

PREVENTION DAILY MATTE MOISTURIZER SPF 30- zinc oxide and homosalate cream

Allure Labs

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.

Drug Facts

Active ingredients

Homosalate 10%

Zinc Oxide 9.3%

Purpose:

Sunscreen

Uses • Helps prevent sunburn • if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings :

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove

Stop use and ask a doctor if rash occurs

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

Directions • apply generously 15 minutes before sun exposure • children under 6 months of age: Ask a doctor • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating

• Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m.-2 p.m. • wear long-sleeved shirts, pants, hats and sunglasses

Other information • protect the product in this container from excessive heat and direct sun

Inactive ingredients AQUA/WATER/EAU, CYCLOPENTASILOXANE, ISODECYL NEOPENTANOATE, GLYCERIN, DIMETHICONE, CETYL PEG/PPG-10/1 DIMETHICONE, BUTYROSPERMUM PARKII (SHEA) NUT EXTRACT, CITRUS AURANTIUM DULCIS (ORANGE) OIL, LIMONENE, POLYACRYLATE-13, DIMETHICONE/PEG-10/15 CROSSPOLYMER, CAPRYLYL METHICONE, PHENOXYETHANOL, POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE, POLYISOBUTENE, CETEARYL DIMETHICONE, TRIETHOXYSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL

DIMETHICONE, EUPHORBIA CERIFERA (CANDELILLA) CERA/EUPHORBIA CERIFERA (CANDELILLA) WAX, XANTHAN GUM, POLYSORBATE 20, ETHYLHEXYLGLYCERIN, PANTHENOL, SORBITAN ISOSTEARATE, CITRUS NOBILIS (MANDARIN ORANGE) PEEL OIL, DISODIUM EDTA, EUGENIA CARYOPHYLLUS (CLOVE) LEAF OIL, DIPROPYLENE GLYCOL, ERYTHRITOL, EUGENOL, SODIUM CITRATE, GLUCOSE, HYDROLYZED PEA PROTEIN, SODIUM CHLORIDE, TOCOPHEROL, PEG-8/SMDI COPOLYMER, TETRAHEVLDECYL ASCORBATE, TOCOPHERYL ACETATE, SODIUM HYALURONATE, POTASSIUM SORBATE, SODIUM BENZOATE, LECITHIN, HOMARINE HCL, SODIUM SUCCINATE, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE, MALUS DOMESTICA FRUIT CELL CULTURE EXTRACT, ARABIDOPSIS THALIANA EXTRACT, MICROCOCCUS LYSATE, PLANKTON EXTRACT, ERGOTHIONEINE.

PREVENTION DAILY MATTE MOISTURIZER SPF 30

zinc oxide and homosalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4223
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	9.3 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
APPLE PEEL (UNII: MA36MNW77O)	
ARABIDOPSIS THALIANA (UNII: AI3L60HQ81)	
CLOVE LEAF OIL (UNII: VCA5491KVF)	
ERGOTHIONEINE (UNII: BDZ3DQM98W)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
AMMONIUM ACRYLOYL DIMETHYLTAURATE/METHACRYLATE, DIMETHYLACRYLAMIDE AND METHACRYLIC ACID COPOLYMER, PPG-3 GLYCERYL TRIACRYLATE CROSSLINKED (100000 MW) (UNII: WR7H9IW2XX)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CANDELILLA WAX (UNII: WL0328HX19)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	
TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
EUGENOL (UNII: 3T8H1794QW)	
SHEANUT (UNII: 84H6HBP32L)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG-8/SMDI COPOLYMER (UNII: CCX72L6NY6)	
HOMARINE HYDROCHLORIDE (UNII: 8866LNG61N)	
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)	
P-METHYLAMINOPHENOL SULFATE (UNII: D3W0VWG12M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
POLYISOBUTYLENE (55000 MW) (UNII: TQ77WR8A02)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PANTHENOL (UNII: WW9CM0O67Z)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
MANDARIN OIL (UNII: NJO720F72R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ORANGE OIL (UNII: AKN3KSD11B)	
MICROCOCCLUS LUTEUS (UNII: LV6L29Z6AX)	
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	

CETEARYL METHICONE (15000 MW) (UNII: VY9RTR7MSY)

ERYTHRITOL (UNII: RA96B954X6)

PEA PROTEIN (UNII: 7Q50F46595)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4223-1	7 g in 1 TUBE; Type 0: Not a Combination Product	12/29/2022	
2	NDC:62742-4223-3	1 in 1 CARTON	12/29/2022	
2	NDC:62742-4223-2	91 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/29/2022	

Labeler - Allure Labs (926831603)

Registrant - Allure Labs (926831603)

Establishment

Name	Address	ID/FEI	Business Operations
Allure Labs		926831603	manufacture(62742-4223)

Revised: 12/2022

Allure Labs