



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

OFFICE OF CHEMICAL  
SAFETY AND POLLUTION  
PREVENTION

**MEMORANDUM**

**SUBJECT:** Materials for Review by Human Studies Review  
Board for the January 11, 2024 Meeting

**TO:** Tom Tracy  
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 January 11, 2024. During this meeting, EPA will ask the Board to respond to specific science and ethics questions focused on the research identified below.

*"Laboratory efficacy test of an Oil of Lemon Eucalyptus (OLE)- and Picaridin-based skin-applied repellent spray against ticks (Ixodidae) using a human-subject test method,"* April 7, 2022, as amended, November 11, 2022. Unpublished document prepared by Carroll-Loye Biological Research, 5100 Chiles Road Suite 108, Davis, CA 95618. IRB approved 15 November 2022. 138 pp. MRID 51905311.

The EPA has reviewed a protocol for research sponsored by SanderStrothmann GmbH and submitted by Carroll-Loye Biological Research. The proposed research is to conduct testing a new skin-applied insect repellent product, Blox Tick Protection Spray, against three species of ticks in a lab-based setting. The product contains two EPA-registered active ingredients - 20% Oil of Lemon Eucalyptus (OLE, also known as Citriodiol) and 20% picaridin. 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 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 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 "Laboratory efficacy test of an Oil of Lemon Eucalyptus (OLE)- and Picaridin-based skin-applied repellent spray against ticks (Ixodidae) using a human-subject test method" likely to generate scientifically reliable data, useful for estimating the amount of time the product tested repels ticks?

**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. SanderStrothmann Tick Protocol OLE Picaridin 51905311
- 1b. SanderStrothmann Tick Protocol OLE Picaridin IRB Review Volume 51905312

EPA Review Document

- 1c. EPA Draft Final Science Ethics Review SanderStrothmann Tick Protocol OLE Picaridin 51905311

Additional Resources

- 1d. OPPTS 810.3700 Guidelines July 7, 2010
- 1e. EPA Product Performance Rule