

**ECZEMA HAND RELIEF- colloidal oatmeal cream**  
**Skinfix, Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**ACTIVE INGREDIENT**

Colloidal Oatmeal 1%

**USES**

Temporarily protects and helps relieve minor skin irritations and itching due to rashes or eczema.

**PURPOSE**

Skin protectant

**WARNINGS**

For external use only.

When using this product avoid contact with eyes. if contact occurs, rinse thoroughly with water.

**KEEP OUT OF REACH OF CHILDREN**

If swallowed get medical help or contact a poison control center right away.

**STOP USE AND ASK A DOCTOR IF**

condition worsens  
symptoms last more than 7 days or clear up and occur again within a few days

**DIRECTIONS**

Apply as needed to hands.

**INACTIVE INGREDIENTS**

Water/Eau/Aqua, Vegetable Oil/Huile Végétale, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Butyrospermum Parkii (Shea) Butter, Polyglyceryl-2 Stearate, Stearyl Alcohol, Glyceryl Stearate, Caprylic/Capric Triglyceride, Caprylyl Caprylate/Caprinate, Jojoba Oil/Macadamia Seed Oil Esters, Annona Cherimola Fruit Extract, Helianthus Annuus

(Sunflower) Seed Wax, Oryza Sativa (Rice) Bran Extract, Cocos Nucifera (Coconut) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Squalene, Helianthus Annuus (Sunflower) Extract, Allantoin, Tocopherol, Rosmarinus Officinalis (Rosemary) Leaf Extract, Phytosteryl Macadamiate, Amylopectin, Phytosterols, Lecithin, Acetyl Glutamine, Lithothamnion Calcareum Extract, Folic Acid, Bacillus/Soybean Ferment Extract, Oligopeptide-3, Sodium Hyaluronate, Oligopeptide-2, Oligopeptide-1, Hexapeptide-11, Lactic Acid, Ceramide NP, Ceramide AP, Phytosphingosine, Cholesterol, Ceramide EOP, Xanthan Gum, Potassium Sorbate, Trisodium Ethylenediamine Disuccinate, Citric Acid, Ethylhexylglycerin, Sodium Citrate, Propanediol, Pentylene Glycol, Phenylpropanol, Sodium Dehydroacetate, Caprylyl Glycol, Sodium Lauroyl Lactylate, Sodium Benzoate, Carbomer, Phenoxyethanol

## QUESTIONS?

1.866.927.2783

<p>targets:</p> <ul style="list-style-type: none"> <li>the symptoms of eczema</li> <li>dry, cracked hands</li> <li>itchy &amp; irritated hands</li> </ul>	 <p><b>skinfix.</b></p> <p><b>eczema<sup>+</sup></b></p> <p><b>HAND RELIEF CREAM</b></p> <p><b>CRÈME APAISANTE POUR LES MAINS</b></p> <p>skin protectant</p> <p>developed with dermatologists</p> <p><b>VEGAN + CRUELTY FREE</b></p> <p>90 mL / 3 fl. oz.</p>	<p><b>1% colloidal oatmeal</b> temporarily protects and helps relieve minor skin irritations and itching due to eczema or rashes.</p> <p><b>1 % de farine d'avoine colloïdale</b> protège temporairement et aide à soulager les irritations mineures de la peau et les démangeaisons dues à l'eczéma ou aux éruptions cutanées.</p>	<p>this calming cream helps soothe skin irritation and itching for dry, overwashed, cracked skin, and even eczema on the hands and feet. this daily hand cream is packed with a blend of colloidal oatmeal, shea butter and emollient oils that absorb quickly and deeply nourishes skin, while helping to improve the barrier.</p> <p><b>directions:</b> for adults and children 6 months and older. apply as needed to hands, especially after hand washing.</p>																												
<p><b>no added</b> steroids, antibiotics, fragrance, parabens, formaldehyde, phthalates, silicones, lanolin, propylene glycol, PEGs, gluten</p> <p><b>sans ajout de</b> stéroïdes, antibiotiques, parfum, parabènes, formaldéhydes, phtalates, silicons, lanoline, propylène glycol, PEGs, gluten</p> <p>cible : symptômes de l'eczéma, mains sèches et craquelées, mains irritées et qui démangent</p> <p>protège la peau</p> <p>développé avec des dermatologues</p>	<p>Medicinal Ingredient/Ingrédient Médicinal : Colloidal Oatmeal 1.0%</p> <p>Non-medical Ingredients: see "Inactive Ingredients"</p> <p>Ingrédients Non Médicinaux : voir "Inactive Ingredients"</p> <p><b>planet love packaging</b></p> <p>our planet is precious and our respect for it influences every decision we make. this carton is made from 100% recycled paper using vegetable-based inks; it is also recyclable and biodegradable. this tube is made of 31% post-consumer recycled plastic.</p> <p>notre planète nous est précieuse et chaque fois que nous prenons une décision, nous le faisons en pensant à elle. cette boîte est faite de papier 100% recyclé et d'encre végétale. elle est aussi recyclable et biodégradable. ce tube est fabriqué à partir de 31 % de plastique recyclé post-consommation.</p>	<table border="1"> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> <tr> <td>Colloidal Oatmeal 1%</td> <td>Skin protectant</td> </tr> <tr> <th colspan="2">Uses</th> </tr> <tr> <td colspan="2">Temporarily protects and helps relieve minor skin irritations and itching due to eczema and rashes.</td> </tr> <tr> <th colspan="2">Warnings</th> </tr> <tr> <td colspan="2">For external use only. 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BY SKINFIX, INC. 1701 HOLLIS STREET, SUITE 800, HALIFAX, NS, CANADA B3J 3M8 1.866.927.2783 SKINFIX.COM</p> <p>MADE IN CANADA WITH GLOBALLY SOURCED INGREDIENTS. / FABRIQUÉ AU CANADA AVEC DES INGRÉDIENTS PROVENANT DU MONDE ENTIER.</p>    <p><b>PLASTIC NEUTRAL</b></p>
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## ECZEMA HAND RELIEF

