2 STUDY SYNOPSIS

Name of Sponsor/Company: Dermal Laboratories Ltd		
Name of Finished Product: Dermal Wash		
Title of Study: A study to determine the effects on stratum corneum of a clinical hand cleansing protocol comparing two antiseptic hand washes, using non-invasive instrumental methods in human volunteers.		
Investigator: V. A. Hart		
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)	2 x 5 days 24 February 2010 12 March 2010 (Testing phase)	Clinical Phase: IV

Objectives:

Using a hand cleansing protocol designed to mimic the frequent hand cleansing regimen typically followed by healthcare professionals, the objective was to compare the effects on skin condition of two antiseptic hand washes in combination with an alcohol cleansing rub.

The primary objectives were to compare changes in skin condition: a) by visual assessment of signs and symptoms measured by a trained investigator; and b) by subjects' assessments of how their skin feels.

The secondary objectives were to compare changes in skin condition: c) by skin hydration using corneometry, d) by transepidermal water loss using TEWL, and e) by measurement of skin pH.

The tertiary objective f) was to compare consumer satisfaction via questionnaire responses.

Methodology:

This was a single-centre, assessor-blind, parallel group comparison conducted in a panel of 40 healthy, adult volunteers. Half the subjects used the test antiseptic wash, the remainder used the comparator wash, Hibiscrub. On days 1, 3 and 5 subjects attended the test centre for the whole day. Washes were done 13 times between approximately 10 am and 4 pm, at half-hourly intervals. Alcohol rub was used 24 times - 10 and 20 minutes after each wash. For days 2 and 4 subjects did not attend the test centre and performed their washes at home. For these two days 7 washes were performed hourly, between approximately 10 am and 4 pm. Alcohol rub was used 12 times - 20 minutes and 40 minutes after each wash.

Number of subjects (planned and analysed):

40 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. Written informed consent obtained and witnessed

Name of Sponsor/Company: Dermal Laboratories **Name of Finished Product:** Hand Wash Dermal Wash		

Exclusion criteria:

1. Females who were pregnant or lactating or if of childbearing potential were not taking adequate contraceptive precautions (although it is generally considered inappropriate for this group to take part in trials, there are no safety concerns regarding these groups)
2. Concurrent skin disease or history of skin disease or allergy relevant to the study
3. Subjects with known allergies to the test products, the alcohol rub or to any of their ingredients
4. Use of any topical or systemic medication or drug likely to affect skin response
5. Any significant visible skin abnormality or excessive hair growth at the test measurement sites
6. Participation in a test, on the same skin site, in the past month
7. Concurrent participation in any other safety test
8. Any irritation, tattoos, scars or birthmarks at the test sites
9. Employees of RSSL Pharma or Dermal Laboratories, or an immediate family member (partner, offspring, parents, siblings or sibling's offspring) of an employee.
10. Any other medical condition which in the judgment of the Investigator would put the subject at unacceptable risk for participation in the study.
11. Any other person in the same household as the subject taking part in the study

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

Dermal wash, as supplied, used as a hand wash – batch number DERL0210.
Spirigel Alcohol rub, as supplied, used as a hand rub – batch number BN5399LE3

Duration of treatment:

The semi-intensive hand cleansing regime continued for 5 consecutive days

Reference therapy, dose and mode of administration, batch number:

Hibiscrub, as supplied, used as a hand wash - batch number – LOT:2AA.
Spirigel Alcohol rub, as supplied, used as a hand rub - batch number BN5399LE3

Criteria for evaluation:

Primary:
Assessment of skin condition a) by investigator, b) by subjects
Secondary:
Instrumental measurements of skin condition c) by corneometry (hydration), d) by TEWL (leakiness) and e) by pH
Tertiary:
Consumer acceptability via questionnaire responses.

Safety:
Adverse effects.

Statistical methods:

Wilcoxon's rank-sum test with PROC NPAR1WAY, and Student T-Tests.

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SUMMARY RESULTS

Primary:

a) Investigator assessments identified scarcely any erythema. Slight clinical dryness was observed, generally only the hands, and in the Hibiscrub group where statistically significant ($p \leq 0.02$) deterioration was evident at the end of 'intensive' days 1, 3 and 5.

b) By the end of treatment, 60% of subjects' in the Dermal wash group assessed their skin condition as mostly feeling 'slightly worse than before the study', as compared to 70% of the Hibiscrub group who assessed this as mostly feeling 'much worse than before the study'. This difference between the treatments was highly significant ($p = 0.001$).

Secondary:

c) In the Dermal wash group, highly statistically significant ($p < 0.009$) *improvements* in hand skin hydration were measured at all time points (19% by the end of day 5). In the Hibiscrub group, highly statistically significant ($p = 0.0023$) *deterioration* in hand skin hydration occurred over this period (18% by the end of day 5). This difference between the treatments was highly significant ($p < 0.0006$).

d) pH measurements in the Dermal wash group showed a tendency to increase (deteriorate) slightly by the end of day 1 and then return to baseline by the end of day 5. In the Hibiscrub group, highly statistically significant ($p \leq 0.0013$) increases in pH were measured by the end of day1, and tended to decline thereafter but with a tendency for higher values at the end of the 'intensive' days 3 and 5.

e) For both treatment groups, highly statistically significant ($p \leq 0.0026$) increases in TEWL were measured by the end of day 5.

Tertiary:

f) Subjects' questionnaire responses generally showed Dermal wash to be statistically more acceptable than Hibiscrub, both in terms of overall liking and numerous specified physical and in use attributes.

SAFETY

15 adverse reactions as such, comprising early signs/symptoms of hand dermatitis, were reported: 13 in the Hibiscrub group and 2 in the Dermal group. As a consequence, 6 subjects withdrew or were withdrawn: 5 in the Hibiscrub group and 1 in the Dermal group.

CONCLUSIONS

Dermal Wash was shown to be significantly more skin friendly than Hibiscrub, making it a more attractive antiseptic hand wash for professional use by healthcare workers who are therefore more likely to use it as frequently as necessary in the clinical setting and with less risk of hand dermatitis developing.

Date of report: **November 2010**