

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.

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/caprate, 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



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
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: 2Z4LRR776S)
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 DIISO STEARATE (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:61328-106-12	60 mL in 1 TUBE; Type 0: Not a Combination Product	09/23/2016	
3	NDC:61328-106-11	30 mL in 1 TUBE; Type 0: Not a Combination Product	09/23/2016	
4	NDC:61328-106-97	7 mL in 1 POUCH; Type 0: Not a Combination Product	09/23/2016	
5	NDC:61328-106-10	10 mL in 1 TUBE; Type 0: Not a Combination Product	03/15/2017	
6	NDC:61328-106-15	150 mL in 1 TUBE; Type 0: Not a Combination Product	10/01/2018	
7	NDC:61328-106-16	148 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/26/2018	

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 - Product Integrity Laboratory, LLC (783863694)

