

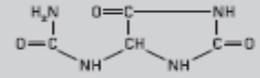
Chemical composition

The product occurs as a tautomeric mixture, the keto and enol forms being in equilibrium.

INCI designation: Allantoin

5-Ureidohydantoin

Structure:



Appearance

White crystalline powder

Odour

Practically odourless

Physico-chemical data

Active Substance	98.6 % – 100 %
Loss on drying Melting range (decomposition)	max. 0.1 % 225 – 236 °C
pH value (0.5 % aqueous solution, 20°C)	4.0 – 6.0

Analytical methods of determination

The analytical methods of determination employed can be obtained on request.

Keratolytic Action

Another important feature is the keratolytic action of Allantoin. Flesch ⁴ carried out further fundamental studies on this topic: he observed in vitro the dispersive power of Allantoin on proteins. This makes Allantoin an ideal and very mild active with keratolytic effect. Application of Allantoin to intact skin on the face and the body leads to a soft, smooth and healthy appearance. The details of the mechanism of action of Allantoin are not yet fully understood. It is believed that Allantoin causes a transient local increase in leucocytes and possibly also improves lymph flow. These properties, of major interest to both dermatologists and cosmeticians, have been confirmed by in-vitro and in-vivo studies.

Beneficial influence on Skin Moisture

An interesting, and no less important, property of Allantoin is its beneficial influence on skin moisture. This underlines the biological equilibrium emphasized again and again by dermatologists and beauty specialists.

Indications

As a substance with healing or prophylactic activity in pharmacology and dermatology, Allantoin is an outstandingly useful additive for a range of pharmaceutical and cosmetic products. It may be present in such formulations as the only active ingredient. Furthermore, it is compatible with most commonly used pharmaceuticals in dermatology, and with most active ingredients used in cosmetics, thus offering many possibilities for the development of products for specific applications. Allantoin's good compatibility with most relevant materials also allows it to be easily incorporated into existing formulations. Because it is effective even at low levels, Allantoin is economical to use as well. The following information is intended to provide the manufacturers of pharmaceutical and cosmetic products with some suggestions for the use of Allantoin.

Mode of Action and Application of Allantoin

Allantoin – active ingredient for the cosmetic and pharmaceutical industries

Allantoin, known for many years for its therapeutic action on skin tissue, is widespread in animal organisms and in plant material. Allantoin has been used for centuries in the folk medicine of many countries, to promote wound healing. In 1912, Macalister² demonstrated that the active substance of black salsify is identical with Allantoin, and in 1935 Robinson was successful in isolating Allantoin from animal organisms as the principal active ingredient. Before its isolation from natural products, Allantoin was successfully synthesized for the first time in 1838 by Woehler and Liebig. Following Robinson's initial publications, the results of his studies were quickly applied in the medical and pharmaceutical sectors. A number of Allantoin-containing wound ointments and healing ointments were newly introduced in surgery and dermatology, and existing products of this type were improved by addition of Allantoin. Allantoin became established in the cosmetic industry many years ago, so it is already present in many cosmetic products. Particularly in this area, consumption has grown steadily.

