

**DEVELOPMENT DEPARTMENT REPORT APPROVAL**

<b>Title: Claims Substantiation for Cetraben Daily Facial Cleanser</b>		
<b><u>DLR/2433</u></b>		
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**Introduction**

Cetraben Daily Facial Cleanser is a new product based on Cetraben Daily Cleansing Cream with an alternative preservation system. Substantiation of the desired claims is required and as none of the claims are novel for the product type or comparative in nature, substantiation via a literature review is considered adequate.

**Formulation**

<b>Ingredient</b>	<b>%w/w</b>
Purified Water	71.9
Paraffin White Soft	12
Liquid Paraffin	4.8
Polysorbate 60	1.44
Disodium Cocoamphodiacetate	2
PPG-5-Ceteth-20	1
Cetostearyl Alcohol	5.76
Phenoxyethanol	1
Citric Acid Monohydrate	0.1

**Justification of Claims**

<b><u>Claim</u></b>	<b><u>Justification</u></b>
<b>For dry skin &amp; also suitable for eczema prone skin</b>	<p>“For dry skin” is supported by the formulation, it contains emollients; Paraffin White Soft Liquid and Liquid Paraffin, which are widely used in the treatment of Eczematous Dermatitis and related dry skin conditions.</p> <p>For “suitable for eczema prone skin”; these emollients; which act locally at the site of application to soothe, smooth/soften and hydrate the skin, by forming an occlusive film on the stratum corneum, (Paraffinum Liquidum) forms a thin layer, protecting the skin from further water loss.[1].</p>
<b>Gentle and non-drying</b>	<p>“Gentle” is supported by the formulation; contains a blend of mild surfactants and doesn’t disrupt the pH of the acid mantel. The outer layer of the stratum corneum, the barrier is slightly acidic pH (4.5 to 6.5), these slightly acid layers of the moisture barrier are known as the acid mantel. If the pH of the acid mantel is disputed, (becomes alkaline), the skin becomes prone to dehydration, roughness and noticeable flaking, therefore, if the pH of the formula is slightly acidic it won’t exhibit dryness in the skin.[2]</p> <p>“Non-drying” is supported by the formulation; contains mineral oil (Paraffinum Liquidum) which forms a thin occlusive layer, protecting the skin from water loss [3].</p>

<b><u>Claim</u></b>	<b><u>Justification</u></b>
<b>Soothes, softens and hydrates skin</b>	<p>“Soothe” is supported by the moisturising/hydrating properties of mineral oil (Paraffinum Liquidum) which has emollient and skin moisturising properties (via occlusivity) [1].</p> <p>“Soften” is supported by the positive effects that mineral oil has on improving skin elasticity [4].</p> <p>“Hydrates skin” is supported by the formulation; contains mineral oil (Paraffinum Liquidum) which forms a thin occlusive layer, protecting the skin from water loss [1]. The application of a product containing emollients and moisturising ingredients will provide an immediate hydration benefit by forming an occlusive film on the stratum corneum [3, 4, 5].</p>
<b>Smooths/improves skin texture</b>	<p>“Smooths” is supported by the formulation containing emollients, which act by forming an occlusive film on the stratum corneum preventing/reducing water loss from the skin, leading to increased hydration and softness. [1, 6, 7].</p> <p>“Improves skin texture” is supported by the inclusion of mineral oil in the formulation. Mineral Oil is effective by means of preventing water loss from the skin, causing the stratum corneum to swell and become more flexible. Stamatas [6] has demonstrated an increase in stratum corneum thickness of almost 10% following the application of mineral oil using Raman spectroscopy.</p>
<b>No added fragrance</b>	The formulation contains no fragrance and has a natural odour of 'base notes'; due to the functional ingredients used in the formula.

### **References**

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5. Overgaard OL and Jemec GB. The influence of water, glycerin, paraffin oil and ethanol on skin mechanics. *Acta Derm. Venereol.* 1993; **73**:404–406.
6. Stamatas GN, de Sterke J, Hauser M, von Stetten O and van der Pol A. Lipid uptake and skin occlusion following topical application of oils on adult and infant skin. *J. Dermatol. Sci.* 2008; **50**:135–142.
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