

# ALLANTOIN

*Category 1 Active Ingredient Skin Protectant*



SKIN PROTECTANT FOR PERSONAL CARE



INTERNATIONAL SPECIALTY PRODUCTS



## INTRODUCTION

Allantoin has been classified by the Food and Drug Administration (FDA) Over-the-Counter (OTC) Topical Analgesic Review Panel as a **Category I (safe and effective) active ingredient skin protectant**. Allantoin has been widely used for decades in cosmetic and OTC topical formulations because it is so effective. The most popular applications are in the prevention and treatment of dry and chapped skin and lips.

## KEY FEATURES AND BENEFITS

Soaps, detergents, acidic or alkaline materials, mechanical means or the environment can irritate skin and lips. Allantoin helps alleviate and prevent symptoms of irritated and dry skin, and dry and chapped lips.

The U.S. Food and Drug Administration in the Tentative Monograph, 48 Federal Register 6820-33 defines Allantoin as a skin protectant. A skin protectant is a drug which protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli.

The FDA has approved the use of 0.5% to 2.0% Allantoin for the:

- Temporary protection of minor cuts, scrapes, burns and sunburns.
- Prevention and temporary protection of chafed, chapped, cracked, or wind-burned skin and lips.
- Relief of dryness and softening of cold sores and fever blisters.
- Treatment and prevention of diaper rash and to help protect/seal out wetness.

The FDA considers such explicit claims as drug claims. ***When 0.5% to 2.0% Allantoin is added to cosmetic and personal care products and no claims are made related to Allantoin, the product remains a cosmetic.***

The FDA does not recognize Allantoin as a wound healing agent.

The most updated FDA regulations should be consulted since the above approved uses are listed in the current tentative Final Monograph and may be modified once the Final Monograph is published.

## TREATMENT STICK with PROLIPID® 151 and ALLANTOIN #10889-27-1

INGREDIENTS	%W/W	SUPPLIER
<b>PHASE A</b>		
Paraffin (Paraffin Wax 160/165)	9.50	Frank B. Ross
Glyceryl Dilaurate (EMULSYNT™ GDL)	20.00	ISP
Petrolatum (Snow White Petrolatum)	63.60	Penreco
Glyceryl Stearate (and) Cetyl Alcohol (and) Stearyl Alcohol (and) Behenyl Alcohol (and) Palmitic Acid (and) Stearic Acid (and) Hydroxyethyl Cetearamidopropyltrimonium Chloride (PROLIPID® 151)	5.00	ISP
<b>PHASE B</b>		
ALLANTOIN, USP	1.00	ISP
<b>PHASE C</b>		
Isopropylparaben (and) Isobutylparaben (and) Butylparaben (LIQUAPAR® OIL)	0.40	ISP
<b>PHASE D</b>		
Silica (Cab-O-Sil M-5)	0.50	Cabot
	100.00%	

### PROCEDURE

Melt Phase A ingredients; heat to 80 °C until melted and uniform. Maintain batch at 80 °C. Add Phase B to batch; mix until uniform. Begin cooling batch to 75 °C. Add Phase C to batch; mix until uniform. Add Phase D to batch; mix until uniform. Pour samples at 75 °C.

## SKIN PROTECTANT BABY LOTION #10804-41-1

INGREDIENTS	%W/W	SUPPLIER
<b>PHASE A</b>		
Deionized Water	73.15	
Glycerin	3.50	
PVM/MA Decadiene Crosspolymer (STABILEZE® QM)	0.30	ISP
<b>PHASE B</b>		
Deionized Water	5.00	
Sodium Hydroxide (10% Solution)	0.75	Fisher Scientific
<b>PHASE C</b>		
Beeswax (Yellow Beeswax NF Prills)	1.00	Frank B. Ross
Ozokerite (Ozokerite Wax SP 1020P)	1.00	Strahl & Pitsch
Ethylhexyl Palmitate (CERAPHYL® 368)	4.00	ISP
Myristyl Myristate (CERAPHYL® 424)	3.00	ISP
Glyceryl Stearate (CERASYNT® SD)	0.50	ISP
Glyceryl Stearate (and) Laureth-23 (CERASYNT® 945)	1.30	ISP
PEG-20 Stearate (CERASYNT® 840)	0.70	ISP
Dimethicone (SI-TEC™ DM 1000)	2.00	ISP
<b>PHASE D</b>		
Cyclopentasiloxane (SI-TEC™ CM 040)	2.50	ISP
<b>PHASE E</b>		
Fragrance (#68665, LSR 17614)	0.20	Intarome
Propylene Glycol (and) Diazolidinyl Urea (and) Iodopropynyl Butylcarbamate (LIQUID GERMALL® PLUS)	0.60	ISP
ALLANTOIN, USP	0.50	ISP
	100.00%	

