

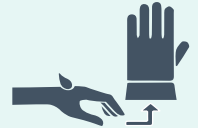
# Triple Active Gel

Anti-Allergen

Anti-Perspirant

Anti-Irritant

**Unique triple active hand protection gel for application under occupational gloves to improve health and comfort and help prevent skin disease.**



### USAGE

For use in any workplace location where protective gloves are being routinely worn. Helps protect workers from contact with various workplace contaminants and allergens; and helps reduce hands sweating while being protected by gloves.



Triple Active Gel has been created by Deb's world leading team of scientific experts using Deb Stoko Technology, drawing on their extensive experience and expertise in developing highly effective protective hand cream formulations.

### METHOD OF APPLICATION

Ensure hands are clean before applying before each work period. Re-apply after washing hands and/or every 2-3 hours. Apply one dose to back of hands. Rub hands back to back then palm to palm interlocking fingers and including around the finger nails. At the end of the day wash off hands using an industrial hand cleanser and apply a moisturising cream.

Features	Benefits
Anti-allergen	Deb Active Defence Molecules encapsulate and absorb allergens encountered in the workplace and associated with some glove materials, to help prevent allergic skin reactions which can lead to allergic dermatitis.
Anti-irritant	Deb Active Defence Molecules neutralise moderately aggressive workplace chemicals to help prevent skin irritation which can lead to irritant dermatitis.
Barrier action	The gel formula creates a light, physical barrier on the skin surface to help prevent moderately aggressive water and non-water based substances from penetrating the skin and potentially leading to irritant dermatitis.
Anti-perspirant	Product incorporates Aluminium Chlorohydrate, a highly effective anti-perspirant, which reacts with sweat from the skin to form non-soluble pore plugs. These plugs help restrict hand sweating and improve hand comfort under gloves.
Reduces glove malodours	Restriction of hand sweating helps reduce malodours associated with glove dampness, improving wearer comfort and prolonging glove lifetime.
Hypoallergenic	Scientifically formulated using ingredients with low allergic potential and independently tested to be declared as "hypoallergenic".
Perfume-free	Leaves no residual skin smell; suitable for both males and females; reduces the potential for skin irritation.
Non-tainting	Independent testing proves the product does not have the potential to taint food, ensuring suitability for use by workers in food manufacturing and processing environments.
Silicone-free formula	The product has no adverse effects when used in paint and spray shops or any other environments where surface coatings are being applied.

## Product Composition

Aqua, Aluminium Chlorohydrate, Isononyl Isonanoate, Glycerine, Octyldodecanol, Deb Active Defence Molecule, Octyldodecyl Xyloside, PEG-30 Dipolyhydroxystearate, Tetrasodium Imminodisuccinate, Sodium Benzoate, Polyacrylate 13, Potassium Sorbate, Polyisobutene, Polysorbate 20

## Anti-Allergen Testing

Langerhans cells represent 2-5% of the cell population present in the epidermis and play an important role in the skin's natural defence to skin sensitisation. Langerhans cells acquire allergens in the epidermis and then naturally migrate to the dermis to present the allergen to cells which contain immune receptors (T cells) to elicit an immune response. The anti-allergen test was based on exposing ex-vivo human skin tissue explants for 18 hours each to a variety of common workplace allergens (see list below) and assessing the percentage of Langerhans cells migrating from the epidermis.

### Glove/Rubber related allergens

- Hevein (Latex)
- Tetramethylthiuram disulphide (Rubber & Neoprene)
- 2-Mercaptobenzo thiazole (Latex)
- Benzyl carbamate (Rubber & Neoprene)

### Workplace allergens

- Ethyl acrylate Kosher (Adhesives and Coatings)
- Araldite 506 Epoxy Resin (Adhesives)
- Formaldéhyde 30% (Preservative used in industrial materials – cutting oils etc...)

Three skin condition types were used: one using the Triple Active Gel; one using a standard protection cream; and one with no cream ("untreated"). The higher the percentage of Langerhans cells migrating from the epidermis, the higher the skin reaction to the allergen. The lower the percentage, the greater the protection provided the gel or cream. The results are given in Figure 1.

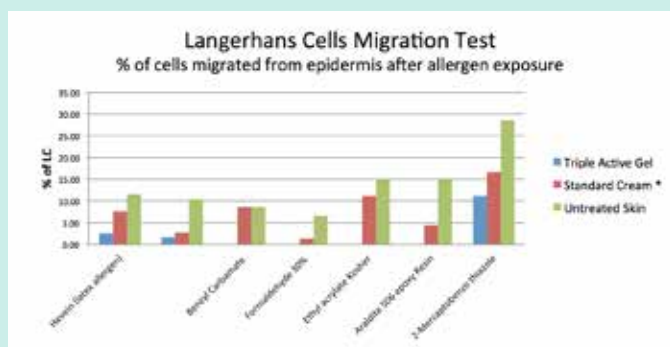


Figure 1: Langerhans cell migration in ex-vivo human skin explants.

