

SALLY HANSEN CRACKED HEEL REPAIR CREME 24 HR MOISTURE- dimethicone cream
Coty US LLC

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

Dimethicone 1%

Purpose

Skin protectant

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Uses

Temporarily protects chapped or cracked skin

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 for more than 7 days or clear up and occur again within a few days☐

Directions

Apply and massage into feet daily, or as needed.

☐**Do not use on**

- Deep or puncture wounds
- Animal bites
- Serious burns

☐**Inactive Ingredients**

Aqua/Water/Eau, Paraffinum Liquidum/Mineral Oil/Huile Minerale, Carthamus Tinctorius (Safflower) Seed Oil, Petrolatum, Palmitic Acid, Stearic Acid, Glycerin, Butyrospermum Parkii (Shea) Butter, Cetyl Alcohol, Isopropyl Lanolate, Isopropyl Palmitate, Sorbitan Stearate, Phenoxyethanol, Parfum/Fragrance, Potassium Hydroxide, Methylparaben, Tocopheryl Acetate, Allantoin, Urea, Disodium Edta, Propylparaben, C12-15 Alkyl Benzoate, Limonene, Myristic Acid, Lineoleamidopropyl PG-Dimonium Chloride Phosphate, Sodium PCA, Ethylparaben, Propylene Glycol, Tribehenin, Linalool, Hydrolyzed Keratin, Magnesium Ascorbyl Phosphate, Retinyl Palmitate, Hexyl Cinnamal, Butylphenyl Methylpropinoal, Glycine Soja (Soybean) Seed Extract, Sodium Sulfate, Citral, Ceramide 2, Aloe

Barbadensis Leaf Extract, Soluble Collagen, Coumarin, PEG-10 Rapeseed Sterol, Geraniol, Citronellol, Imidazolidnyl Urea, Potassium Sorbate, Benzoic Acid, Sodium Benzoate, Tocopherol, BHT, Palmitoyl Oligopeptide, FD&C Yello No. 5, FD&C Yello N



SALLY HANSEN CRACKED HEEL REPAIR CREME 24 HR MOISTURE

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66 184-152
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1.133 g in 113 g
Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0K00R)		
MINERAL OIL (UNII: T5L8T28FGP)		
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)		
PETROLATUM (UNII: 4T6H12BN9U)		
PALMITIC ACID (UNII: 2V16EO95H1)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
GLYCERIN (UNII: PDC6A3C0OX)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)		
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)		
SHEANUT OIL (UNII: O88E196QRF)		
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)		
METHYL PARABEN (UNII: A2I8C7HI9T)		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
ALLANTOIN (UNII: 344S277G0Z)		
UREA (UNII: 8W8T17847W)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
PROPYL PARABEN (UNII: Z8IX2SC1OH)		
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)		
MYRISTIC ACID (UNII: 0I3V7S25AW)		
LINOLEAMIDOPROPYL PG-DIMONIUM CHLORIDE (UNII: 7461U1YLB7)		
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)		
ETHYL PARABEN (UNII: 14255EXE39)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
TRIBEHENIN (UNII: 8OC9U7TQZ0)		
LINALOOL, (+/-)- (UNII: D81QY6I88E)		
HYDROLYZED ELASTIN, BOVINE, ALKALINE (1000 MW) (UNII: ZR28QKN0WT)		
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)		
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)		
SOYBEAN (UNII: L7HT8F1ZOD)		
SODIUM SULFATE (UNII: 0YPR65R21J)		
CERAMIDE 2 (UNII: C04977SRJ5)		
PEG-10 RAPESEED STEROL (UNII: 258O76T85M)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
BENZOIC ACID (UNII: 8SKN0B0MIM)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
TOCOPHEROL (UNII: R0ZB2556P8)		
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
SHEA BUTTER (UNII: K49155WL9Y)		

.ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I)	
Citral (UNII: T7EU0O9VPP)	
CERAMIDE 2 (UNII: C04977SRJ5)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COUMARIN (UNII: A4VZ22K1WT)	
GERANIOL (UNII: L837108USY)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66184-152-02	1 in 1 BOX		
1	NDC:66184-152-01	113 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	01/01/2012	

Labeler - Coty US LLC (789573201)

Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies and Packaging Inc.		809172885	manufacture(66184-152)

Revised: 2/2013

Coty US LLC