

US EPA ARCHIVE DOCUMENT

Supplemental Submission to EPA MRID 48053802

TITLE

Efficacy Test of KBR 3023 (Picaridin, Icaridin)-Based Personal Insect Repellents (20% Cream and 20% Spray) with Black Flies Under Field Conditions

DATA REQUIREMENT

U.S. EPA Health Effects Test Guidelines OPPTS 810.3700

AUTHOR

Original Report: Scott P. Carroll, Ph.D.
Supplemental Report: Scott P. Carroll, Ph.D.

STUDY COMPLETION DATE

Original Report: April 5, 2010
Supplemental Report: April 19, 2010

PERFORMING LABORATORY

Carroll-Loye Biological Research
711 Oak Avenue
Davis, CA 95616

LABORATORY PROJECT ID

LNX-002-1

Statement of No Data Confidentiality Claims

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 10(d) (1) (A), (B), or (C).

Company: LANXESS Corporation

Company Agent: Heather F. Collins

Title: Senior Regulatory Affairs Specialist

Date: 4/20/10

Signature: Heather F Collins

GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

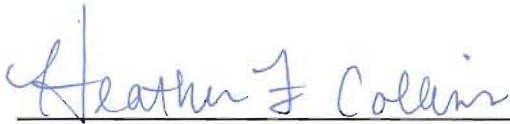
No Good Laboratory Practice Statement is required for the information presented in this volume according to FIFRA Good Laboratory Practice Standards (40 CFR Part 160)



19 April 2010

Scott P. Carroll, Ph.D.
Study Director

Date



4/20/10

Sponsor and Study Submitter
Heather F. Collins
Senior Regulatory Affairs Specialist
LANXESS Corporation

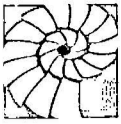
Date

Summary

This supplement provides additional documentation of ethical conduct of Carroll-Loye repellent efficacy study LNX-002 pursuant to 40 CFR 26 subparts K and L, to be appended to MRID 48053802, Study Report LNX-002, as requested by John Carley, Program Analyst, US Environmental Protection Agency, on April 12, 2010.

This supplement adds information to assist review of Appendix 11 of the Study Report. The following documents are provided:

<u>Document Description</u>	<u>Pages of this supplement</u>
IIRB, Inc. 8/18/09 Approval Letter for Amendment 1	5-6



**INDEPENDENT
INVESTIGATIONAL
REVIEW BOARD INC.**

Your Advocate for Clinical Research Participants

14141
14141

Anna M. Blasingame, MD
President

DATE: August 18, 2009

TO: Scott P. Carroll, PhD
Principal Investigator

FROM: Authorized Signatory *Julie Blasingame*
Independent Investigational Review Board, Inc.

SUBJECT: Revised Protocol;

- Treated Informed Consent Form version 8/18/2009
- Untreated Informed Consent Form version 8/18/2009
- California Experimental Subject's Bill of Rights
- Efficacy Test Protocol dated 8/13/2009
- Amendment 1 dated 8/13/2009
- CLBR Training Manual
- Lotion dosimetry recording form
- Lotion dosimetry data entry
- Biting Fly LIBes at 15 Minutes Intervals Form
- Efficacy Data Form
- Repellent Applications Form

PROTOCOL: LNX-002

At the meeting held on August 18, 2009 the Independent Investigational Review Board, Inc. had an opportunity to review the above referenced Treated Informed Consent Form, Untreated Informed Consent Form, California Experimental Subject's Bill of Rights, Efficacy Test Protocol, Amendment 1, CLBR Training Manual, Lotion dosimetry recording form, Lotion dosimetry data entry, Biting Fly LIBes at 15 Minutes Intervals Form, Efficacy Data Form and Repellent Applications Form for the above noted research study. The Protocol was revised to include the California Department of Pesticide and HSRB request as well as the Sponsor's request for additional dosimetry data to be added. In addition, other administrative changes were made throughout the document.

The Treated Informed Consent Form, Untreated Informed Consent Form, California Experimental Subject's Bill of Rights, Efficacy Test Protocol and Amendment 1 are unanimously approved. The CLBR Training Manual, Lotion dosimetry recording form, Lotion dosimetry data entry, Biting Fly LIBes at 15 Minutes Intervals Form, Efficacy Data Form and Repellent Applications Form are acceptable with favorable opinion. The Independent Investigational Review Board does not require these documents be stamped and no other evidence of approval is required. The Treated Informed Consent Form and Untreated Informed have been revised to accommodate the Protocol. The California Experimental Subjects Bill of Rights has been revised to accommodate the California Department of Pesticide.

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The approved revised Treated Informed Consent Form and approved revised Untreated Informed Consent Form are both identified as Version 8/18/2009 and are both stamped, "Approved 8/18/2009". The approved revised California Experimental Subject's Bill of Rights is stamped, "Approved 8/18/2009". All current subjects and future research participants must sign the revised consent forms.

Thank you for your cooperation.

KL/AMS/yc:rr