The results show that Triple Active Gel reduces the migration of Langerhans cells and protects against skin sensitisation more than a standard cream and skin not treated with any protective cream.

## Anti-Irritant Testing

The anti-irritation performance of Triple Active Gel was tested on 15 healthy voluntary test persons using a well-established Repetitive Occlusive Irritation Test (ROIT) protocol.

In the ROIT, one water soluble irritating substance (Sodium Dodecyl Sulphate) and one non-water based irritating substance (a blend of Ethyl Acetate and Undecylenic Acid, 1:1) were used. These were applied to untreated skin and skin treated with Triple Active Gel. Over a 5 day period each substance was applied to the skin for a 30 minute period, alternating with one in the morning and the other in the afternoon. The results in Figure 2 show that when exposed to both water and non-water based irritating substances, using Triple Active Gel reduces skin redness by 31% and as shown in Figure 3, reduces the rate of water loss by 63% compared to untreated skin.

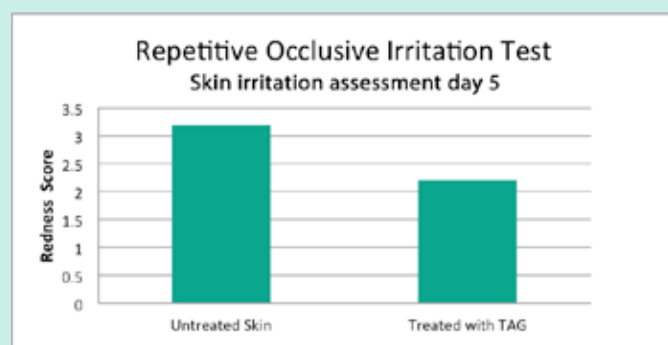


Figure 2 - Skin Irritation assessment on untreated skin vs treated with Triple Active Gel.

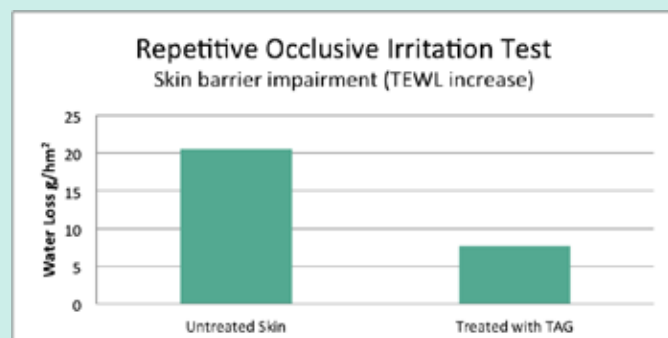


Figure 3 - Trans Epidermal Water Loss Assessment on untreated skin vs treated with Triple Active Gel.

### Anti-Perspirant Testing

The Anti-perspirant effectiveness of Triple Active Gel was measured on 15 subjects over a period of 7 days. Triple Active Gel was applied to one hand as per dosage instructions and the other hand left untreated. Powder free nitrile gloves were then donned and worn for a period of 4 hours and this was repeated for 7 days. The results show that after 7 days for hands treated with Triple Active Gel, sweating is significantly reduced by over 51% compared to untreated hands.

### Skin Compatibility Testing

Triple Active Gel has been independently tested and does not show any human cutaneous irritant potential when assessed on 31 panellists by application using an occluded patch according to ISO 10993-10\_2010.

### Hypoallergenic Testing

Independent testing confirms Triple Active Gel meets the criteria for being described as 'Hypoallergenic' i.e. one with reduced allergenic potential.

### Non-Taint Testing

Triple Active Gel has been tested according to 'Sensory Analysis – Methodology - Triangle Test BS EN ISO 4120:2007' and proven to not have the potential to taint food when used as an under glove work cream.

### Medical Device Classification

Triple Active Gel is classified as a Class 1 Medical Device in accordance with the Medical Device Directive 93/42/EEC. This is not to be confused with medicinal products (also called pharmaceuticals or drugs) which achieve their principal action by pharmacological, metabolic or immunological means. Medical devices are used to diagnose, prevent, or treat disease or other conditions and do not achieve their purposes through chemical interaction with the body, either within or on the surface of the body.

### Quality Assurance

Triple Active Gel meets the bacterial purity standard as they apply to Class 1 Medical Devices for external use (as defined by Ph. Eur);

<10<sup>2</sup> reproducible germs/g product

Verification tests in this respect are a regular feature of the products quality assurance procedures.

### Storage Information

Triple Active Gel can be stored in an unopened container at room temperature for more than 36 months. For shelf life after opening: see indication on the packaging.

### Safety Data Sheet

Can be downloaded from [www.tripleactivegel.com](http://www.tripleactivegel.com)

### Available Pack Sizes

Stock Code	Size	Case Quantity
HC111003	30ml Tube	30
HC111002	100ml Tube	12
HC111001	1 Litre Cartridge	6
HC111004	1 Litre Dispenser	15

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