

Evaluation of the bactericidal activity of two antiseptic emollient formulations against *Streptococcus pyogenes*

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Introduction and Objective

Streptococcus pyogenes (*S. pyogenes*), also known as the 'flesh-eating' bacteria, is the cause of group A streptococcal infections that usually start on the surface of the skin or in the throat. From there, the bacterium can spread into deeper areas of the skin causing illnesses such as impetigo, cellulitis and necrotizing fasciitis.

The objective of this study was to investigate the *in vitro* activity of two commercially available antiseptic skin products, Dermol Lotion™ (DERL) and Dermol Cream™ (DERC), against *S. pyogenes* NCTC 10872.

Both DERL and DERC are UK licensed antiseptic emollients indicated for the treatment of dry and pruritic skin conditions, especially eczema and dermatitis, and for use as soap substitutes. They have been specially developed for their antimicrobial action and lack of topical irritancy. This is achieved by the inclusion of two antiseptic ingredients, namely chlorhexidine dihydrochloride and benzalkonium chloride, at a relatively low concentration of only 0.1% w/w, as their antimicrobial activity was shown to be synergistic. Furthermore, a non-ionic soap substitute is used in the formulation, thus avoiding the irritant effect of ordinary anionic soaps and detergents, whilst still providing cleansing properties.

Materials and Methods

- The suspension test protocol used was based on the European Standard for evaluating the bactericidal activity of chemical disinfectants and antiseptics (BS EN 1276:2009).
- This stringent standard requires a large reduction in microbial count (at least 5 log) within 5 minutes contact time with the test substance at 20°C in both clean and dirty conditions.
- One bacterial strain was tested, *S. pyogenes* NCTC 10872.
- Both DERL and DERC were tested undiluted.
- Interfering substance was bovine serum albumin (BSA) at 0.3 g/l (clean conditions) and 3 g/l (dirty conditions).
- In summary, 1ml of *S. pyogenes* suspension (containing 2.9×10^8 cfu/ml) was added to 1ml of 0.3 g/l BSA or 3 g/l BSA. Following incubation for 2 minutes, 8ml of each test product was then added to each challenge and mixed. After specified contact times (5 min, 10 min and 20 min) aliquots were added to neutraliser and water, mixed, left for 5 minutes, then the number of surviving bacteria determined and the reduction in viable counts calculated.

Results and Discussion

Within 5 minute contact time, DERL lotion met the requirement under both clean and dirty conditions, and DERC cream passed under clean conditions only (Table 1). Both DERL and DERC exhibited satisfactory bactericidal activity (>5 log reduction) within 10 and 20 minutes contact time under both clean and dirty simulated conditions.

Table 1. Bactericidal activity of DERL lotion and DERC cream against *S. pyogenes*

Test Product	Contact Time (min)	Log Reduction	Log Reduction	BS EN 1276 Pass requirement	Pass/Fail
		Clean	Dirty		
DERL	5	>5.0	>5.0	≥5.0	Pass
DERL	10	>5.0	>5.0	≥5.0	Pass
DERL	20	>5.0	>5.0	≥5.0	Pass
DERC	5	>5.0	<5.0	≥5.0	Fail
DERC	10	>5.0	>5.0	≥5.0	Pass
DERC	20	>5.0	>5.0	≥5.0	Pass

The EN 1276 is a particularly stringent standard as it requires a very significant reduction in microbial count (≥5 log) within only 5 minutes. To put this into perspective, this equates to reducing an initial bacterial count of one hundred and fifty million cfu/ml by 99.999%. This standard is normally applied to disinfectants used in non clinically-sensitive circumstances where 'skin friendliness' is not a priority. The performance of DERL and DERC is therefore all the more remarkable because the formulations were specially developed for chronic use on sensitive skin owing to their lack of irritancy.

Conclusion

The results of this test confirm that topical antiseptic emollient products, Dermol Lotion™ and Dermol Cream™, are effective *in vitro* against *S. pyogenes*.

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Streptococcus pyogenes (*S. pyogenes*), also known as the 'flesh-eating' bacteria, is the cause of group A streptococcal infections. These usually start on the surface of the skin or in the throat and can spread into deeper areas of the skin causing illnesses such as impetigo, cellulitis and necrotizing fasciitis.

Dermol Lotion and Dermol Cream are topical antimicrobial emollients and soap substitutes, licensed for the treatment of dry and pruritic skin conditions, especially eczema and dermatitis. They have been specially developed for their antimicrobial action and lack of topical irritancy. This is achieved by the inclusion of two antiseptics, chlorhexidine dihydrochloride and benzalkonium chloride, that work synergistically and so are present at the low but effective level of 0.1% each.

The study summarised overleaf shows that, tested *in vitro*, Dermol Lotion and Dermol Cream are effective against *S. pyogenes*.

Summary of Poster Overleaf:

- This study was based on the stringent European Standard for evaluating the bactericidal activity of chemical disinfectants and antiseptics used in non clinically-sensitive circumstances where 'skin-friendliness' is not a priority (BS EN 1276:2009).
- This standard requires a large reduction in microbial count (at least 5 log) within 5 minutes contact time with the test product, Dermol Lotion or Dermol Cream, in both clean and dirty simulated conditions (i.e. the addition of bovine serum albumin at 0.3 g/l (clean conditions) and 3 g/l (dirty conditions)).
- Within 5 minute contact time, Dermol Lotion met the required criteria of ≥ 5 log reduction in *S. pyogenes*, under both clean and dirty conditions, and Dermol Cream passed under clean conditions only (5 log reduction = 99.999%).
- Both Dermol Lotion and Dermol Cream exhibited satisfactory bactericidal activity (>5 log reduction) within 10 and 20 minutes contact time under both clean and dirty simulated conditions.

Conclusion:

"The results of this test confirm that topical antiseptic emollient products, Dermol Lotion and Dermol Cream, are effective *in vitro* against *S. pyogenes*."

PRESCRIBING INFORMATION.

Dermol® 500 Lotion

Benzalkonium chloride 0.1% w/w,
chlorhexidine dihydrochloride 0.1% w/w,
liquid paraffin 2.5% w/w,
isopropyl myristate 2.5% w/w.

Dermol® Cream

Benzalkonium chloride 0.1% w/w,
chlorhexidine dihydrochloride 0.1% w/w,
liquid paraffin 10% w/w,
isopropyl myristate 10% w/w.

Uses: Antimicrobial emollients for the management of dry and pruritic skin conditions, especially eczema and dermatitis, and for use as soap substitutes.

Directions: Adults, children and the elderly: Apply direct to the dry skin or use as soap substitutes.

Contra-indications, warnings, side-effects etc: Please refer to SPC for full details before prescribing. Do not use if sensitive (especially generalised allergic reaction) to any of the ingredients or a possible history of allergic reaction to a chlorhexidine compound. In the unlikely event of a reaction stop treatment. Keep away from the eyes. Take care not to slip in the bath or shower.

Package quantities, NHS prices and MA numbers:

Dermol 500 Lotion: 500ml pump dispenser £6.04, PL00173/0051.

Dermol Cream: 100g tube £2.86, 500g pump dispenser £6.63, PL00173/0171.

Legal category: P

MA holder: Dermal Laboratories, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR, UK.

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'Dermol' is a registered trademark.

Adverse events should be reported.
Reporting forms and information can be found
at www.mhra.gov.uk/yellowcard. Adverse events
should also be reported to Dermal.