Mode of Action

Promotion and acceleration of cell proliferation

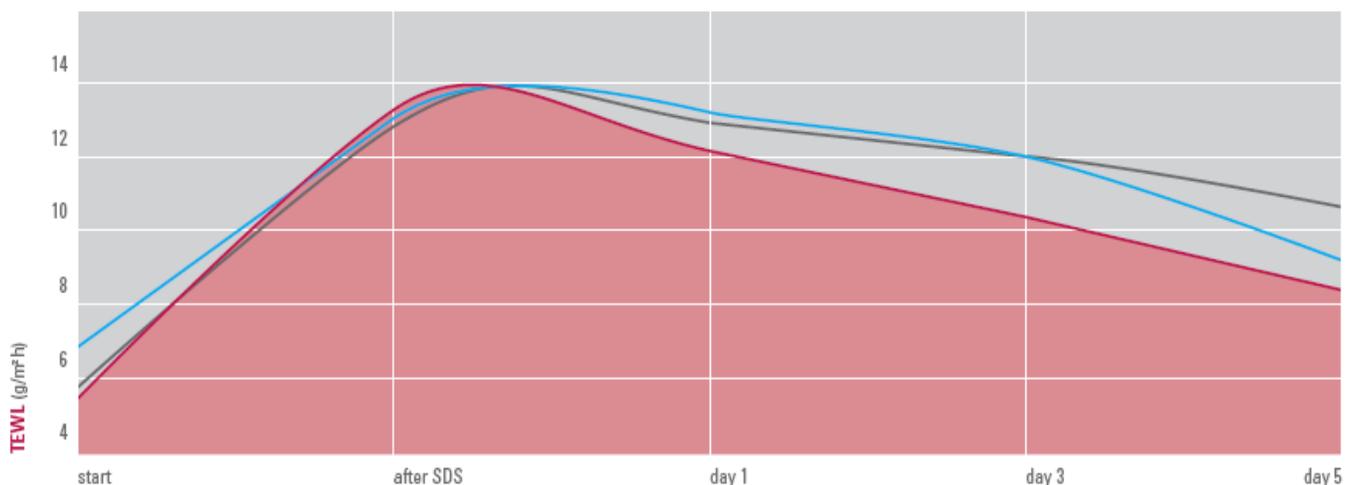
The effects promoted by Allantoin in wound healing are complex. First, dead tissue is removed and the wound area cleansed. This is followed by one of the essential effects of Allantoin, the promotion and acceleration of cell proliferation, growth of healthy granular tissue and finally, epithelization. In the majority of cases, wound pain disappears after the first few applications. Allantoin also promotes cell proliferation and swift epithelialisation in skin areas which are superficially injured, heavily stressed, or exposed to harsh weather. Skin irritation, roughness, chapped skin, and other unpleasant characteristics disappear.²

Use in pharmaceuticals and dermatology

Addition of Allantoin to wound ointments and healing compositions promotes wound cleansing and healing. The indications for formulations of this kind are many, ranging from small, everyday injuries (cuts, burns, abrasions, chapped skin), to wounds that are slow to heal or purulent, refractory ulcers of various origins, to treatment of burns of various degrees and origins (thermal or radiation). Fisher⁵ showed in several studies that a preparation of 5 % Allantoin in Vaseline[®] gave benefit in the treatment of leg ulcers, psoriasis and dry skin. Formulations containing Allantoin also have beneficial effects on eczema, contact dermatitis of the hands, hyperkeratosis, periodontosis and heat blisters in the mouth and on mucous membranes. What is especially advantageous is that the wounds heal without keloid formation. Internal and external haemorrhoids will respond well to suppositories and ointments containing Allantoin. Suitable vehicles for Allantoin include washable ointments of the oil-in-water emulsion type. It is advisable to incorporate Allantoin in the aqueous phase of the formulation.

Use in the cosmetic industry

In cosmetic products, Allantoin promotes cell regeneration in skin exposed to and weakened by environmental factors, and helps to promote and maintain the health of intact skin on the body and face. Addition of Allantoin to hand lotions and hand creams helps eliminate rough, chapped skin, and leaves hands smooth and soft. Le Van⁶ et al. have studied e.g. the action of a skin-care product containing Allantoin in a large number of women with badly damaged skin. In 90% of the women using the hand lotion daily, the symptoms were completely eliminated, and for the remaining 10 %, at least a distinct improvement was observed. Skin areas superficially damaged through shaving are also renewed by the use of aftershaves containing Allantoin. Allantoin formulations are also highly suitable for use on the particularly sensitive skin of babies and infants. In various types of skin creams (e.g. "skin nourishing" creams, day and night creams), lip-care products, powders for various uses, after-sun lotions, and other cosmetic formulations, Allantoin potentiates the healing and regenerating activity of the skin. In lipsticks, deodorants, and suntan products it protects the skin from damage. Because of its extraordinarily good keratolytic properties, Allantoin is a valuable additive in various hair care products, especially for the treatment of dandruff. The good effect of Allantoin against periodontosis and heat blisters in the mouth and on mucous membranes makes this active ingredient a reliable additive in oral hygiene products. Typical use levels for Allantoin in cosmetic products are 0.1– 0.5%.



