

PROJECT NUMBER: 252-0059

STUDY TITLE:

EVALUATION OF THE EFFICACY OF LICEFREEE!® HEAD LICE TREATMENT SPRAY AGAINST ADULT BODY LICE

PROTOCOL NUMBER: N252040856078

IN-LIFE COMPLETION DATE: June 13, 2008

STUDY COORDINATOR: Timothy Foard

PERFORMED FOR:

Tec Laboratories, Inc. PO Box 1958 615 Water Avenue NE Albany OR 97321

TESTING FACILITY:

ICR, Inc 1330 Dillon Heights Avenue Baltimore, MD 21228-1199

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Tec Laboratories, Inc. Adult LouseTest ICR Project No. 252-0059 In-Life Completion Date: June 13, 2008

EXECUTIVE SUMMARY

The efficacy of Lice Freee! Read Lice Treatment Spray, Lot No. B2074D was tested against adult body lice by directly spraying patches of corduroy fabric with the product and introducing the lice onto the treated fabric.

Timothy Foard Study Coordinator

17/00 Date:

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Tec Laboratories, Inc. Adult LouseTest ICR Project No. 252-0059 In-Life Completion Date: June 13, 2008

OBJECTIVE:

To evaluate a liquid louse product for pediculicidal activity against adult body lice.

This is not a GLP (Good Laboratory Practices) study or protocol.

MATERIALS & METHODS:

The materials and methods used are as described in N252060859078 (APPENDIX I), without any deviations.

RESULTS:

Table 1 summarizes the results:

| Variable | 1 Hour | 24 Hour | Amount Disp | ensed (g) |
|--------------|-----------|-----------|-----------------|-------------|
| | Knockdown | Mortality | Treatment Patch | Cover Patch |
| Control | 0.8 | 1.6 | NA | NA |
| Lice Freee!® | 100.0 | 100.0 | 3.26 | 3.33 |

Table 1. Efficacy summary of Lice Freee!® Head Lice Treatment Spray.

After lice were sandwiched between the treated fabric squares, the insects appeared to be very agitated, actively crawling out from between the two patches and all over the fabric's surface and onto the bottom of the Petri dish. This continued for several minutes and as early as 30 minutes many of the lice were immobile, and by 1 hour all were completely immobile. Also at the one hour observation time none of the insects were dead, as peristalsis of the gut cavity was readily observed in all the specimens exposed to treatment. After the one hour observation was made, five immobile specimens were removed from the patches and placed at the bottom of the Petri dish to determine whether recovery would have occurred in the absence of constant contact with



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the product. At 24 hours, these five specimens, along with all members of the treatment group, had not recovered. Peristalsis of the gut cavity was not observed from any of the individuals at this time. By contrast, control lice remained between the corduroy patches for most of the first hour, with a few crawling out on the patch surface mainly in the darkness of the incubator, where the Petri dishes were being stored.

CONCLUSION:

Lice Freee! The Head Lice Treatment Spray is very effective against body lice, completely immobilizing them within one hour and killing all of them within 24 hours.

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APPENDIX I: PROTOCOL

PROTOCOL NUMBER: N252060859078 ©2008 by ICR. Inc.

PROJECT NUMBER 252-0059

PROTOCOL TITLE

EVALUATION OF THE EFFICACY OF LICEFREEE® LEAVE-IN LICE TREATMENT SPRAY AGAINST ADULT BODY LICE

> PROTOCOL VERSION DATE: June 4, 2008

PROPOSED START DATE TBD

PROPOSED COMPLETION DATE TBD

STUDY COORDINATOR Timothy Foard

SPONSOR

Tec Laboratories, Inc. 7100 Tec Labs Way SW Albany, OR 97321

TESTING FACILITY

ICR, Inc. 1330 Dillon Heights Avenue Baltimore, MD 21228

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OBJECTIVE:

To determine the efficacy of a leave-in lice treatment spray against adult body lice.

This is not a GLP (Good Laboratory Practices) study or protocol.

MATERIALS:

The sponsor will supply the following sample for evaluation:

TEST ARTICLE:

1. Licefreee! leave-in lice treatment spray formula B2074D.

A Material Safety Data Sheet (MSDS) shall be provided for each test, control, and/or reference sample, which will include any hazardous information of the samples. The percentage of all active ingredients and any hazardous constituents must be included in all MSDS.

