UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Preliminary Technical Screen of the Efficacy Data and Information Presented for the Product WB1 Males (EPA File Symbol: 89668-I) Containing the *Wolbachia pipientis* wAlbB strain in male *Aedes aegypti*. Data and Information Were Provided in Support of a FIFRA Section 3 Application.

Decision Number:	555950
Submission Number:	1040979
DP Number:	454921
EPA File Symbol:	89668-I
Chemical Class:	Microbial
PC Codes:	069039, 806431
MRID Numbers:	50945301

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I. BACKGROUND

MosquitoMate, Inc. (MosquitoMate or the applicant) requests new end-use product registration under FIFRA section 3 for a new end-use product containing the new active ingredient *Wolbachia pipientis* wAlbB strain in male WB1 *Aedes aegypti* mosquitoes.

Wolbachia pipientis wAlbB strain infected male WB1 *Ae. aegypti* mosquitoes are purported to be cytoplasmically incompatible with wild type *Ae. aegypti* mosquitoes. When infected males are released and subsequently mate with uninfected, wild-type females, reproduction is unsuccessful thereby suppressing the population.

The proposed new product has been tested under Experimental Use permits 89668-EUP-1, -2, and -3. Product performance has been tested under a variety of climates including tropical and arid sites. MosquitoMate submitted product performance data in support of this application for product use in all US states and territories that are infested with *Ae. aegypti*.

II. SUMMARY

To satisfy the product performance data requirements, the applicant submitted information on the end-use product (EP). The following **deficiencies** were identified in the review of MRID 50945301.

- Data and information related to product identity and manufacturing process (e.g., pathogenic virus testing, shipping viability data, Wolbachia presence in WB1 males) should be in MRIDs related to product identity and manufacturing process.
- Submit the approved EUP protocol used to generate the data and indicate any deviations. If there are different versions of the approved protocol for different locations/years (i.e., protocol amended under PRIA), clearly indicate which locations/years correspond to specific protocols.
- Data must be placed in the context of the label as it is unclear how the rates tested support the ratio on the label. For example, the minimum release ratio tested was one replicate of 11:1. The lowest labeled rate/ratio needs to be supported by multiple replicates. The label needs to be revised to reflect tested application rates. Labeling for efficacy is based on the lowest labeled rate; adequate, replicated data are needed to support the lowest labeled rate.
- As mentioned in the product characterization screen, the Kulkarni et al. (2019) study identified the presence of the wAlbB strain in wild populations of *Ae. aegypti*. Provide a discussion of this study in the context of product efficacy and discuss any potential geographic restrictions that may be warranted.
- Details of the trials need to be clearly articulated in the MRID, or if these details are located in attached publications, specific citations (i.e., page number and section reference) as to what details the publications are being used in the place of are needed to adequately evaluate the submitted MRID. Methods must be presented at the level of detail that another scientist could recreate the study without additional questions. Although not exhaustive, below are specific examples of inadequate methods identified in the submitted study:

Stock Island:

- Indicate number of traps per area, provide methods for collecting mosquitoes from traps.
- Indicate dates for when releases and trapping began/ended.
- Indicate whether mosquito captures per trap are weekly captures or cumulative for the study duration.
- Provide a graph of weekly mosquito captures.

California:

- Additional detail is needed to describe phases 1 and 2 in 2017.
- Provide release rates in numerical form for phases 1, 2, and 3 in all treatment locations.
- Describe how the variable release rate reflects the proposed minimum labeled release ratio.

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