Science Assessment: Field Testing of S.C. Johnson Personal Mosquito Repellent Mark-5 Product to Support the Use of the EPA Repellency Awareness Graphic

Kevin Sweeney
Registration Division
Office of Pesticide Programs

Mark-5 Study

- Conducted on July 28, 2015 in Wisconsin and September 29, 2015 in Florida.
- 7% DEET pump-spray
- EPA Reg. No. 4822-395

Mark-5 Application Rate

- Applied at 0.5 g/600 cm^2 $\pm$ 10%
- Mean = reported as 100% of the target amount but when calculated = 101.75 or 102%.
- Range was 100-109% of the target amount.

Mosquito Landings on Controls - Wisconsin

- Study Director did not record untreated control mosquito landings in first exposure period (Protocol Deviation #4).
- Five mosquito landings were recorded in less than one minute on three of the five subsequent exposure periods.
- Time to five mosquito landings ranged from 35 seconds to 3¼ minutes across both control subjects through the five exposure periods.

Mosquito Landings on Controls - Florida

- Five mosquitoes landed on an untreated control subject in less than one minute in five out of seven exposure periods.
- Time to five mosquito landings ranged from 30 seconds to 2½ minutes across both untreated control subjects through seven exposure periods.

Wisconsin – July 28, 2015

- 10 subjects plus 4 alternates
- 5 treated males and 5 treated females
- 2 untreated control subjects (1 M & 1 F)
- 4 female alternates and 0 male alternates. (Protocol Deviation #1)
- Protocol Deviation #1 had no impact on study outcome.

Results -Wisconsin July 28, 2015

- All subjects reported a First Confirmed Landing (FCL) through 2.5 hours post-treatment.
- All subjects completed the study.

Florida –September 29, 2015

- 1 male and 0 female alternates. (Protocol Deviation #1)
- 10 subjects plus 1 alternate
- 5 treated males and 5 treated females
- 2 untreated control subjects (1 M & 1 F)

Results – Florida September 29, 2015

- Eight of ten subjects reported a FCL through 3.0 hours post-treatment.
- The Study Director stopped the study at 3.0 hrs. post-treatment.
- All subjects completed the study.

Data Analysis

- Kaplan-Meier Survival Analysis used to calculate Median CPT.
- In this experiment only two subjects in the experiment did not receive a FCL. This resulted in 10% of the data points being “right-censored”.
- For those subjects who did not experience a FCL by the end of the study, their CPT values are conservatively assumed to be the post-treatment duration of the study in a given site.

Complete Protection Times

Measure	Wisconsin	Florida
Median CPT	2.0	2.5
95% LCL	1.5	1.0
95% UCL	2.0	3.5
Range	1.5 – 2.5	1.0 - 3.5

Conclusions

- The study is acceptable and the data support a Median CPT for the Repellency Awareness Graphic = 2.0 hours.

Ethics Assessment: Mark 5 Product

Maureen Lydon
Office of the Director
Office of Pesticide Programs

Study Specific Data for Mark-5

- 44 subjects were enrolled for the Mark-5 study
- 10 no-shows (8 for training, 2 for testing)
- 24 subjects assigned to participate in tests with 12 alternates/extras
- 24 subjects completed testing

Protocol Amendment & Deviations

- One amendment to protocol reflected change in study director. Original director took 10 week sabbatical.
- Appendix B to study documents 4 deviations
- The deviations did not raise ethical concerns or deficiencies.

Protocol Amendment & Deviations

- SCJ adhered to IRB instructions and protocol in documenting the amendment and deviations
- The amendment and deviations did not negatively impact subjects' rights, health or safety

Reporting of Incidents

- No subjects withdrew from the study
- There were no adverse events or incidents of concern reported during or after test implementation

Substantive Acceptance Standards

- 40 CFR §26.1703
  - Prohibits reliance on data involving intentional exposure of pregnant or nursing women or of children
- 40 CFR §26.1705
  - Prohibits reliance on data unless EPA has adequate information to determine substantial compliance with subparts A through L for 40 CFR 26. Subparts K & L applicable to third-party research.
- FIFRA §12(a)(2)(P)
  - Makes it unlawful to use a pesticide in human tests without fully informed, fully voluntary consent

Findings

- Study in compliance with acceptance standards
- All subjects were at least 18; pregnant and nursing women were excluded
- No significant deficiencies in ethical conduct of the research
- Deviations did not compromise health and safety, consent or rights of subjects
- Subjects were fully informed and their consent was fully voluntary, without coercion or undue influence

Conclusion

- Available information indicates that the study was conducted in substantial compliance with subparts K and L of 40 CFR Part 26

Charge Questions to HSRB

- Is the study sufficiently sound, from a scientific perspective, to be used to estimate the duration of complete protection against mosquitoes provided by the tested repellent?
- Does available information support a determination that the research was conducted in substantial compliance with 40 CFR Part 26, subparts K and L?