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New efficacy studies

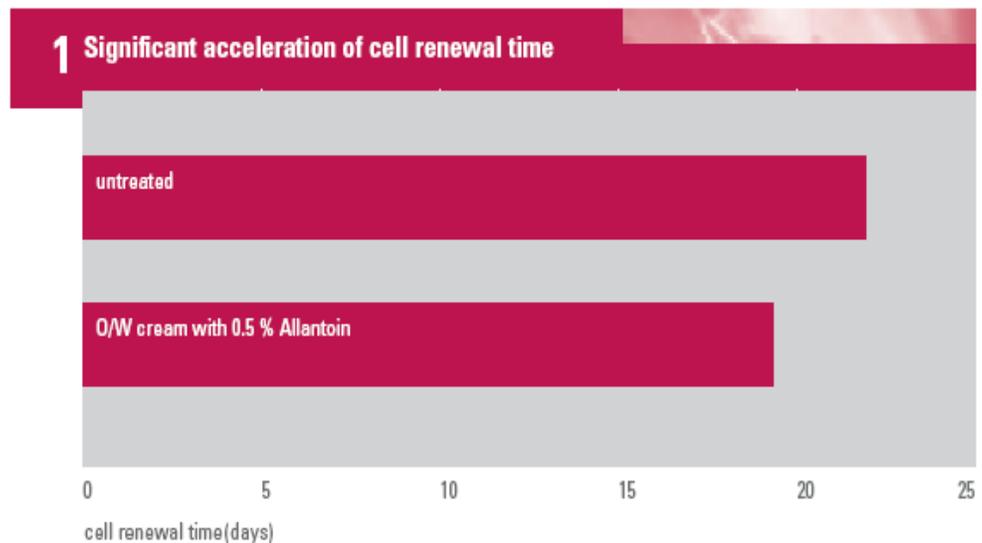
Allantoin – described in international pharmacopoea and other literature – is well known for its excellent moisturising effects. New efficacy studies, 7 in 1998 on human test subjects have shown good performance with regard to:

- 1. cell renewal**
- 2. skin soothing effect**
- 3. skin moisturising effect.**

These trials have been carried out by Derma Consult GmbH, Germany. All methods are available on request.

1. Cell renewal

Evaluation by fluorescence method: The study shows that the cell renewal time of the Stratum Corneum is decreased significantly by applying a cream containing 0.5% Allantoin.



2. Soothing effect

The soothing effect and reduction of skin redness has been tested after:

mechanically-induced irritation

chemically-induced irritation

UV-induced irritation.

Evaluation by:

Transepidermal water loss =TEWL (caused by surfactants, sodium dodecyl sulphate)

In cases of mechanical and chemical irritation, significant decrease of TEWL and redness of the skin after treatment with a cream containing 0.5% Allantoin has been observed. After UV irritation, the redness decreases with a cream containing 0.5% Allantoin.