The sponsor is solely responsible for conducting the complete test sample, control sample, and any reference sample characterizations, and for retaining this documentation. If any of the test samples are currently available for consumer use and/or purchased in the marketplace, the sponsor should still conduct the same sample characterizations.

The stability of the test, control, and/or reference samples should be determined by the sponsor prior to the experimental start date. When relevant to the conduct of this study, the solubility of each test, control, and/or reference sample should be determined prior to the experimental start date.

The stability of test, control, and/or reference samples stored under the test site conditions should be determined by the sponsor prior to any studies.

All unused test samples will be returned to the sponsor within 30 days after the final report is sent to the sponsor. The sponsor will be responsible for all costs for the return of the samples, including any costs associated with hazardous materials shipping.

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| TEST ORGANISM: | The human body louse, <i>Pediculus humanus humanus</i> , will be used as a surrogate subspecies, for the head louse, <i>P. h. capitis</i> . Twenty-five adults (mixed sex) per replicate and five replicates will be used. The strain maintained by ICR, INC. is insecticide susceptible and has been adapted to the New Zealand White Rabbin for taking blood meals. |
|------------------|--|
| TEST SUBSTRATE: | Cotton corduroy 2" X 2" patches (dark colors to make the lice conspicuous). |
| TEST CONTAINERS: | Plastic petri dishes. |
| HEAT SURFACE: | Electric heating pad. |
| MISC: | Mettler® balance, forceps. |

METHODS

The study design consists of five replicates of twenty-five adult lice. There will be an equal number of untreated controls.

Spray application:

The weight of test sample delivered will be 5 sprays from the spray pump and container provided by the sponsor, from a distance of ca. 10 cm from the Petri dish containing lice. The rate of discharge will be determined by weighing the spray container before and after discharge.

Preparation:

Twenty-five mixed sex adult lice will be picked for each of five replicates after being blood fed.

Treatment:

The adults will be placed on a 2 x 2-inch piece of corduroy fabric and placed in a Petri dish. The dish will be sprayed with 5 pumps from the sprayer from a height of ca. 10 cm as described above. The weight of formula will be determined for each strip of corduroy by weighing the spray unit before and after the application. After treatment, the lice will be left on the treated 2" x 2" patch, covered with another treated patch, placed in an open clean Petri dish, and held in the incubator (31.7°C and 60% RH) for 24 hours.

At one hour, and again at 24 hours the lice will be removed from the incubator. All the lice in each replicate will be placed on the top of the upper corduroy patch. The corduroy patches will



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At one hour, and again at 24 hours the lice will be removed from the incubator. All the lice in each replicate will be placed on the top of the upper corduroy patch. The corduroy patches will then be placed on a heated (ca. 90°F) surface. Any live lice will crawl to the underside of the patch within 5 minutes. After 5 minutes, counts of live, moribund and dead lice will be taken and recorded.

DATA ANALYSIS

The counts of dead or moribund lice will be converted to percentages. These percent mortalities will be corrected for any control mortality, using Abbott's formula.

SCHEDULE OF EVENTS

| DATE | PROCEDURE |
|-------------------------|---------------------------------|
| Time Zero | Samples Received |
| Within 2 days | Test Conducted |
| At end of test | Telephonic or Electronic Report |
| Within 30 days of test | Report Written |
| After Report Submission | Samples Returned |

STATEMENT OF DEVIATION OR AMENDMENT

Any amendments to this protocol must be discussed with and approved by the Sponsor. All amendments to, and/or deviations from, this protocol will be documented in the final report.

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Study Coordinator, ICR, Inc

Wendy S. Langley Date Regulatory Affairs Director

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RAW DATA COLLECTION SHEET #1 Weights Delivered of Licefreee Leave-In Lice Treatment Spray

Project No:

Sponsor: Tec Labs

Date:

| | | | | | Lice | | | | | |
|-----------------------|---|----------|------------|---------------|------|---|---|---|---|---|
| | | Treatmer | nt Patches | Cover Patches | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 5 |
| wt initial, g | | | | | | | | | | |
| wt final, g | | | | | | | | | | |
| wt delivered | | | | | | | | | | |
| avg. wt. delivered | | | | | | | | | | |
| # pumps | | | | | | | | | | |

