


85645 20515

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85645-205(NDC:58892-205)	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	200 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)				
CYCLOHEXASILOXANE (UNII: XHK3U310BA)				
GLYCERIN (UNII: PDC6A3C0OX)				
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)				
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
WATER (UNII: 059QF0KO0R)				
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)				
CAPRYLYL GLYCOL (UNII: 00YIU5438U)				
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)				
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)				
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)				
TRIETHANOLAMINE (UNII: 9O3K93S3TK)				
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)				
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)				
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)				
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85645-205-15	1.5 g in 1 PACKET; Type 0: Not a Combination Product	06/05/2024	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC Monograph Drug	M020	06/05/2024	
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Labeler - LEILANI VIDAL (119708018)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85645-205)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85645-205)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85645-205)