

2 STUDY SYNOPSIS

Name of Sponsor/Company: Dermal Laboratories		
Name of Finished Product: Hand Wash Dermol 500 Lotion		
Title of Study: A Study to Compare the Effects on Stratum Corneum of two medical hand wash formulations, using Non-Invasive Instrumental Methods in Human Volunteers.		
Investigator: V. A. Hart		
Study centre(s): RSSL		
Publication (reference): None		
Studied period:	2 x 8 days (date of first enrolment) 6 June 2008 (date of last completed) 30 June 2008	Clinical Phase: IV
Objectives: The objective was to compare the potential for Dermol 500 Lotion and Hibiscrub, when used repeatedly as a 'professional' antiseptic hand wash soap substitute, to <u>not</u> cause deterioration in skin condition. The primary objective was to compare changes in skin condition by skin hydration (corneometry) measurements. The secondary objective was to compare changes in skin condition by Transepidermal Water Loss (TEWL) measurement and by visual assessment of skin signs and symptoms The tertiary objective was to compare user satisfaction via questionnaire responses.		
Methodology: The study was a single-centre, double-blind parallel group comparison of the effects on skin condition of washing the hands and forearms 7 times daily for 7 consecutive days with the test and control products.		
Number of subjects (planned and analysed): 40 planned, 39 analysed		
Diagnosis and main criteria for inclusion: Inclusion criteria: 2. Male or Female 3. Between 18 and 65 years of age 4. Written informed consent obtained and witnessed Exclusion criteria: 1. Females who are pregnant or lactating (although it is generally considered inappropriate for these groups to take part in trials, there are no safety concerns regarding the use of either product in these groups) 2. History of skin disease or allergy relevant to the study 3. Subjects who have known allergies to the test products or 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 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 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.		

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Name of Finished Product: Hand Wash Dermol 500		
Test product, dose and mode of administration, batch number: Dermol 500, as supplied, topically - (batch number -ES57/16)		
Duration of treatment: 7 daily washes for 7 consecutive days		
Reference therapy, dose and mode of administration, batch number: Hibiscrub, as supplied, topically - (batch number -ES57C/1)		
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). Visual assessment of skin condition, signs and symptoms. Consumer acceptability via questionnaire responses. Safety: Adverse effects		
Statistical methods: Wilcoxon's rank-sum test with PROC NPAR1WAY, and Student T-Tests.		
SUMMARY – CONCLUSIONS EFFICACY RESULTS: Following repeated washing with either product, there were no deleterious effects that were measurable by either corneometry or TEWL. Investigator assessments showed some evidence of mainly slight erythema and dryness, and this was significantly more prevalent with Hibiscrub than with Dermol 500. Participants' subjective feedback also showed greater satisfaction with Dermol 500 Lotion than with Hibiscrub. SAFETY RESULTS: Five subjects using Hibiscrub experienced sore elbows, itching, dryness and / or skin tightness. Two subjects using Dermol experienced itching and / or skin tightness		
CONCLUSIONS Dermol 500 was generally shown to be more skin friendly than Hibiscrub, making it a more attractive antiseptic hand wash for professional use by healthcare workers who are more likely to use it as frequently as necessary in the clinical setting and with less risk of hand dermatitis developing		
Date of report: 3 April 2009		