Comments:

Recording Technician:



RAW DATA SHEET #2 Lice Mortality Counts

Project No:

Sponsor: Tec Labs

Date:

| | | | | | 1 Hour | | | | | | | |
|-------------------------------------|---|-----------|-----------|---|--------|---------|--|--|--|--|--|--|
| | | Untreated | d Control | | | Treated | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 1 2 3 4 | | | | | | |
| # dead | | | | | | | | | | | | |
| # moribun d | | | | | | | | | | | | |
| # alive | | | | | | | | | | | | |
| % mortality | | | | | | | | | | | | |
| avg. corrected % mortality | | | | | | | | | | | | |

Comments:

Recording Technician:



RAW DATA SHEET #4 Lice Mortality Counts

Project No:

Sponsor: Tec Labs

Date:

| | | | 1 | 1 | 24 Hours | 5 | | | | | | |
|-------------------------------------|---|-----------|-----------|---|----------|---------|---|---|---|---|--|--|
| | | Untreated | d Control | | | Treated | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 5 | | |
| # dead | | | | | | | | | | | | |
| # moribun d | | | | | | | | | | | | |
| # alive | | | | | | | | | | | | |
| % mortality | | | | | | | | | | | | |
| avg. corrected % mortality | | | | | | | | | | | | |



APPENDIX II: SPREADSHEET AND RAW DATA SHEETS

| | | | | | Data Re | duction Tal | ble | | | | |
|------------|-------|---------|---------|---------------|---------|----------------------|----------------------|---------------------|-------|----------|-----------------|
| | | | | | 1 | HOUR | | | | | |
| | | PRO | JECT #: | 252-0059 | | | SPONSO | R: Tec Labs | DATE: | 06/11/08 | 3 |
| Formula | Rep # | Total # | ALIVE | MORI- BUND | DEAD | Control Mortality | Treated Mortality | Abbott's correction | Asin | Ave | UnCrt'd Mi % |
| Control | 1 | 25 | 24 | 1 | 0 | 4.0 | | | 11.54 | | |
| | 2 | 25 | 25 | 0 | 0 | 0.0 | | | 0.00 | | |
| | 3 | 25 | 25 | 0 | 0 | 0.0 | | | 0.00 | | |
| | 4 | 25 | 25 | 0 | 0 | 0.0 | | | 0.00 | | |
| | 5 | 25 | 25 | 0 | 0 | 0.0 | | | 0.00 | 2.31 | 0.8 |
| Licefreee! | 1 | 25 | 0 | 25 | 0 | 0.8 | 100.0 | 100.0 | 90.00 | | |
| | 2 | 25 | 0 | 25 | 0 | 0.8 | 100.0 | 100.0 | 90.00 | | |
| | 3 | 25 | 0 | 25 | 0 | 0.8 | 100.0 | 100.0 | 90.00 | | |
| | 4 | 25 | 0 | 25 | 0 | 0.8 | 100.0 | 100.0 | 90.00 | | |
| | 5 | 25 | 0 | 25 | 0 | 0.8 | 100.0 | 100.0 | 90.00 | 90.00 | 100.0 |

| | | | | | Data Re | duction Ta | able | | | | |
|------------|--------|------------|-------|---------------|---------|----------------------|----------------------|---------------------|-------|----------|------------|
| | | | | | 24 | HOURS | | | | | |
| | PROJEC | T #: 252-0 | 0059 | | | SPONSO | R: Tec Lab | S | DA' | ГE: 06/1 | 2/08 |
| Formula | Rep # | Total # | ALIVE | MORI- BUND | DEAD | Control Mortality | Treated Mortality | Abbott's correction | Asin | Ave | UnCrt'd Mi |
| Control | 1 | 25 | 24 | 1 | 0 | 4.0 | | | 11.54 | | |
| | 2 | 25 | 25 | 0 | 0 | 0.0 | | | 0.00 | | |
| | 3 | 25 | 25 | 0 | 0 | 0.0 | | | 0.00 | | |
| | 4 | 25 | 25 | 0 | 0 | 0.0 | | | 0.00 | | |
| | 5 | 25 | 24 | 1 | 0 | 4.0 | | | 11.54 | 4.61 | 1.6 |
| Licefreee! | 1 | 25 | 0 | 0 | 25 | 1.6 | 100.0 | 100.0 | 90.00 | | |
| | 2 | 25 | 0 | 0 | 25 | 1.6 | 100.0 | 100.0 | 90.00 | | |
| | 3 | 25 | 0 | 0 | 25 | 1.6 | 100.0 | 100.0 | 90.00 | | |
| | 4 | 25 | 0 | 0 | 25 | 1.6 | 100.0 | 100.0 | 90.00 | | |
| | 5 | 25 | 0 | 0 | 25 | 1.6 | 100.0 | 100.0 | 90.00 | 90.00 | 100.0 |