colloidal oatmeal cream

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:61328-010

<b>Route of Administration</b>	TOPICAL
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### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OATMEAL</b> (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1 g in 100 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>HELIANTHUS ANNUUS SEED WAX</b> (UNII: 42DG15CHXV)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>AMYLOPECTIN, UNSPECIFIED SOURCE</b> (UNII: 4XO4QFV777)	
<b>CAPRYLYL CAPRYLATE/CAPRATE</b> (UNII: 22MCG4RSMR)	
<b>RICE GERM</b> (UNII: 7N2B70SFEZ)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>CERAMIDE NP</b> (UNII: 4370DF050B)	
<b>CERAMIDE 1</b> (UNII: 5THT33P7X7)	
<b>MACADAMIA SEED OIL GLYCERETH-8 ESTERS</b> (UNII: C6734SM77O)	
<b>PHYTOSTERYL MACADAMIATE</b> (UNII: 233VSF903M)	
<b>ACEGLUTAMIDE</b> (UNII: 01J18G9G97)	
<b>PHENYLPROPANOL</b> (UNII: 0F897O3O4M)	
<b>LACTIC ACID</b> (UNII: 33X04XA5AT)	
<b>PHYMATOLITHON CALCAREUM</b> (UNII: 6J1M3WA0ZK)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYGLYCERYL-2 STEARATE</b> (UNII: 253MC0P0YV)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>HEXAPEPTIDE-11</b> (UNII: NCJ63VWJ6BY)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>CHERIMOYA</b> (UNII: 33WWT714QS)	
<b>SUNFLOWER SEED</b> (UNII: R9N3379M4Z)	
<b>TRISODIUM ETHYLENEDIAMINE DISUCCINATE</b> (UNII: YA22H34H9Q)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>SODIUM DEHYDROACETATE</b> (UNII: 8W46YN971G)	
<b>FOLIC ACID</b> (UNII: 935E97BOY8)	

<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)
<b>SODIUM LAUROYL LACTYLATE</b> (UNII: 7243K85WFO)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>CERAMIDE AP</b> (UNII: F1X8L2B00J)
<b>PHYTOSPHINGOSINE</b> (UNII: GIN46U9Q2Q)
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)
<b>SQUALENE</b> (UNII: 7QWM220FJH)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61328-010-00	90 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2023	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	10/01/2023	

**Labeler** - Skinfix, Inc. (203158183)

**Registrant** - Skinfix, Inc. (203158183)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
SIGAN INDUSTRIES INC		255106239	manufacture(61328-010)

Revised: 8/2023

Skinfix, Inc.