2 STUDY SYNOPSIS

Name of Sponsor/Company: Dermal Laboratories		
Name of Finished Product: Doublebase Emollient Bath Additive		
Title of Study: Arm immersion test to compare the skin effects of routine bathing with and without the use of an emollient bath additive		
Investigator: V. A. Hart Medical Investigator: Dr S Louth		
Study centre: RSSL, Science & Technology Centre, The University of Reading, Earley Gate Entrance, Whiteknights Road, Reading, Berkshire, RG6 6BZ.		
Publication (reference): None		
Studied period: (date of first enrolment) (date of last completed)	15 days 7 June 2010 28 June 2010 (Testing phase)	Clinical Phase: IV
Objective: The objective of the study was to compare, using objective instrumental efficacy endpoints, and under controlled laboratory conditions simulating normal clinical use, the effects on skin condition of repeated daily bathing with, and without, addition of an emollient bath additive.		
Methodology: The study was an assessor-blind, single-centre, randomised study using controlled laboratory conditions designed to mimic normal bathing in clinical use. Subjects followed a bathing routine that involved immersing one hand and forearm for 20 minutes in a tank of warm tap water with added bath emollient (to simulate bathing with the bath emollient according to its label instructions), and the other hand and forearm in a tank of warm tap water alone (to simulate bathing without added emollient). Subjects repeated this immersion (bathing) at the test centre, once daily, for 14 consecutive days. Corneometer, pH and TEWL measurements, and subjects' assessments of their skin condition were performed at specified time points over the 14 day period.		
Number of subjects (planned and analysed): 12 planned and analysed		
Diagnosis and main criteria for inclusion/exclusion: **Inclusion criteria:** 1. Male or female 2. Between 18 and 65 years of age 3. History of eczema and presenting with dry skin on the arms and hands 4. Written informed consent obtained and witnessed 5. Prepared to refrain from using moisturisers and moisturising soaps on arms and hands in the week prior to the study and for the duration of the study		

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Exclusion criteria:

1. Any significant concurrent illness or skin disease at the test sites
2. History of other skin disease or allergy relevant to the study
3. Subjects who have known allergies to the test product or its ingredients
4. Use of any topical or systemic medication or drug likely to affect the skin or its response to treatment
5. Eczema visually differing in severity between left/right test sites
6. Any significant visible skin abnormality at the test site
7. Participation in an irritation test, on the same skin site, in the past month, or a sensitisation test, on any skin site, during the past 3 months
8. Females who are lactating, or are pregnant, or are not taking adequate contraceptive precautions during their time in the study. (N.B there are no safety concerns at all regarding these groups using the bath additive – their exclusion is simply because it is generally considered inappropriate for them to take part in clinical trials. Negative pregnancy testing is not necessary, and there are no safety concerns, as such, about female subjects potentially conceiving while taking part in the study).
9. Concurrent participation in any other safety test
10. Any irritation, tattoos, scars or birthmarks at the test sites
11. Use of any unlicensed medicine within the previous 30 days
12. Employees of RSSL Pharma or Dermal Laboratories, or an immediate family member (partner, offspring, parents, siblings or sibling's offspring) of an employee.

Test product, dose and mode of administration, batch number:

Doublebase Emollient Bath Additive, as supplied, topical – (batch number – W9125)

Duration of treatment:
14 daily immersions.

Reference therapy, dose and mode of administration, batch number:
Water, topical – (Batch number N/A)

Criteria for evaluation:

Efficacy:

Skin moisturisation by measurements of skin hydration (corneometry).

Skin barrier damage by measurements of TEWL (Trans Epidermal Water Loss, using TEWAMeter).

Skin pH (pH Meter)

Subject Questionnaires

Safety:
Adverse effects.

Statistical methods:

Paired Student T-tests with Proc GLM in SAS and Wilcoxon's rank-sum test with Proc NPAR1WAY in SAS.

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SUMMARY

EFFICACY RESULTS: - Primary
Corneometry
For the Corneometry, the mean readings for each arm site and the hand site over the study period indicated very little change in values for the dorsal and volar forearm, the dorsal hand had a greater increase in readings which was marginally greater for the treated hand than the control hand however the difference is not clinically significant.

pH
For the pH readings there was generally an approximately one point increase in pH between baseline and 1 hour and baseline and day 12, 1 hour reading for all sites. This was true for both the treated hand/arm and the control indicating very little change to skin pH due to the test product.

TEWL
For TEWL, there was increase in TEWL reading for both the test and control sites indicating that there was no significant deterioration in skin condition for either the test or control treatment, however the change was very slightly greater for the treated side for each location.

EFFICACY RESULTS: - Secondary
Subject opinion of change in skin condition although unblinded, showed that the treated arms generally had higher means on most days.

For Skin Smoothness, Tightness and Overall Condition there is evidence ($p<0.05$) that a difference can be detected in favour of the treated arms for skin smoothness and overall condition.

From the frequency tables it can be seen that the responses of the five rating questions do appear to have a slight bias, subjects who had their left arm treated being more likely to associate typical emollient attributes with that arm. This pattern is repeated in the final question, where all 6 subjects who had the left arm treated find that treatment beneficial, while only 4 of the subjects who had the right arm treated report a benefit to that arm.

SAFETY RESULTS:
There were 21 adverse events suffered by 9 subjects. All with the exception of 5 adverse events suffered by 2 subjects were considered to be mild in severity and not related to test participation. The 2 subjects (007 and 009) who suffered possibly related AE's had sensations to the untreated arm of itching or tightness on the hand, however subject 007 also had a sensation on the treated and untreated dorsal forearm. All events are presented in table 15.

CONCLUSIONS

Under the conditions of the test there was some evidence that there were statistically significant improvement in skin condition in terms of moisturisation for the treated arm, however, the overall differences were small with the exception of the dorsal hand and the increases were similar for both the treated and control sites. pH showed statistically significant differences with the control arm showing less difference from baseline however, again the differences were small. TEWL showed no statistically significant differences between the test and control arms.

Consumer opinion of the treatments, which was not blind to the subjects, was that in almost all cases the subjects considered the treated arm to be smoother and had better overall skin condition.

Date of report: 10 January 2012