

SKIN DEFENSE MATTE TINTED SUNSCREEN- zinc oxide cream
Gentlehomme LLC

DRUG FACTS

ACTIVE INGREDIENT:

ZINC OXIDE 16%

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 AGING CAUSED BY THE SUN.

WARNINGS:

FOR EXTERNAL USE ONLY. DO NOT USE ON DAMAGED OR BROKEN SKIN. STOP USE AND ASK A DOCTOR IF RASH ACCURS. WHEN USING THIS PRODUCT, KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE. **KEEP OUT OF REACH OF CHILDREN.** IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS:

• APPLY LIBERALLY 15 MINUTES BEFORE SUN EXPOSURE

• USE A WATER RESISTANT PRODUCT IF SWIMMING OR SWEATING

• REAPPLY AT LEAST EVERY 2 HOURS

• CHILDREN UNDER 6 MONTHS: ASK FOR DOCTOR

• 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, SPECIALLY FROM 10 AM - 2 PM

• WEAR LONG-SLEEVE SHIRTS, PANTS, HATS, AND SUNGLASSES

INACTIVE INGREDIENTS:

CAPRIC/CAPRYLIC TRIGLYCERIDE, CERAMIDE 3, CYCLOHEXASILOXANE, CYCLOPENTASILOXANE, DIMETHICONE, DIMETHICONE CROSSPOLYMER, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, DIMETHICONOL, HYDROGEN DIMETHICONE, IRON OXIDE, PEG-10 DIMETHICONE, POLYHYDROXYSTEARIC ACID, TETRAHEXYLDECYL ASCORBATE, TOCOPHERYL ACETATE, VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER

OTHER INFORMATION:

• PROTECT THE PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN

• MAY STAIN SOME FABRICS.

MANUFACTURED FOR GENTLEHOMME LLC
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MADE IN THE USE WITH US AND IMPORTED MATERIALS



NDC 385366208506



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GENTLEHOMME[®]
MADE FOR MEN

SKIN DEFENSE
MATTE TINTED SUNSCREEN

BROAD SPECTRUM SPF 40

Gentle, moisturizing, lightly tinted sunscreen with iron oxides to blend with virtually all skin tones. Dries quickly, leaving an elegant, matte finish. 16% Zinc Oxide calms and soothes; perfect for dry, damaged and mature skin. Ceramides, antioxidant vitamins C & E to prevent future UV damage while aiding in the repair of existing damage.

Net Wt. 1.75 oz /50 g

SKIN DEFENSE MATTE TINTED SUNSCREEN
zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85366-208(NDC:58892-208)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	160 mg in 1 g
Inactive Ingredients			

Ingredient Name	Strength
CI 77491 (UNII: 1K09F3G675)	
CI 77499 (UNII: XM0M87F357)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CERAMIDE 3 (UNII: 4370DF050B)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CI 77492 (UNII: EX438O2MRT)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85366-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/28/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/28/2024	

Labeler - Gentlehomme LLC (064612699)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85366-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85366-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85366-208)

