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Our Ref: MRN/VEN/L

Your Ref:

28 July 2004

The Skin Care Company Ltd  
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For the attention of Mr B Collins

TESTING FOR EFFICACY OF 'DERMAGUARD' SKIN PROTECTION LOTION

Other Names of Product:

DermaProtekt  
SkinProtect  
Skin Shield

## Summary

In vitro and in vivo tests have been performed on 'DermaGuard' Skin Protector and evidence has been found in support of the labelled claims of the Product, except that one claim is considered presently to be slightly overstated.

## Product Claims and the Aims of the Testing

In vitro and in vivo tests have been developed for the purposes of testing DermaGuard against its various claims. The claims on the labelling concerning use and efficacy are as follows:-

- (1) Moisturises whilst protecting
- (2) Prevents odours clinging to skin
- (3) Helps prevent nappy rash
- (4) Use at home, at work, in recreation, DIY, hobbies, crafts and gardening
- (5) Protects under rubber or latex gloves
- (6) Helps prevent dermatitis
- (7) Remains effective, even after washing with ordinary soap and water
- (8) Will not block pores
- (9) Allows skin to breathe
- (10) Gives protection from water, detergents, soaps, bleach, chemicals, oils, dirt, soils, fertilisers and many other skin irritants.

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Testing for Efficacy of 'DermaGuard' Skin Protection Lotion

Product Claims and the Aims of the Testing (Continued)

General barrier properties are required for Claims 2, 3, 4, 5, 6, 7 and 10 and the reports below of in-vitro and in-vivo testing are generally concerned with the extent of barrier properties. In addition, the ability to allow air to pass a film of the Product has been tested, which is a requirement or part-requirement of Claims 3, 5, 8 & 9. Claim 1 has been tested subjectively in the in-vivo tests.

In-Vitro Testing of Barrier Properties

A layer of approximately 1 mm of the Product was spread onto 26 mm diameter filter papers (Whatman No 4, 20 - 25 micron porosity). The coated papers were each allowed to dry at 30°C for 1 hour and were each placed into a filter housing, fed by a vertical length of plastic or rubber tubing and a funnel, acting as a fluid reservoir.

Using this apparatus, a head of test liquid was introduced, in such a manner that the liquid was in full contact with a coated filter paper and filled the tubing and funnel to a head of 230 mm (3.1 kPa for water), without presence of air bubbles. Various liquids were tested at this head pressure, in order to determine the time for which no passage of liquid was observable. Times in excess of 24 hours are shown as such.

The results were as follows:-

Fluid (Note No)	Time prior to passage of fluid
Water	>24 hours
Sunflower Oil	2 hours
5% Detergent Powder in Water (1)	12 hours
1% Soap Powder in Water (2)	>24 hours
25% Bleach Solution in Water (3)	1 hour 10 minutes
2% Ammonia in Water	>24 hours
2% Hydrochloric Acid in Water	12 hours
Concentrated Fertiliser (4)	3¼ hours
Petrol (Lead-free)	approx 1 minute
Light Liquid Paraffin	50 minutes
Paint Brush Cleaner (5)	10 minutes
5% Washing-Up Liquid in Water (6)	12 hours

Notes

- (1) 'Daz' handwash and twin tub variety of Proctor & Gamble, UK.
- (2) 'DP Soap Flakes' of Dripak Ltd
- (3) 'Parazone' thick bleach variety of Jeyes Ltd
- (4) 'Miracle-Gro' concentrated outdoor plant food variety of The Scots Co (UK) Ltd.
- (5) 'Paint Brush Cleaner' own brand of Wilkinson Ltd
- (6) 'Fairy Liquid' of Proctor & Gamble UK.

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In-Vitro Testing of Air-Passage

In similar manner to the above testing of barrier properties, a 1 mm layer of the Product was spread onto a 44 mm diameter filter paper (Whatman No 4) and was allowed to dry at 30°C for 1 hour. The paper was then mounted in a filter housing and subjected to an air pressure provided by a syringe and weight. In this manner, it was found that air slowly passed the DermaGuard film, when subjected to the pressure provided by a 500 g weight (approximately equivalent to a pressure of 3.3 kPa for the diameter of the paper employed).