### PROCEDURE

Combine water and glycerin with mixing and then sprinkle in STABILEZE® QM. Heat at 80 °C for at least 45 minutes. Combine Phase B and Phase C separately. Heat Phase C to 75-80 °C with mixing. After heating Phase A for 45 minutes add Phase B with mixing. As soon as Phase C heats to 75-80 °C add it to the batch with mixing. Begin to cool the batch. Add Phase D at 55 °C with mixing. Add Phase E at 35-30 °C in order listed, mixing between addition. QS for water loss and mix to RT. pH = 6.13 Viscosity = 26,000 cps (Brookfield Model RVT, TB @ 5 RPM)

*This formula has passed a 28-day double challenge efficacy test. However, the preservative system has not been optimized to its lowest effective level.*

## RECOMMENDED APPLICATIONS

The benefits of Allantoin can be effectively used in:

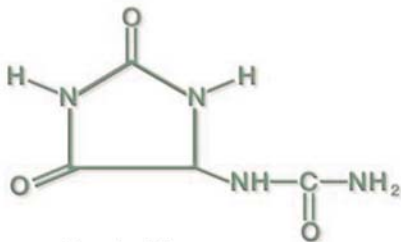
- Hand and body creams and lotions
- Lipsticks and lip ointments
- Shaving products
- Sun and after-sun care products
- Face and baby wipes
- Baby and foot powders
- Acne products
- Anti-perspirants and deodorants
- Diaper rash creams

Allantoin is also used in the topical pharmaceutical market in psoriasis medications and analgesic gels. Allantoin has been used in various dental preparations such as toothpastes and oral rinses.

## PRODUCT DESCRIPTION

### • Chemistry

Allantoin is a heterocyclic organic compound that conforms to the formula:



### • Chemical Names:

(2,5-Dioxo-4-Imidazolidinyl) Urea  
Glyoxylic Diureide  
Urea (2,5-Dioxo-4-Imidazolidinyl)-  
5-Ureidohydantoin

### • INCI Name: Allantoin

Allantoin is an amphoteric compound that is anionic under basic conditions.

## TYPICAL PROPERTIES

Appearance @ 25 °C	White, crystalline powder
% Assay (titration, SQ-TM-005)	98.0 - 101.5
Identification Test A (IR, SQTM-021)	Match reference
Identification Test B (TLC, SQTM-057)	Pass
Identification Test C (SQTM-060)	Pass
% Loss on Drying @ 150 °C (SQTM-061)	0.10 maximum
% Residue on Ignition (SQ-TM-030)	0.10 maximum
Reducing Substances	Pass
Related Compounds (SQTM-063)	Pass
Heavy Metals, ppm (SQTM-020)	10 maximum
Angular Rotation, °C (SQTM-059)	-10.0 ± 0.10
Total aerobic plate count, CFU/g (Q200)	500 maximum
Mold/Yeast, CFU/g (Q200)	100 maximum
E. coli, CFU/g (Q200)	Absent
Pseudomonas aeruginosa, CFU/g (Q200)	Absent
Salmonella, CFU/g (Q200)	Absent
Staphylococcus Aureus CFU/g (Q200)	Absent

*This product meets the requirement for Allantoin in current USP.*



## TYPICAL PROPERTIES

### Solubility data

Solvent	Solubility @25 °C (g/100g solvent)
Water	0.45g
Ethanol	<0.1g
Methanol	<0.1g
Propylene Glycol	<0.1g
10% HCl	<0.4g
10% NaOH	39.0g

## MODE OF ACTION

Allantoin produces its desirable effects by promoting healthy skin. It is postulated that Allantoin cleanses away necrotic tissue, speeding up the growth of new, healthy tissue. Since Allantoin stimulates new and healthy tissue growth, healing epithelization may take place.