Tec Laboratories, Inc. Adult LouseTest Protocol No.: N252060859078 ICR Project No. 252-0059

RAW DATA COLLECTION SHEET #1 Weights Delivered of Licefreee Leave-In Lice Treatment Spray

Project No: 252-0055

Sponsor: Tec Labs

Date: 6/11/ 8 1:00 Pm

Lice freee Spray

| | | | | | Lice | | | | | |
|-----------------------|--------|----------|-----------|--------|---------|---------|-----------|--------|--------|--------|
| | | Treatmen | t Patches | 3 | | Со | ver Patch | nes | | |
| | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 5 |
| wt initial, g | 20029 | 191.87 | 183.48 | 175.48 | 1 69,70 | 196,38 | 18791 | 179.68 | 17250 | 165.70 |
| wt final, g | 196,93 | 188.46 | 18026 | 172,54 | 166.32 | -192,73 | 184.25 | 175.98 | 169.70 | 16285 |
| wt delivered | 3.36 | 3.41 | 3,22 | 2.94 | 3.38 | 3.65 | 3.66 | 3.20 | 2.80 | 2.85 |
| avg. wt. delivered | | 3. | 26g | | | | 3. | 333 | | |
| # pumps | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | S |

Comments:

Recording Technician:



Tec Laboratories, Inc. Adult LouseTest Protocol No.: N252060859078 ICR Project No. 252-0059

RAW DATA SHEET #2 Lice Mortality Counts

Project No: 252-059 Sponsor: Tec Labs

Date: 6/11/08

| | | | | | 1 Hour | | | | | |
|-------------------------------------|--------------|----------|----------------------------|------------------|--------|----------|-------------|---------|---------|-------|
| | | Untreate | d Control | | | | | Treated | | |
| | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 5 |
| # dead | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | σ | 0 |
| # moribun d | l | 0 | 0 | 0 | 0 | 25 | 25 | 25 | 25 | 25 |
| # alive | 24 | 25 | 25 | 25 | 25 | 0 | 0 | 0 | 0 | 0 |
| % mortality | 4.0 | 0-0 | 0-0 | 0-0 | 0-0 | 1000 | 100.0 | 100.0 | 100.0 | 100-0 |
| avg. corrected % mortality | | 0, | 8 | | | | 100. | . Ə | | |
| Comments: | forice to T. | helis of | get so put to cie ai | mà tro hal Ar | record | e ct the | non atch | would g | workges | |
| Recording To | echnician: | 11 | \cap | | | | | | | |

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Tec Laboratories, Inc. Adult LouseTest Protocol No.: N252060859078 ICR Project No. 252-0059

RAW DATA SHEET #4 Lice Mortality Counts

Project No: 252-057

Sponsor: Tec Labs

Date: 6/12/8

| | | | | | 24 Hours | 5 | | | | | |
|-------------------------------------|-----|-----------|-----------|-----|----------|---------|------|-------|------|-------|--|
| | | Untreated | d Control | | | Treated | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 5 | |
| # dead | X | 0 | Ð | 0 | l | 25 | 25 | 25 | 25 | 25 | |
| # moribun d | 0 | 0 | б | 0 | 0 | 0 | 0 | 0 | 0 | 6 | |
| # alive | 24 | 25 | 25 | 25- | 24 | 0 | 0 | 0 | 0 | 0 | |
| % mortality | 4.0 | 0.0 | 0.0 | 0.0 | 4.0 | 100-0 | 1000 | 102-2 | 1000 | 100-0 | |
| avg. corrected % mortality | | 1. | 6 | | | | / | 00-0 | | | |