

**A Proof of Claims three-arm study to
compare the efficacy of Omniche
Consumer Products Co, Mayday Lice
Prevention Shampoo, Mayday Lice
Prevention Conditioner and Mayday
Lice Treatment Products in effectively
treating and/or repelling head lice
verses the nonuse of a lice repellent or
treatment agent.**

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Organization: LSRN

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Study Report: Final Report

LSRN

Protocol Information

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1.0 Introduction

Over three thousand varieties of lice exist yet only three types claim humans as their host, *Pediculus Capitis* (head lice), *Pediculus Humanus* (body lice), and *Pthirus pubis* (pubic lice). The prevalence of head lice is well documented and continues to grow. Although there is no reliable data on exact numbers of cases seen each year, the CDC estimate of 6-12 million cases in the US annually¹ has been the accepted baseline for the last 50 years. It's not all bad news however, according to a survey in Glasgow, UK between 1910 to 1930 they reported a prevalence as high as 50% in some areas². Thanks to the use of lice treatment products that number has significantly declined in developed countries³. Nonetheless lice continue to be a worldwide problem with an estimated 19% of school age children inflicted with head lice each year.⁴

To further complicate this growing concern is the realization that products once used to help curtail the growing number of cases seen each year, are now less effective as resistance to such products has become an increasing problem.⁵

The study sponsor, Omniche Consumer Products Co., has developed a safe, nontoxic, proprietary line of lice products in hopes to address this ongoing problem. The testing of these products and their effects on head lice was performed by LSRN, a subsidiary of Shepherd Enterprises.

Shepherd Enterprises and their founder Katie Shepherd have been studying head lice and how they impact the families dealing with it, for the past 30 years.

2.0 Objectives

The purpose of this study was to determine if regular use of Omniche's Mayday Lice Prevention and Treatment Products did in fact help in the prevention of head lice, as well as potential efficacy of Omniche Products in the event that exposure did exist. All test runs were conducted 'in vitro'. The three study formulas tested in this project were designed for use on human heads in the same manner as other marketed, similar-type, hair care products. All ingredients used in Omniche Products fall under the GRAS guidelines by the FDA. Products samples tested in this project were provided by the study sponsor and labeled Mayday Lice Prevention Shampoo, Mayday Lice Fighting Conditioner and Mayday Lice Treatment product.

The Primary objective of this study was to test each product individually to determine the efficacy of each of the three test products in repelling and or killing head lice. All testing was done 'in vitro' using treated tufts of human hair and monitoring the lice responses to each product. In each individual test run a control was used and the lice reaction to the Omniche test product vs the control was recorded over a 7-hour time period. Study personnel was blinded to actual product based on a predetermined randomization schedule.

3.0 Study Procedures

Freshly harvested adult and/or third stage head lice were donated by willing individuals and would have otherwise been discarded. Head lice used in each individual test run came from the same willing donor and were not identified other than by donor sample number. Study procedures commenced within 30 minutes of separation from their human host to ensure the most viable samples possible for this study. Only samples collected from individuals that had not pretreated within the 7 days prior to the lice being removed from their host were used in this project.

Study was conducted over two phases with three arms each. The purpose of phase one was to ensure study results were significant enough to warrant further testing or if formula modifications were needed. Additional test runs were also completed to determine the recommended exposure time for the application of the Mayday Lice Prevention Shampoo product to ensure the best possible results for the user. During the phase one testing, five individual test runs containing five adult lice each were completely covered in the Mayday Lice Prevention Shampoo product. They were then monitored for a period of three minutes to determine if, and if so at what point, the Mayday Lice Prevention Shampoo product compromised the viability of the louse. Upon completion of the three-minute observation only three of the 25 lice used showed some slight movement while the remaining 22 lice displayed no movement at all. Observation found that in all cases gut rupture of the lice occurred at 2.5 minutes thus ultimately resulting in the louse death. Based on these findings the recommended exposure time would be no less than 2.5 minutes. It's worth noting that this determination was based on direct and complete exposure and thus why recommended application should include a minimum of 2.5 minutes with a thorough and complete saturation of the Mayday Lice Prevention Shampoo product. Additionally, since children generally shampoo their own hair, it would be advisable for parents dealing with lice exposure to assist the child in this process to ensure recommended application procedures are followed completely.

For the purpose of this final report only findings from the Phase 2 portion of the study were included other than the exposure timeline noted above.

The Mayday Lice Prevention Shampoo and Mayday Lice Fighting Conditioner products were tested against similar generic products.

The Mayday Lice Treatment product was tested against Rid.

Arm 1 — Mayday Lice Prevention Shampoo

The Mayday Lice Prevention Shampoo product arm consisted of blinded test runs with 15 individual Petri dishes. Each dish utilized 7 adult and/or 3rd stage head lice per specified side of Petri dish in each individual test run. In this arm of the study 14 preselected healthy adult and/or 3rd stage head lice from the same willing donor were placed directly on identical tufts of hair that had been pretreated with either the test product or generic shampoo. The lice reaction to each product was then recorded over a 7-hour time period.

Since the Mayday Lice Prevention Shampoo is intended for prevention purposes, additional test runs were performed to determine if the Mayday Lice Prevention Shampoo product also displayed ovicidal effect. To make this determination 20 fully developed, viable eggs, that had been prequalified for use (based on the expectation that they would hatch within the next 24 hours due to their stage of development and embryo functions at that level) via a 10x microscope, were placed with 10 eggs on each side (20 eggs per tray) of the midline of a disposable plastic Petri dish. (9cm diameter x 1.5 cm depth) Using a separate pipette for each side of the Petri dish one drop of the Mayday Lice Prevention Shampoo was applied directly on top of each egg on side A.