Allantoin also has been described as a cell proliferant, an epithelization stimulant and a chemical debrider in texts such as the United States Dispensatory, Merck Index, and British Pharmaceutical Codex.

## REGULATORY STATUS

Allantoin is approved for use in the U.S. and in Europe.

CAS Number: 97-59-6  
EINECS Number: 202-592-8  
FDA Classification: Category I (safe and effective) OTC Tentative Final Monograph on Skin Protectant Drugs.

## FORMULATING WITH ALLANTOIN

Allantoin is compatible with most ingredients used in personal care formulations. Water solubility at monograph-approved levels is an issue. Suspending the material in a thick base is the best way to resolve this issue. When conducting stability testing, care must be taken to look for Allantoin recrystallization.

### • Incorporation

To incorporate 0.5% Allantoin, or more, into an emulsion product, the emulsion is made and Allantoin is added during the cooling process below 50 °C. Good agitation is required to thoroughly disperse the Allantoin to achieve a suitable suspension. Addition of Allantoin at 0.5% or more or at temperatures above 50 °C in aqueous systems can cause solubilization and recrystallization upon cooling into larger particles which are perceptible during product use.

### • Use levels

Recommended use levels: 0.5 - 2.0%



## GLOBAL LOCATIONS FOR SALES & CUSTOMER SERVICE

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Tel: 973-628-4000  
www.ispcorp.com info@ispcorp.com

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Fax: 1 973 628-4117  
emitchell@ispcorp.com

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Toll Free: 1 (800) 505-8984  
Fax: +1 818-906-3504  
ujenkins@ispcorp.com

#### CANADA

Tel: +1 905 607-2392  
Toll Free: 1 (800) 465-5094  
Fax: +1 905 607-9086  
adumancic@ispcorp.com

#### CUSTOMER SERVICE:

Toll Free: 1 (800) 622-4423  
Fax: 1 973 628-4001  
nmurphy@ispcorp.com  
**SAMPLE CENTER:**  
Toll Free: 1 (800) 243-6788  
isp@chemicalmarketing.com

### LATIN AMERICA CUSTOMER SERVICE

#### ARGENTINA

Tel: +54 11 4314-8971/0659/  
3293  
Fax: +54 11 4314-8976  
ispargentina@ispcorp.com

#### BRAZIL

Tel: +55 11 3649-0469  
Fax: +55 11 3835-4212  
ispbrasil@ispcorp.com

#### COLOMBIA

Tel: +57 (0) 1 638-6203  
Fax: +57 (0) 1 616-3030/6030  
dnelson@ispcorp.com

#### MEXICO

Tel: +52 55 5589-0721  
Fax: +52 55 5589-7345  
relmos@ispcorp.com

#### VENEZUELA

Tel: +58 212 991-4545  
Fax: +58 212 992-9703  
+58 212 991-7775  
Fax: +58 212 991-9705  
dnelson@ispcorp.com

### EUROPE & AFRICA CUSTOMER SERVICE

#### AFRICA

Tel: +49 (0) 2236 9649-237  
Fax: +49 (0) 2236 9649-212  
info.africa@ispcorp.com

#### CZECH REPUBLIC

Tel: +420 (0) 2 72 123-332  
Fax: +420 (0) 2 72 123-305  
info.czech@ispcorp.com

#### ITALY

Tel: +39 (0) 2 75 419-642  
Fax: +39 (0) 2 75 419-644  
info.italy@ispcorp.com

#### POLAND

Tel: +48 (0) 22 556 25 20  
Fax: +48 (0) 22 556 25 22  
info.poland@ispcorp.com

#### SWITZERLAND

Tel: +41 (0) 1 439 53-66  
Fax: +41 (0) 1 439 53-68  
info.switzerland@ispcorp.com

#### AUSTRIA

Tel: +43 (0) 1 360 27-71220  
Fax: +43 (0) 1 360 27-71221  
info.austria@ispcorp.com

#### FRANCE

Tel: +33 (0) 1 49 93 21-58/59  
Fax: +33 (0) 1 49 93 21-62  
info.france@ispcorp.com

