



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

March 25, 2025

MEMORANDUM

SUBJECT: Materials for Review by Human Studies Review Board for the April 2-4 Meeting

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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 2-4, 2025. During this meeting, EPA will ask the Board to respond to specific science and ethics questions focused on the research identified below.

"Evaluation of Topically Applied Insect Repellent Products Containing Oil of Lemon Eucalyptus (Citriodiol) Against Mosquitoes in the Field." March 22, 2024. Sponsored by Citrefine International Ltd. Moorfield Rd. Yeadon, Leeds. LS19 7BN U.K. MRID 523504. Protocol version 0.1 as amended March 11, 2024. IRB approved March 7, 2024. 117 p.

The EPA has reviewed a protocol for research sponsored by Citrefine International Ltd. and proposed to be carried out by arctech. The proposed research is to test the efficacy of two new skin-applied insect repellent products against mosquitoes in the field, using human subjects. The protocol notes that the products would contain an EPA-registered biopesticide active ingredient – Oil of Lemon Eucalyptus (OLE, also known as Citriodiol) at 10-15% and 30% respectively. The study is designed to determine the median complete protection time (mCPT) for each product, and the data will be used to support product registration. 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, EPA's Product Performance Rule (40 CFR 158, Subpart R) as well as the recommendations from the EPA and the 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.

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

Charge to the Board - Science:

- Is the protocol “*Evaluation of Topically Applied Insect Repellent Products Containing Oil of Lemon Eucalyptus (Citriodiol) Against Mosquitoes in the Field*” likely to generate scientifically reliable data, useful for estimating the amount of time each of the products tested repels mosquitoes?

Charge to the Board - Ethics:

- If amended to address the EPA’s and the HSRB’s recommendations, 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. Citrefine OLE Mosquito Protocol MRID 523504

EPA Review Document

1b. EPA Draft Final Science and Ethics Review Citrefine OLE Mosquito Protocol - 2-28-2025

Additional Resources

1c. OPPTS 810.3700 Guidelines July 7, 2010

1d. EPA Product Performance Data Requirements April 2022