In-Vivo Testing of Barrier Properties

A limited panel (4 members) were tested for odour retention on the backs of hands. DermaGuard was first massaged into the skin of one hand until dry. The area of both hands was rubbed with (1) fresh-cut onion and in totally separate with (2) motor-petrol. The areas on both hands were then washed with soap and water, dried by towel and then compared for odour. The panel member then provided a subjective assessment as to any reduction in odour between their DermaGuard-treated and untreated hands.

<u>Panel Member</u>	<u>Reduction of Odour*</u>	
	<u>For Onion</u>	<u>For Petrol</u>
1	++	+
2	++	+
3	++	+
4	++	+

\* Total loss of odour = +++

Strong reduction in odour = ++

Slight reduction in odour = +

No reduction in odour = -



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In-Vivo Testing of Barrier Properties (Continued)

In similar manner, the panel also tested for staining of the skin by red dye (0.1 % aqueous E124, Ponceau 4R solution) and wet garden soil. After washing of the hands, the skin was inspected for the degree of staining as compared to that obtained on the untreated hands. In a further experiment, the hand pre-treated with DermaGuard was lightly washed with soap and water and the experiment with the red dye solution was repeated in the same manner as above.

The results were assessed as follows:-

Panel Member	Reduction in Staining* after DermaGuard application	
	Red Dye Solution	Garden Soil
1	+++	+++
2	++	+++
3	++	+++
4	+++	+++

Panel Member	Reduction in Staining* after DermaGuard application and washing in soap and water	
	Red Dye Solution	
1	+	
2	+	
3	+	
4	+	

* No staining observed	=	+++
Faint staining observed, much reduced compared to staining on untreated hand	=	++
Staining observed, but slightly less than untreated hand	=	+
Staining observed, with no appreciable difference from untreated hand	=	-

In these tests, all members of the Panel noted that a pleasant lubricity was imparted to the skin by DermaGuard, similar to that provided by 'moisturising' cosmetic creams.

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Testing for Efficacy of 'DermaGuard' Skin Protection Lotion

Discussion of Results

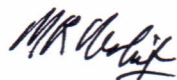
The above fluid in-vitro tests are considered to confirm that DermaGuard provides general barrier properties to the skin. A reasonable barrier was observed for oils, detergent and soap solutions and chemicals such as Hypochlorite Bleach, Ammonia, Hydrochloric Acid, Concentrated Fertiliser, Paraffin and Paint Brush Cleaner. The degree of resistance varied and for Petroleum, the barrier properties (under a slight pressure) were very weak, at only 1 minute's resistance. Similarly, for the Paint Brush Cleaner, the barrier only held for 10 minutes. In use on the hands, with no appreciable pressure, excellent barrier properties can be expected for most of the tested liquids, and some degree of barrier properties for the Paint Brush Cleaner but minimal for Petroleum. It is to be noted that Petroleum is not stated on the claims. It is considered that Claims 4 and 10 are proved worthy by these tests and also Claims 3 & 6, since nappy rash is usually associated with Ammonia contact on the skin and dermatitis with direct contact of sensitising agents.

The in-vitro test for passage of air indicated that a thin film of DermaGuard does allow such passage. This test supports claims 5, 8 & 9.

The in-vivo tests demonstrated that the odour of onion after application to the skin was strongly reduced by the presence of DermaGuard. The odour of Petroleum was only slightly reduced, again demonstrating that DermaGuard is not a perfect barrier to this substance, but does provide some resistance to its absorption. In these tests, a generally effective barrier against staining by wet earth was demonstrated. It was further found that following DermaGuard application, a strong red dye solution only yielded faint staining on some hands and none on others, against bright red staining when DermaGuard was not employed. This resistance to staining however, was reduced after pre-washing (soap and water) of the DermaGuard-treated hand. The panel members also noted cosmetic 'moisturising' properties.

It is thus considered that these in-vivo tests provide general support for Claims 1, 2, 4, 7 & 10, but suggest that Claim 7 is somewhat overstated.

It is thus concluded that evidence has been provided for the labelled efficacy claims of DermaGuard. The claim: 'remains effective, even after washing with ordinary soap and water' however is considered to require some qualification as some protection is clearly lost. A statement such as 'Even after washing with ordinary soap and water, some barrier properties are retained' is considered warranted.



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