#### NETHERLANDS

Tel: +31 (0) 20 65 45-361  
Fax: +31 (0) 20 65 45-368  
info.netherlands@ispcorp.com

#### RUSSIA

Tel: +7 095 232-0214  
Fax: +7 095 232-3385  
info.russia@ispcorp.com

#### TURKEY

(Also Middle East)  
Tel: +90 (0) 216 485-0972  
Fax: +90 (0) 216 485-0973  
info.turkey@ispcorp.com  
info.middleeast@ispcorp.com

#### BELGIUM

Tel: +32 (0) 2 626-49 30/34  
Fax: +32 (0) 2 626-49 32  
info.belgium@ispcorp.com

#### GERMANY

Tel: +49 (0) 2236 9649-260/64/66  
Fax: +49 (0) 2236 9649-295  
info.germany@ispcorp.com

#### NORDEN

(Denmark, Estonia, Iceland,  
Finland, Norway, Sweden)  
Tel: +46 (0) 8 519 920-10  
Fax: +46 (0) 8 519 920-12  
info.norden@ispcorp.com

#### SPAIN

(Also Portugal)  
Tel: +34 91 375-3026  
Fax: +34 91 375-3028  
info.spain@ispcorp.com

#### UK

Tel: +44 (0) 207 519-5054/55  
Fax: +44 (0) 207 519-5056  
info.uk@ispcorp.com

#### BULGARIA

Tel: +359 (0) 2 958-2596  
Toll Fax: +359 (0) 2 581-5480  
info.bulgaria@ispcorp.com

#### HUNGARY

Tel: +36 (0) 1 385-8288  
Fax: +36 (0) 1 466-2550  
info.hungary@ispcorp.com

### ASIA PACIFIC CUSTOMER SERVICE

#### N.S.W. AUSTRALIA

Tel: +612 9648-5177  
Fax: +612 9647-1608  
roppy@ispcorp.com

#### GUANGZHOU, CHINA

Tel: +8620 3758-9970  
Fax: +8620 3758-9907  
hwng@ispcorp.com

#### MUMBAI, INDIA

Tel: +9122 2837-0472  
Tel: +9122 2839-2624  
Tel: +9122 2837-0449  
ispindia@bom2.vsnl.net.in

#### KOREA

Tel: +822 554-6622/6934  
Fax: +822 554-6944  
kswh@ispcorp.com

#### TAIWAN

Tel: +8862 2508-0212  
Fax: +8862 2504-3543  
chchang@ispcorp.com

#### VICTORIA, AUSTRALIA

Tel: +613 9899-5082  
Fax: +613 9899-5102  
roppy@ispcorp.com

#### SHANGHAI, CHINA

Tel: +8621 6249-3900  
Fax: +8621 6249-3908  
hwng@ispcorp.com

#### INDONESIA

Tel: +6221 530-7181/82  
Fax: +6221 530-7183  
mchondrodhardjo@ispcorp.com

#### MALAYSIA

Tel: +603 5513-1448/28/98  
Fax: +603 5512-8311  
ffoo@ispcorp.com

#### THAILAND

Tel: +662 267-8103  
Fax: +662 236-0041  
pvlwians@ispcorp.com

#### BEIJING, CHINA

Tel: +8610 6515-6265  
+8610 6515-6409/6474  
Fax: +8610 6515-6267  
hwng@ispcorp.com

#### HONG KONG

Tel: +852 2881-6108  
Fax: +852 2895-1250  
hwng@ispcorp.com

#### OSAKA, JAPAN

Tel: +816 6838-5544  
Fax: +816 6838-5566  
myamashita@ispcorp.com

#### PHILIPPINES

Tel: +632 848-7188  
Fax: +632 848-7191  
bmanusque@ispcorp.com

#### SINGAPORE

Tel: +656 223-3778  
Fax: +656 226-0853  
ffoo@ispcorp.com

#### CHENGDU, CHINA

Tel: +8628 557-1040  
Fax: +8628 557-2313  
hwng@ispcorp.com

#### HYDERABAD, INDIA

Tel: +9140 2335-1009  
Fax: +9140 2335-1009  
ispindia@bom2.vsnl.net.in

#### TOKYO, JAPAN

Tel: +813 5566-8661  
Fax: +813 5566-8682  
myamashita@ispcorp.com

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