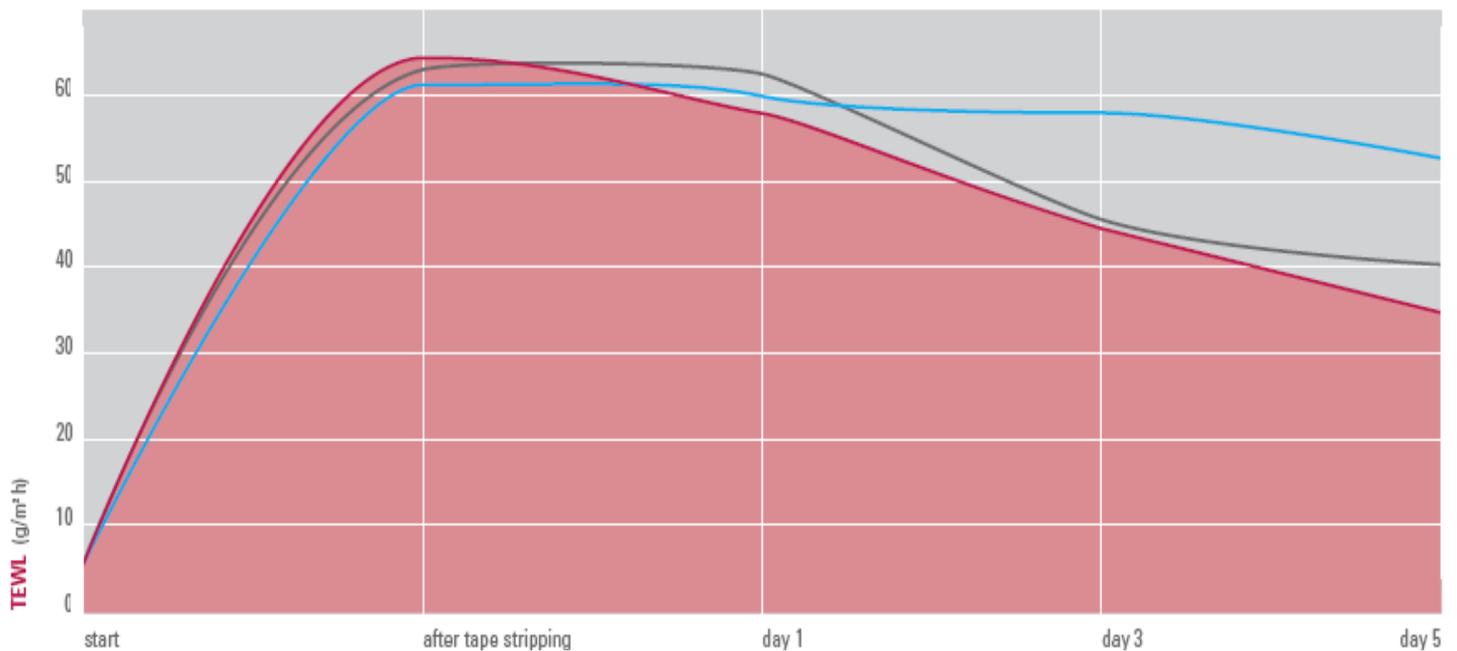
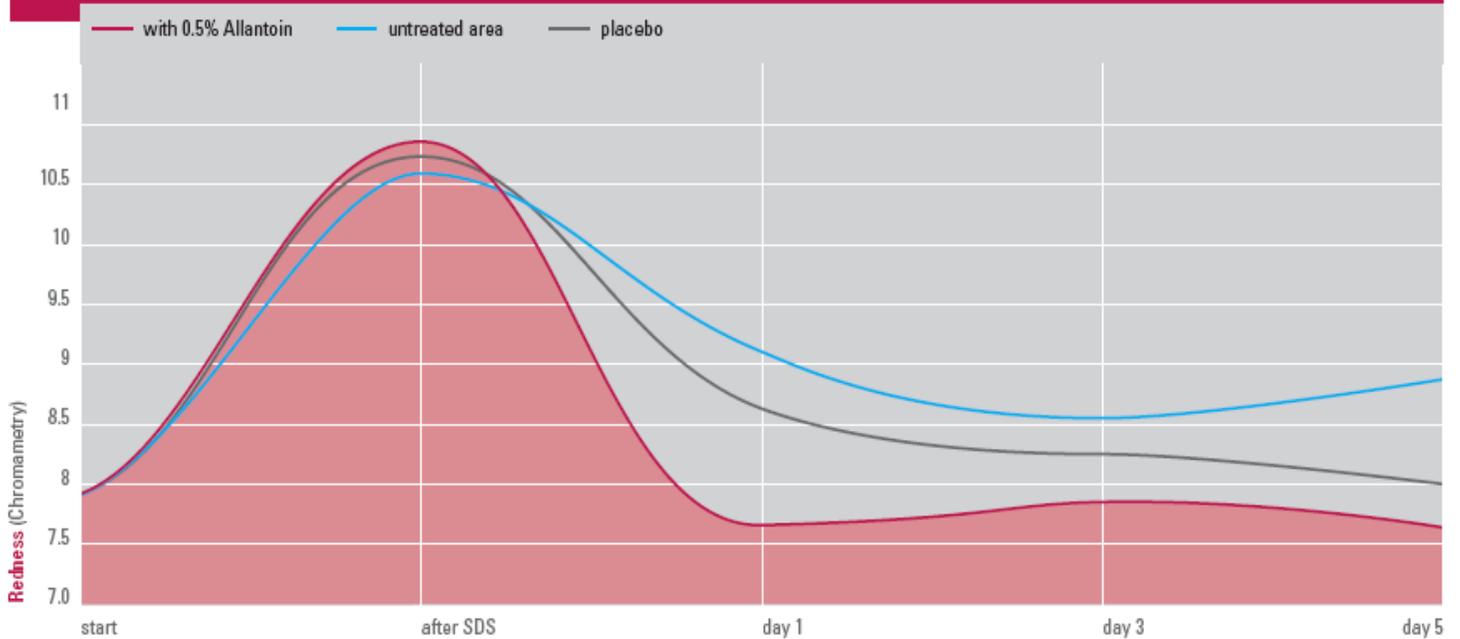
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2.1 Soothing effect: significant skin repair after sodium dodecyl sulphate-induced skin irritation