Eggs on side B received one drop each, of the generic shampoo. All eggs, regardless of side A or side B, were fully encased in product ensuring that the operculum was completely covered. The process of testing eggs for products ovicidal effect was repeated 5 individual times. Once eggs had been completely covered with designated shampoo product, the Petri dish was then placed in an incubator at a temperature of 30 degrees C and 70% relative humidity, for a period of 24 hours. Dishes were then removed from incubator and the eggs were reexamined with results recorded on source docs.

Arm 2 — Mayday Lice Fighting Conditioner

The Mayday Lice Fighting Conditioner arm consisted of 9 individual, blinded test runs resulting in 1 test run per Petri dishes. Two identical tufts of hair which had been pretreated with either the test product or generic conditioner were positioned on side A and side B and equal distance from the midline. Each individual test run utilized 7 adult and/or 3rd stage head lice per Petri dish. In this arm of the study, 7 preselected healthy adult and/or 3rd stage head lice from the same willing donor were placed directly on the midline of the Petri dish allowing the lice to move freely between the two pretreated hair tufts. The goal was to determine if the scent and/or direct exposure to the Mayday Lice Prevention Conditioner would repel lice or had any other negative impact on the lice and if so to what extent. The lice were then monitored over a 7 hour time frame and their reaction to both the test product as well as the control is noted in the study source docs.

Arm 3 — Mayday Lice Treatment Product

Arm 3 of this limited bench study was for the purposes of testing the Mayday Lice Treatment Product against the readily available Rid product. In these blinded test runs the Petri dish was divided in half by a mid-line and pretreated hair tufts from the same head of hair were placed on either side of the mid-line based on a predetermined randomization chart. In all cases one hair tuft was dipped directly into the Mayday Lice Treatment product and the other was dipped into the Rid treatment product. Dipping hair directly into product was done to ensure a through saturation as would be expected in an actual use environment. Seven adult and/or 3rd stage head lice were then placed directly on each pretreated hair tuft and within 30 minutes of separation from their human host. In an effort to ensure all lice used in each individual test run came from the same environment, all 14 lice used in each test run were collected from the same human host. The lice reaction to said product was monitored and recorded over a

7-hour time frame. The goal was to determine if direct exposure to either of the lice treatment products had a negative impact on the lice and if so to what extent.

For the purposes of this limited bench study final results were based on the 7 hour or final time line.

4.0 Data Collection and Documentation

Source Docs were maintained for each numbered Petri dish and can be found in the source docs of study binder. Raw data was tabulated per data sheet and was summarized with corresponding graphs per each phase of the study.

5.0 Results

Based on this limited study Mayday Lice Prevention Shampoo proved to be 99.05% effective in controlling head lice. Additional testing found that when viable eggs were fully submersed in the Mayday Lice Prevention Shampoo results found it to be 100% effective in killing lice eggs. Based on these limited test runs, lab studies showed that the regular use of Mayday Lice Prevention Shampoo is a viable tool when it comes to killing both lice and their nits.

Mayday Lice Fighting Conditioner proved to be 95.24% effective in repelling head lice verses an everyday generic conditioner, which notably is not intended as a repellent agent. Not surprisingly 73.2% of the lice choose to live in hair treated with the generic conditioner or otherwise hair that had not been properly protected. Of the few lice that did have direct contact with the Mayday Lice Fighting Conditioner, 100% of them reacted in a stunned response which had a negative impact on the lice ability to respond in a normal manner. This stunned response prevented them from escaping dangers quickly therefore increasing odds of combing or washing

them out. The fact that studies found Mayday Lice Fighting Conditioner to both repel and stun lice is a practical reason for parents to incorporate this preventative tool in their regular routine.

While parents hate to admit it, head lice are an amazing parasite. Lice have been around from the beginning of mankind, in part due to their strong survival instincts. Regardless of preventative steps there is always the risk that a few lice may still make their way over. Recognizing this fact, Omniche Consumer Products acknowledged the need to provide a treatment product as well and thus Mayday Lice Treatment Product with its Dimethicone ingredient was born. As is true with dimethicone products, it offers a gelatin coating to slow lice down and a slippery slope which allows for a more productive comb out. Nonetheless in these limited bench studies results found it to be 79.37% effective in eliminating head lice verses Rid which was only 44.44% effective.

6.0 Conclusion

Recent test studies found the Mayday Lice Prevention Shampoo to be 99.05% effective in controlling head lice and when fully submersed in the Mayday Lice Prevention Shampoo results showed it was 100% effective in killing nits. Such results indicate that the Mayday Lice Prevention Shampoo is a viable option for parents looking for a prevention shampoo that will help kill both lice and their eggs.

Lab studies also found Mayday Lice Fighting Conditioner to be equally effective, showing that it both stunned and repelled head lice 95.24% of the time. Lice experts suggest using both the Mayday Lice Prevention Shampoo and Mayday Lice Fighting Conditioner 2 to 3 times a week to ensure the best odds in the fight against head lice.

For those parents that opt to keep a bottle of lice treatment on hand just in case the inevitable happens, the Mayday Lice Treatment product, with its easy to use dimethicone base, is a great on hands alternative.

7.0 Bibliography

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