

ECZEMA DERMATITIS RELIEF BALM- colloidal oatmeal cream
Skinfix, Inc.

ECZEMA DERMATITIS RELIEF BALM

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/Caprinate, 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) | | |

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| 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 Drug | M016 | 10/01/2023 | |

Labeler - Skinfix, Inc. (203158183)

Registrant - Skinfix, Inc. (203158183)