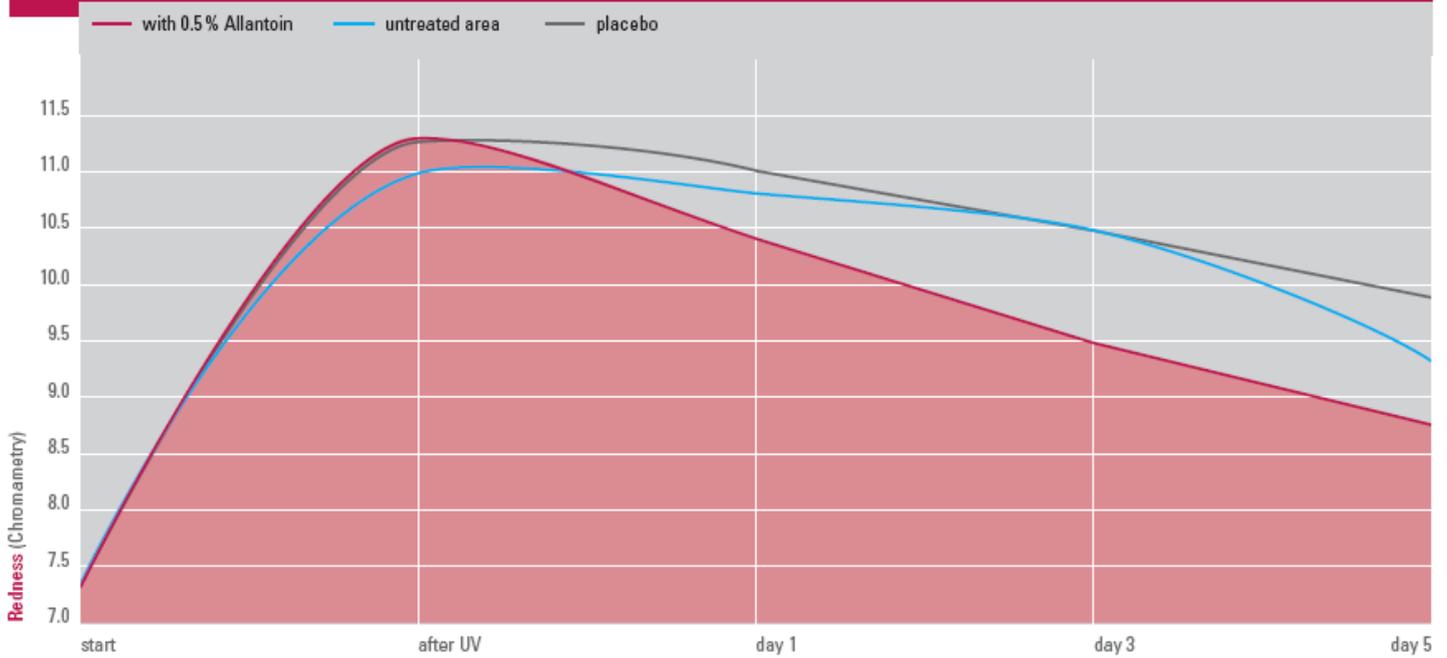


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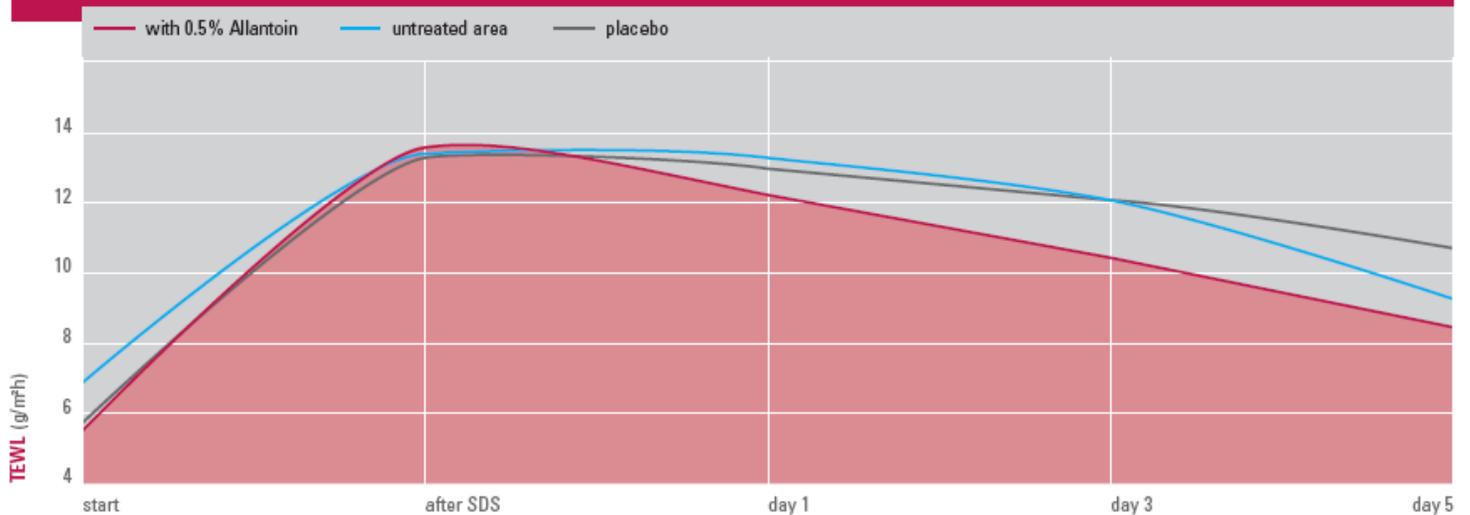
2.3 Soothing effect: significant skin repair after UV-induced skin irritation



