

SKINFIX HAND REPAIR- 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.

SKINFIX - HAND REPAIR CREAM (61328-106)

Active Ingredients

Colloidal Oatmeal 1%

Purpose

Skin Protectant

Warnings

For external use only.

When using this product Avoid contact with eyes.

Stop use and ask a doctor if condition worsens.

If symptoms last more than 7 days or clear up and occur again within a few days.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

Uses

Temporarily protects dry cracked skin and helps relieve minor skin irritations and itching due to eczema.

Directions

Apply cream liberally as needed, especially after hand washing.

Inactive Ingredients:

allantoin, aloe barbadensis leaf juice, avena sativa kernel oil, beeswax, butyrospermum parkii (shea) butter, calendula officinalis extract, caprylic/capric triglyceride, caprylyl-caprylate/caprates, chamomilla recutita (matricaria) flower extract, citric acid, ethylhexylglycerin, glyceryl stearate, helianthus annuus (sunflower) seed oil, oryza sativa (rice) bran extract, petrolatum, phenoxyethanol, polyglyceryl-2-stearate, potassium sorbate, prunus amygdalus dulcis (sweet almond) oil, rosmarinus officinalis (rosemary) leaf extract, simmondsia chinensis (jojoba) seed oil, stearyl alcohol, tocopherol, trisodium

ethylenediamine disuccinate, water (aqua), xanthan gum

30 ml

Sealed Area

REST OF BEAUTY
FOR NIGHT EVENT
2018

REST OF BEAUTY
FOR NIGHT EVENT
2017

skinfix.

eczema⁺

HAND REPAIR CREAM

clinically proven to treat eczema
& dry, cracked skin on hands &
improve skin moisturization by 111%*

skin protectant

tested & recommended
by unbiased derms

1%
colloidal
oatmeal

5%
sweet
almond oil

30 ml e 1 fl oz liq

targets

eczema	dermatitis	dryness
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itchy, cracked & sensitive hands

allergy tested and pH balanced.

free from steroids, antibiotics, fragrance,
parabens, formaldehyde, phthalates, silicones,
lanolin, propylene glycol, PEGs and gluten

Drug Facts

Active Ingredients	Purpose
Colloidal Oatmeal 1%	Skin protectant

Uses Temporarily protects and helps relieve minor skin irritation and itching due to eczema.

Warnings For external use only.

When using this product • do not get into eyes. 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.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions Apply generously as needed, especially after hand washing.

Inactive Ingredients Aflatoxin, Aloe Barbodensis Leaf Juice, Avana Sativa Kernel Oil, Butyrospermum Parkii (Shea) Butter, Calendula Officinalis Extract, Caprylic/Capric Triglyceride, Caprylic/Capric Triglyceride, Chamomilla Recutita (Matricaria) Flower Extract, Citric Acid, Dihydroxyglycerol, Glycerin, Glyceryl Stearate, Helianthus Annuus (Sunflower) Seed Oil, Onyza Sativa Root Bran Extract, Petrolatum, Phytosteryl/Behenyl Polyglyceryl-2 Stearate, Potassium Sorbate, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Stearyl Alcohol, Tocopherol, Triethylhexylammonium Disuccinate, Water/Aqua, Xanthan Gum.

Questions? 1 866 927 2793

UPC FPO

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PRINCESS CRACK 20
2514 AD THE HAVIC
THE NETHERLANDS

NORTH AMERICA 1 866 927 2793
1490 LOWER WATER ST., SUITE 314
HALIFAX, NOVA SCOTIA, CANADA
B3J1B9 1 866 927 2793 SKINFIX.COM
MADE IN CANADA

90 ml



SKINFIX HAND REPAIR

oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61328-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OAT KERNEL OIL (UNII: 3UVP41R77R)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SHEA BUTTER (UNII: K49155WL9Y)	
CALENDULA OFFICINALIS WHOLE (UNII: PFR03EBU0H)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL CAPRYLATE/CAPRATE (UNII: 22MCG4RSMR)	
MATRICARIA CHAMOMILLA WHOLE (UNII: G0R4UBI2ZZ)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ORYZA SATIVA WHOLE (UNII: 84IVV0906Z)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-2 DIISOSTEARATE (UNII: DG195GP57P)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ROSMARINUS OFFICINALIS WHOLE (UNII: EA3289138M)	
JOJOBA OIL (UNII: 724GKU717M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61328-106-13	90 mL in 1 TUBE; Type 0: Not a Combination Product	07/02/2014	
2	NDC:61328-106-11	30 mL in 1 TUBE; Type 0: Not a Combination Product	09/23/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/02/2014	

Labeler - Skinfix, Inc. (203158183)

Registrant - Skinfix, Inc. (203158183)

Establishment

Name	Address	ID/FEI	Business Operations
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SIGAN INDUSTRIES INC		255106239	manufacture(61328-106)
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Revised: 12/2022

Skinfix, Inc.