ALLANTOIN

Category 1 Active Ingredient Skin Protectant

SKIN PROTECTANT FOR PERSONAL CARE

ISP

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
PHASE A		
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 Cetearamidopropyldimonium Chloride (PROLIPID® 151)	5.00	**ISP**
PHASE B		
ALLANTOIN, USP	1.00	**ISP**
PHASE C		
Isopropylparaben (and) Isobutylparaben (and) Butylparaben (LIQUAPAR® OIL)	0.40	**ISP**
PHASE D		
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
PHASE A		
Deionized Water	73.15	
Glycerin	3.50	
PVM/MA Decadiene Crosspolymer (STABILEZE® QM)	0.30	**ISP**
PHASE B		
Deionized Water	5.00	
Sodium Hydroxide (10% Solution)	0.75	Fisher Scientific
PHASE C		
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**
PHASE D		
Cyclopentasiloxane (SI-TEC™ CM 040)	2.50	**ISP**
PHASE E		
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:

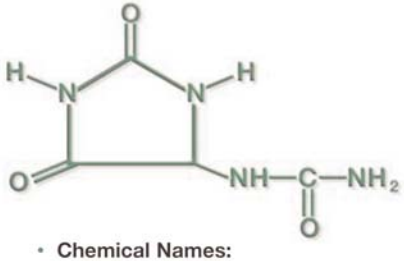
- Hand and body creams and lotions
- Lipsticks and lip ointments
- Shaving products
- Sun and after-sun care products
- Face and baby wipes
- Baby and foot powders
- Acne products
- Anti-perspirants and deodorants
- Diaper rash creams

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%

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