



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

March 26, 2021

MEMORANDUM

SUBJECT: Materials for Review by Human Studies Review Board for the April 20-21, 2021 Meeting

TO: Tom O'Farrell
Designated Federal Official Human Studies Review Board Office of Science Advisor

FROM: Michelle Arling
Human Research Ethics Review Officer
Office of the Director
Office of Pesticide Programs

This memorandum identifies the materials that the Environmental Protection Agency's (EPA's) Office of Pesticide Programs is providing for review by the Human Studies Review Board (HSRB or Board) at the virtual meeting scheduled for April 20-21, 2021. During this meeting, EPA will ask the Board to respond to specific science and ethics questions focused on the research identified below.

- Protocol: "Field Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-based Repellent Spray Against Mosquitoes." Protocol No. MIM-006
- Protocol: "Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-based Repellent Spray with Ticks under Laboratory Conditions." Protocol No. MIM-007

"Field Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-based Repellent Spray Against Mosquitoes." Protocol No. MIM-006

The EPA has reviewed the aforementioned protocol for a field testing a new skin-applied insect repellent product, MIMIKAI Lilly-Pilly Repellent, against mosquitoes at two ecologically distinct sites. The product contains two EPA-registered active ingredients already registered with the EPA - 11% Oil of Lemon Eucalyptus (OLE, also known as Citriodiol) and 7.75% 2-undecanone (methyl nonyl ketone or MNK). The study is designed to determine the median complete protection time (CPT) for the product, and the data will be used to support product

registration. This protocol was submitted by Carroll-Loye Biological Research. The study is sponsored by MIMIKAI. This review assesses the scientific aspects of the proposed research for a product performance study to evaluate the efficacy of a skin applied insect repellent product according to the EPA guideline OPPTS 810.3700: Insect Repellents to be Applied to Human Skin, as well as the recommendations from the U.S. Environmental Protection Agency (EPA) and the Human Studies Review Board (HSRB). Ethical aspects of the proposed research are assessed in terms of the standards defined by 40 CFR 26 subparts K and L, as well as the recommendations from the HSRB.

A protocol dated February 17, 2020, which included all correspondence with the overseeing IRB, was submitted to the EPA. The EPA identified deficiencies with the February 17, 2020 version of the protocol. In response, the sponsor revised the protocol and submitted the revised protocol version dated December 23, 2020 to the overseeing institutional review board (IRB) for review and approval. Following approval by the IRB, the sponsor submitted the revised protocol and updated IRB review documents to the EPA. The revised protocol submission did not include the original IRB correspondence volume, rather it includes only the information related to the approval of the revised protocol. Therefore, the EPA is providing to the HSRB both submissions in order to provide the complete set correspondence with the IRB about this protocol. The EPA's review only covers the protocol dated December 23, 2020.

The charge questions for the HSRB's consideration are provided below:

Charge to the Board - Science:

- Is the protocol "Field Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-based Repellent Spray Against Mosquitoes" likely to generate scientifically reliable data, useful for estimating the amount of time each of the product tested repels mosquitoes?

Charge to the Board - Ethics:

- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

Documents for Review

The documents provided to the HSRB for review are listed below.

Submission to EPA

- 1a. MIM-006 Protocol & IRB Feb 17, 2020 (note: file included to provide IRB correspondence volume only)
- 1b. MIM-006 Protocol Revised Dec 23

EPA Review Documents

- 1c. EPA Science Ethics Review Memo w Att Mimikai Mosquito MIM-006 3-25-2021

“Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-based Repellent Spray with Ticks under Laboratory Conditions.” Protocol No. MIM-007

The EPA has reviewed the aforementioned protocol for a testing a new skin-applied insect repellent product, MIMIKAI Lilly-Pilly Repellent, against three species of ticks in a lab-based setting. The product contains two EPA-registered active ingredients already registered with the EPA - 11% Oil of Lemon Eucalyptus (OLE, also known as Citriodiol) and 7.75% 2-undecanone (methyl nonyl ketone or MNK). The study is designed to determine the median complete protection time (CPT) for the product, and the data will be used to support product registration. This protocol was submitted by Carroll-Loye Biological Research. The study is sponsored by MIMIKAI. This review assesses the scientific aspects of the proposed research for a product performance study to evaluate the efficacy of a skin applied insect repellent product according to the EPA guideline OPPTS 810.3700: Insect Repellents to be Applied to Human Skin, as well as the recommendations from the U.S. Environmental Protection Agency (EPA) and the Human Studies Review Board (HSRB). Ethical aspects of the proposed research are assessed in terms of the standards defined by 40 CFR 26 subparts K and L, as well as the recommendations from the HSRB.

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The charge questions for the HSRB’s consideration are provided below:

Charge to the Board - Science:

- Is the protocol “Efficacy Test of an Oil of Lemon Eucalyptus and Methyl Nonyl Ketone-based Repellent Spray with Ticks under Laboratory Conditions” likely to generate scientifically reliable data, useful for estimating the amount of time each of the product tested repels ticks?

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Charge to the Board - Ethics:

- Is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

Documents for Review

The documents provided to the HSRB for review are listed below.

Submission to EPA

2a. MIM-007 Protocol & IRB Feb 17, 2020

2b. MIM-007 Protocol Revised Dec 23

EPA Review Documents

2c. EPA Science Ethics Review Memo w Att Mimikai Ticks MIM-007 3-25-2021