

ECZEMA DERMATITIS RELIEF BALM- 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.

ACTIVE INGREDIENT

Colloidal Oatmeal 5%

PURPOSE

Skin protectant

USES

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

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 face and body.

INACTIVE INGREDIENTS

Water/Aqua/Eau, Glycerin, Annona Cherimola Fruit Extract, Jojoba Oil/Macadamia Seed Oil Esters, Cetearyl Alcohol, Glyceryl Stearate, Cetearyl Oliviate, Coco-Caprylate/Caprates, Sorbitan Oliviate, Squalane, Helianthus Annuus (Sunflower) Seed Oil, Butyrospermum Parkii (Shea) Butter, Octyldodecanol, Triheptanoin, Allantoin, Zinc Oxide, Squalene,

Helianthus Annuus (Sunflower) Seed Wax, Phytosteryl Macadamiate, Phytosterols, Lecithin, Acetyl Glutamine, Castanea Sativa (Chestnut) Leaf Extract, Ceramide NP, Amylopectin, Chlorophyllin-Copper Complex, Phytosphingosine, Ceramide AP, Cholesterol, Folic Acid, Hexapeptide-11, Oligopeptide-1, Oligopeptide-2, Bacillus/Soybean Ferment Extract, Sodium Hyaluronate, Oligopeptide-3, Tocopherol, Lithothamnion Calcareum Extract, Ceramide EOP, Carbomer, Sodium Stearoyl Glutamate, C9-12 Alkane, Polyurethane-100, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Caprylic/Capric Triglyceride, Sodium Lauroyl Lactylate, Sodium Hydroxide, Sodium Citrate, Propanediol, Polyhydroxystearic Acid, Pentylene Glycol, Sodium Dehydroacetate, Phenylpropanol, Citric Acid, Xanthan Gum, Lactic Acid, Sodium Carbonate, Sodium Chloride, Potassium Sorbate, Sodium Benzoate, Phenoxyethanol.

QUESTIONS?

1.866.927.2783



ECZEMA DERMATITIS RELIEF BALM

colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61328-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	5 g in 100 g
Inactive Ingredients		
Ingredient Name	Strength	
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)		
AMYOLECTIN, UNSPECIFIED SOURCE (UNII: 4XO4QFV777)		
PHENYLPROPANOL (UNII: 0F897O3O4M)		
PHYTOSTERYL MACADAMIATE (UNII: 233VSF903M)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM CARBONATE (UNII: 45P3261C7T)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
MACADAMIA SEED OIL GLYCERETH-8 ESTERS (UNII: C6734SM77O)		
HEXYLENE GLYCOL (UNII: KEH0A3F75J)		
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)		
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)		
SHEA BUTTER (UNII: K49155WL9Y)		
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)		
PENTYLENE GLYCOL (UNII: 50C1307PZG)		
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)		
HYALURONATE SODIUM (UNII: YSE9PPT4TH)		
TOCOPHEROL (UNII: R0ZB2556P8)		
PHYMATOLITHON CALCAREUM (UNII: 6J1M3WA0ZK)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)		
SORBITAN OLIVATE (UNII: MDL271E3GR)		
OCTYLDODECANOL (UNII: 461N1O614Y)		
SQUALANE (UNII: GW89575KF9)		
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)		
ZINC OXIDE (UNII: SOI2LOH54Z)		
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
PROPANEDIOL (UNII: 5965N8W85T)		
CASTANEA SATIVA LEAF (UNII: IV3S2HH53G)		
SODIUM COPPER CHLOROPHYLLIN (UNII: 1D276TYV9O)		
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)		
HEXAPEPTIDE-11 (UNII: NCJ63WU6BY)		
LACTIC ACID (UNII: 33X04XA5AT)		
CERAMIDE 1 (UNII: 5THT33P7X7)		
WATER (UNII: 059QF0KO0R)		
TRHEPTANOIN (UNII: 2P6O7CFW5K)		
ALLANTOIN (UNII: 344S277G0Z)		
SQUALENE (UNII: 7QVM220FJH)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
CHOLESTEROL (UNII: 97C5T2UQ7J)		

XANTHAN GUM (UNII: TTV12P4NEE)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CETEARYL OLIVATE (UNII: 58B69Q84JO)
SUNFLOWER OIL (UNII: 3W1JG795YI)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)
ACEGLUTAMIDE (UNII: 01J18G9G97)
CERAMIDE NP (UNII: 4370DF050B)
CERAMIDE AP (UNII: F1X8L2B00J)
FOLIC ACID (UNII: 935E97BOY8)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
CHERIMOYA (UNII: 33WWT714QS)

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61328-112-20	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2023	

Marketing Information

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)

Establishment

Name	Address	ID/FEI	Business Operations
SIGAN INDUSTRIES INC		255106239	manufacture(61328-112)