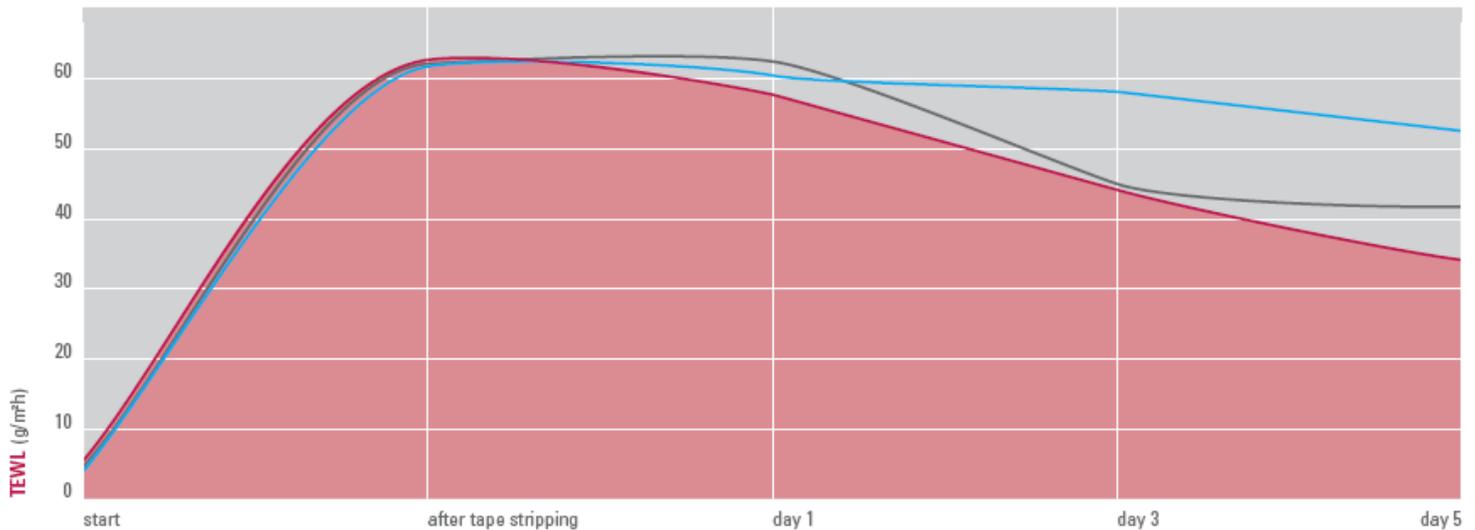
3. Moisturising effect

The TEWL shows the capacity of the Stratum Corneum to fix water. The significant decrease of TEWL after mechanically- and chemically induced irritations are treated with a cream containing 0.5% Allantoin, confirms the moisturising effect of Allantoin.

3 Moisturising effect: after sodium dodecyl sulphate- and tape strip-induced skin irritation



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Solubility

Allantoin is soluble in the aqueous phase of cosmetic products, but is insoluble in the commonly used cosmetic oils. Allantoin is best incorporated by addition to the aqueous phase and heating to 50°C, but can also be dissolved at 25°C with stirring. The content of Allantoin in cosmetic preparations may be determined by HPLC analysis.⁸

Stability

In water-free formulations, Allantoin can be stored virtually indefinitely under normal storage conditions. Aqueous solutions are stable in the range pH 3 to 8. Allantoin decomposes when heated for a long time in aqueous solution; strong alkalis have the same effect.

Water	20°C	0,4 %
Water	75°C	4,0 %
Ethanol	20°C	0,1 %
Glycerol solution (5 % in water)	20°C	0,8 %
Sodium laureth sulfate (30%)	20°C	0,8 %
Sodium cocoyl glutamate (30%)	20°C	0,8 %

Recommended uses

Facial Lotions and Creams



Technical Sheet

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Hand and Body Lotions and Creams
After-Sun Lotions
Aftershave Balms
Baby Creams and Lotions
Antidandruff Shampoos
Bath and Shower Gels
Mouthwash
Toothpaste

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