

In vitro efficacy comparison of Elimax to a dimethicone (4%) containing head lice treatment

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This study has been conducted by an independent contract research organization. All data have been interpreted and reported by the external researchers.

*Frank Eertmans Ph D.
R&D Project Leader
Oystershell laboratories*

BACKGROUND

Infections with head lice have traditionally been treated using conventional insecticides. However, problems have arisen in several parts of the world due to selection of lice strains showing resistance to one or more insecticides. As a consequence, consumers have been disillusioned by many existing products because claims cannot completely be justified any longer.

The desire to find alternative therapies has prompted many consumers to experiment and resort to untested methods. Also, several formulators have decided to market products which are neither adequately tested for safety/efficacy nor are they licensed products for use in this application. Other drawbacks include potential toxicity of applied materials and the possibility to enhance resistance to these products because of inappropriate formulations. For these reasons, Oystershell continuously investigates new formulations and active substances with the intention to release anti-lice products showing both high efficacy and safety. From this point of view, the present study is part of a battery of tests to evaluate these parameters.

SCOPE

Oystershell laboratories wanted to evaluate the killing efficacy of three anti-lice formulations, including Elimax lotion. For this purpose, an *in vitro* study has been set-up by an independent contract research organization (CRO).

MATERIAL AND METHODS

Test products

Three formulations, prepared by Oystershell, have been included in this study. Briefly, Elimax lotion has been compared with two alternative test formulations, one of which is a 4% silicone based formula (X92000850). The other formulation X92001306 was used for internal research.

Controls

Tap water served as a negative control.

Insects

Several schools in the proximity of the CRO have been included into a community support program for lice screening. This allowed collection of lice from different sources and ensured an accurate representation of the normal variation of head lice likely to be encountered in the community. Therefore, any variation of response was representative for the range likely to be encountered in consumer use.

Briefly, head lice were collected by combing, performed according to a standard operating procedure of the CRO. Lice were placed on close meshed nylon gauze, to provide a hair-like substrate for the lice to crawl on, in a 90 mm plastic Petri dish.

Test method

Aliquots of approximately 5-10 ml of each test formulation were transferred to a 55 mm plastic Petri dish. Next, the gauze bearing the lice was immersed into the fluid for 10 seconds. Importantly, the gauze was rotated at least two times to ensure air bubble elimination. After removal of the fluid, the gauze and lice were carefully dabbed dry to remove excess fluid and transferred to a new 55 mm Petri dish. All treated gauze squares containing lice were placed under normal environmental conditions (30 +/- 2°C; 15% relative humidity) during the remaining test period (15 min). Following exposure, insects and gauze were washed using a bland frequent use toiletry shampoo (dilution 1:15 in water) and consequently rinsed with 500 ml warm (35° C) tap water, poured through and over the gauze squares. They were then dabbed dry using medical wipe tissue and placed under normal environmental conditions in plastic Petri dishes with appropriate size until results were assessed. The same procedure has been applied for the negative control, using tap water instead of the test formulation. All products (including the negative control) were exposed for 15 min before washing, as described above.

Result recording

Lice were observed to assess the effects of each individual product 1 and 2 hours following exposure and the morning after. The assessment after 1 hour and 2 hour instead of after 15 minutes serves as a control for the revival of any immobilized lice. Lice are categorized as 'living', 'moribund' and 'immobile', respectively. 'Immobile' refers to a state of no movement at all, 'moribund' describes slight uncoordinated movement and 'Alive' is used to describe lice with full movement.

Results

As shown in table 1, the three test formulations completely immobilized all lice following exposure. In other words, a 100% mortality rate is obtained within 1 hour after being washed off. In contrast, in the negative control group, 24 of 28 lice were still walking around, yielding a mortality rate of only 14.2%. Identical results were observed at the 2h reading (cfr. table 2) for all test formulations except for the control group. One additional louse ceased movement, resulting in an overall “mortality” of 17.8%.

Table 1 – Assessment of lice viability 1h after washout post 15 min exposure.

Test product	Number of lice				
	Total	Living	Moribund	Immobile	% Mortality
X92001306	33	0	0	33	100
Elimax lotion	20	0	0	20	100
X92000850	32	0	0	32	100
Negative control	28	24	1	3	14.2

Table 2 – Assessment of lice viability 2h after washout post 15 min exposure.

Test product	Number of lice				
	Total	Living	Moribund	Immobile	% Mortality
X92001306	33	0	0	33	100
Elimax lotion	20	0	0	20	100
X92000850	32	0	0	32	100
Negative control	28	23	1	4	17.8

The next morning (+/- 18h later), final reading demonstrated that all three formulations remained active against lice, achieving 100% mortality (cfr. table 3). In the control group, only 39.2% mortality was observed, which is extremely low in relation to the time that the lice were deprived of their natural environment.

Table 3 – Assessment of lice viability 18h after washout post 15 min exposure.

Test product	Number of lice				
	Total	Living	Moribund	Immobile	% Mortality
X92001306	33	0	0	33	100
Elimax lotion	20	0	0	20	100
X92000850	32	0	0	32	100
Negative control	28	17	3	8	39.2

CONCLUSION

The above-described experimental data demonstrate that lice, once treated, consistently remain immobile throughout all observation time points. The conclusion is that the three formulations, including Elimax lotion, exhibit the highest efficacy against head lice.