C container from the loading device. User may optionally confirm the number of WB1 males in the 8400C and 1200T containers by following instructions provided with the loading device. Return empty 1200T container(s) to the manufacturer. Call +1-859-429-0501 for instructions on returning the empty 1200T containers. Apply only at contiguous areas that are 20 acres or larger in size.

Overflooding ratio in treatment areas should be used to adjust release rates as required to maintain desired overflooding ratio of WB1:Wild type male *Ae. aegypti* of >10:1 and to compensate for estimated higher levels of *Ae. aegypti* in treatment areas as appropriate. Overflooding ratio is determined by comparing the pre- and post-release average male trap counts in treatment areas or by using molecular methods on males sampled from treatment areas (to differentiate WB1 males from Wild Type see Crawford et al 2020<sup>1</sup> for similar methods). Contact MosquitoMate for more information on how to determine overflooding ratio.

## METHOD OF APPLICATION

- If receipt of the shipment is delayed by more than 48 hours or if the males appear damaged, then release any viable mosquitoes and discard dead mosquitoes in the trash. Contact MosquitoMate for a new shipment to replace the delayed or damaged material.
- Keep container closed until ready to release the *WB1 Males*.
- The male mosquitoes should appear vigorous within the container. If males do not appear vigorous or appear damaged, then release any viable mosquitoes and discard dead mosquitoes in trash. Contact MosquitoMate for a new shipment to replace the delayed or damaged material.
- Multiple release points are required to cover the treatment area that is 20 acres or larger in size, and the user must ensure that treatment areas overlap.
- Determine the release point(s) and release routes to ensure even coverage and adhere to this regimen until the end of the yellow fever mosquito season to ensure the highest possible efficacy
- For point releases, when ready to release:
  1. Carry the container to the predetermined release site.
  2. Point opening of container away from face and open lid.
  3. Gently shake or rotate the container to facilitate release of the WB1 Males.
- Vehicle releases are to be performed only at contiguous areas that are 20 acres or larger in size.
  - Vehicle release WB1 Males from roads immediately adjacent to (within 40 yards of) the desired treatment locations.
  - Vehicle release strips proceed from an initial release point along the release route and cover up to 120 yards from the initial release point, i.e. two acres (120 x 80 yds<sup>2</sup>) centered on the driving route. Each 8400C unit can be used to treat multiple release strips, and multiple units may be required to treat an area, depending on the size of the treatment area and desired weekly treatment rate.
  - To compute the number of mosquitoes that will be applied at each release strip, divide the number of mosquitoes in the 8400C container by the number of segments in the container (56, unless otherwise indicated on the container). For example, 8,400 mosquitoes divided by 56 segments = 150 mosquitoes per segment. Use this mosquito number to determine how many segments to apply over the desired treatment area. For example, for a one-acre release strip, eight segments at 150 mosquitoes per segment are required to achieve 1,200 males per acre.
  - Vehicle releases may be initiated manually by the user or automatically by the release

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<sup>1</sup> Crawford, J.E., Clarke, D.W., Criswell, V. et al. (2020). Efficient production of male Wolbachia-infected *Aedes aegypti* mosquitoes enables large-scale suppression of wild populations. *Nat Biotechnol* 38, 482– 492. doi: <https://doi.org/10.1038/s41587-020-0471-x>

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- equipment, as the vehicle reaches release points along the release routes.
- Conduct releases when Vehicle is moving at <25 mph.
  - Ensure that all planned release locations have been covered by the vehicle releases, adding manual releases from the vehicle or on foot as necessary to complete the planned treatment.
  - Contact MosquitoMate for more information on vehicle releases and vehicle release planning, and to enable automated releases.

## USE IN INTEGRATED VECTOR MANAGEMENT PROGRAMS

*WB1 Males* are meant to 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 *WB1 Males* that are released into the treatment area. Consult the pesticide label of the adulticide to determine the most appropriate timing of release of *WB1 Males* 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 *WB1 Males* out of direct sunlight and at moderate temperatures 45°F - 95°F (7°C - 35°C).

### PESTICIDE DISPOSAL

Release all living *WB1 Males* present in container as soon as possible and within 72 hours of receipt. Discard dead individuals in trash. If *WB1 Males* are not released within 72 hours of receipt, if the males exceed the minimum or maximum allowed temperatures [45°F - 95°F (7°C - 35°C)], or if the males are damaged, 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

**Refillable container:** Do not reuse this container for any other purpose. Return to point of sale by calling +1-859-429-0501 for instructions on returning the empty container or offer for recycling if available or dispose of in trash, or in a sanitary landfill, or by incineration. If not returning to the manufacturer, cleaning the container before final disposal is the responsibility of the person disposing of the container. To clean, 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. Do not burn, unless allowed by state and local ordinances.

## 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.



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**Manufactured by:**  
**MosquitoMate, Inc.**  
**210 Malabu Drive, Suite 110**  
**Lexington, KY 40502**  
**Phone: (859) 429-0501**

**EPA Registration No. 89668-X**  
**EPA Est. No.: XXXXX**  
**Batch Code: XXX**

**Optional Images and Graphics**

