

## Soya oil-based shampoo superior to 0.5% permethrin lotion for head louse infestation [Corrigendum]

Burgess IF, Kay K, Burgess NA, Brunton ER. *Med Devices (Auckl)*. 2011;4:35–42.

In March 2011 we published a report of a clinical study investigating the efficacy of a shampoo for the treatment of head louse infestation.<sup>1</sup> The report stated that the shampoo used contained, as an active component, 1% soya oil. However, it has now come to light that this product may have a considerably different formulation, and possibly contained no soya oil at all.

The sponsor of the study had been supplied for some years with the ready manufactured shampoo from a third party via a contract manufacturer. That third party was, at the time, a combined organization consisting of a commercial medical device company and a private research institute. The Certificates of Analysis for the samples delivered for use in the clinical study were signed off by what we were told was a qualified person (QP) from the private research institute, stating that the product complied with the specification that had been supplied to us when we drew up the protocol, i.e. the product contained 1% soya oil together with purified water, sodium laureth sulfate, cocamidopropyl betaine, hydrolyzed collagen, glycosphingolipids, and geranium as excipients.

Subsequent to publication the combined organization underwent a falling out so that the medical device company and the private research institute went their separate ways. At some point the new management of the medical device company reviewed the products that were being manufactured on their behalf and discovered inconsistencies between the original technical documentation for the shampoo formulation and the analytical documentation that was operating in practice.

The original technical documentation from 2002 showed that the formulation should contain the components listed in our protocol, with the exception that the soya oil content was supposed to be 2% rather than 1%. Other components were listed by their proportions (Table 1). However, the analytical documentation from the contract manufacturer showed a completely different formulation, with no soya oil included.

Consequently, there is the possibility that the Certificates of Analysis were falsely compiled and the QP was fooled by this or alternatively the QP was aware of the discrepancy and signed it incorrectly. In either scenario we were misled.

As a result of this discovery the sponsor of the clinical study withdrew the product from the market immediately. We have now drawn up this corrigendum, which we believe is necessary because we have no clear idea which, if any, of these formulations was used in the clinical study, although it is likely the shampoo contained no soya because it smelled of geraniol, which would fit with the non-soya formulation. Therefore, we believe it is incumbent upon us to inform readers of this problem.

In order to make this clear to all readers of the report we believe the product should no longer be identified as “Soya oil based shampoo” in the title of the study. How this material should now be identified is unclear, perhaps “High-foaming sodium laureth sulfate-based shampoo”?

Whatever the case, we apologize for inadvertently misleading all those who have read and downloaded the article into

**Table 1** Specifications for the original soya shampoo and the shampoo at time of withdrawal

Technical document 2002	Components by name	Analytical documentation
82.20%	Water	78.38%
10.00%	Sodium laureth sulfate	13.49%
4.00%	Cocamidopropyl betaine	1.53%
2.00%	Soybean oil/glycine soya	–
1.00%	Hydrolyzed animal protein/hydrolyzed collagen	–
–	Laurdimonium hydroxypropyl/hydrolyzed collagen	0.12%
0.50%	Glycoceramide/glycosphingolipids	–
–	Perfume/etheric oils	0.30%
–	Potassium hydroxide	0.40%
–	Cocamide diethanolamine	0.65%
–	2-hexyldecanol	0.50%
–	Caprylic acid	3.01%
–	Hydrolyzed wheat protein	0.10%
–	Preservative	0.02%
–	Sodium chloride	1.50%

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believing that soya oil can contribute towards elimination of head louse infestation.

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## Reference

1. Burgess IF, Kay K, Burgess NA, Brunton ER. Soya oil based shampoo superior to 0.5% permethrin lotion against head louse infestation: randomized clinical trial. *Med Devices (Auckl)*. 2011;4:35–42.

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