

ACCEPTED

For shipment and use of product for experimental purposes under the provision of the Federal Insecticide, Fungicide, and Rodenticide Act, subject to attached comments.

Permit No. 93167-EUP-2

Issued On 03/07/2022

FOR EXPERIMENTAL USE ONLY

Experimental Use Permit Number:

Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Program

THIS LABEL MUST BE IN THE POSSESSION OF THE USER AT THE TIME OF APPLICATION FOR USE ONLY AT AN APPLICATION SITE OF A COOPERATOR AND IN ACCORDANCE WITH THE TERMS AND CONDITIONS OF THE EXPERIMENTAL PROGRAM.

For use in the following states only: Florida, California

OX5034 *Aedes aegypti*

Species-specific larvicide effective in killing female *Aedes aegypti* mosquito larvae

Active Ingredient: Tetracycline Trans-Activator Variant (tTAV-OX5034) protein and the genetic material (from vector pOX5034) necessary to produce the protein *in vivo* <0.00021%*

Other Ingredients: DsRed2-OX5034 fluorescent protein and the genetic material (from vector pOX5034) necessary to produce the protein *in vivo* <0.00245%*

* Percent (w/w) of adult male mosquito.

KEEP OUT OF REACH OF CHILDREN

Net Contents: 20,000 eggs to produce 2,500 adult male OX5034 mosquitoes per egg Mosquito Rearing Box.¹

OR

1,000 adult male OX5034 mosquitoes per adult release pot.

EPA Registration No. 93167-EUP-2 EPA Establishment No.

Batch No.:

Oxitec Ltd.

71 Innovation Drive, Milton Park, Abingdon, Oxfordshire, OX14 4RQ, United Kingdom

¹ Mosquito Rearing Boxes designed to produce other numbers of male mosquitoes, e.g. 500 males per box, 1,000 males per box, etc. may also be used. In all cases, the maximum number of males/acre/week indicated in the trial designs would not be exceeded.

Directions for Use: OX5034 Egg Mosquito Rearing Box

FOR EXPERIMENTAL USE ONLY

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

Transport: Deliver to release site in original containers. Ambient vehicle temperature should not exceed 82°F ± 4°F (28°C ± 2°C) during storage or transport. If temperature is higher than 86°F (30°C), cooling for the Mosquito Rearing Boxes (e.g., ice packs) may be used, although the minimum storage temperature for mosquito eggs should not be lower than 59°F (15°C).

Application: At the release site, assemble the Mosquito Rearing Box. Place disposable box liner into the outer Box. Place eggs, hatch stimulant, larval diet and water conditioners/preservatives into the Mosquito Rearing Box, and 2.5L of water to the Mosquito Rearing Box, and close the lid. Place in a shaded or partially shaded location. Do not release within 500 m of wastewater treatment facilities, commercial citrus crops and fruit orchards (apple, pear, nectarine, peach) or commercial livestock facilities (including cattle, poultry, pigs).

Application rates

Application rates must not exceed 20,000 OX5034 adults per acre per week in Florida, or 30,000 OX5034 adults per week in California, with a minimum of 500 males per acre per week. Application rates are based on area; each Mosquito Rearing Box (2,500 OX5034 males²) is able to cover up to two acres. If required, more than one Mosquito Rearing Box per two acres can be used but application rates must not exceed 8 Mosquito Rearing Boxes per acre per week in Florida or 12 boxes per week in California. All Mosquito Rearing Boxes must be serviced or replaced within 28 days of being placed. Distribute mosquito rearing boxes evenly over the area to be treated.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Keep unopened containers at 86°F (30°C) or less. Mosquito egg storage should not be lower than 59°F (15°C). Do not freeze.

PESTICIDE DISPOSAL: Dispose of unused OX5034 mosquitoes by freezing and dispose with trash.

CONTAINER HANDLING: Refillable durable outer container. Refill the outer durable container with pesticide only, according to assembly instructions, and dispose of outer durable container in sanitary landfill. Do not reuse this container for any other purpose.

Non-refillable liner and contents. Liquid contents of liner can be disposed of in general waste or municipal drains. Dispose of non-refillable liner and solid contents in a sanitary landfill or return to facility for disposal.

² Mosquito Rearing Boxes designed to produce other numbers of male mosquitoes, e.g. 500 males per box, 1,000 males per box, etc. may also be used. In all cases, the maximum number of males/acre/week indicated in the trial designs would not be exceeded.

Usage Restrictions

In the event of tropical storms, hurricanes, known advancing wildfires, or other significant natural disasters Oxitec will return Mosquito Rearing Boxes to a secure facility under triple containment (with two of the three containment layers being shatterproof) before the disaster is predicted to reach the trial area, if safe to do so.

Boxes will be both transported to and stored in the facility under triple containment (with two of the three containment layers being shatterproof) and may be returned to the field sites as live Mosquito Rearing Boxes if/when safe to do so, to enable ongoing mosquito rearing in the boxes and to minimize trial disruption as a result of natural disasters, while ensuring that mosquitoes are only released in the approved trial areas. Boxes may alternatively be disposed of in accordance with the approved disposal procedures (i.e. killed by freezing and then disposed of in general waste).

Directions for Use: OX5034 Adult Male Release Pots

FOR EXPERIMENTAL USE ONLY

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

Transport: Deliver to release site in original containers. Ambient vehicle temperature should not exceed 82°F ± 4°F (28°C ± 2°C) during storage or transport. If temperature is higher than 86°F (30°C), cooling for the Male Release Pots (e.g., ice packs) may be used, but the temperature should not be lower than 71°F (22°C).

Application: At the release site, open the lid of the release pot and gently shake to remove all the mosquitoes. Releases can occur from a vehicle or on foot. Do not release within 500 m of wastewater treatment facilities, commercial citrus crops and fruit orchards (apple, pear, nectarine, peach) or commercial livestock facilities (including cattle, poultry, pigs).

Application rates

Application rates must not exceed 20,000 OX5034 per acre per week in Florida, or 30,000 OX5034 adults per week in California, with a minimum of 500 males per acre per week. Application rates are based on area, each release pot (1,000 OX5034 males) is able to cover up to two acres. If required, more than one release pot per 0.8 acres can be used but application rates must not exceed 20 release pots per acre per week in Florida, or 30 release pots per week in California. Distribute mosquito releases evenly over the area to be treated.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Keep unopened containers at 86°F (30°C) or less. Male mosquito storage should not be lower than 71°F (22°C). Do not freeze.

PESTICIDE DISPOSAL: Dispose of unused OX5034 mosquitoes by freezing and dispose with trash.

CONTAINER HANDLING: Non-refillable container. Return used and unused containers to facility for reuse or recycling.

Usage Restrictions

In the event of tropical storms, hurricanes, known advancing wildfires, or other significant natural disasters Oxitec will return Mosquito Rearing Boxes to a secure facility under triple containment (with two of the three containment layers being shatterproof) before the disaster is predicted to reach the trial area, if safe to do so.

Boxes will be both transported to and stored in the facility under triple containment (with two of the three containment layers being shatterproof) and may be returned to the field sites as live Mosquito Rearing Boxes if/when safe to do so, to enable ongoing mosquito rearing in the boxes and to minimize trial disruption as a result of natural disasters, while ensuring that mosquitoes are only released in the approved trial areas. Boxes may alternatively be disposed of in accordance with the approved disposal procedures (i.e. killed by freezing and then disposed of in general waste).