

SUNSHINE SKIN TINT BROAD SPECTRUM SPF 30 - REFILL- sunshine skin tint broad spectrum spf 30 - refill lotion

Milk Makeup LLC

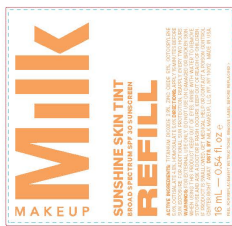
Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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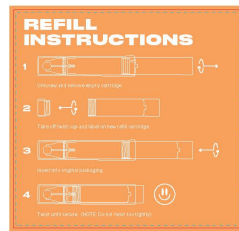


SUNSHINE SKIN TINT REFILL (US)
REGULATORY ARTWORK REVIEW

PRIMARY BOTTLE OVERLABEL ARTWORK



EXTERIOR OF WRAP



INTERIOR OF WRAP

PRIMARY SHADE LABEL ARTWORK



SECONDARY CARTON ARTWORK



INKJET BATCH CODE PLACEMENT
SHOWN IN NEON GREEN "XXXXX"



EXTERIOR



INTERIOR

SUNSHINE SKIN TINT BROAD SPECTRUM SPF 30 - REFILL

sunshine skin tint broad spectrum spf 30 - refill lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80778-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 mg in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	5 mg in 100 mL

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 mg in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.1 mg in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.9 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED OLIVE OIL UNSAPONIFIABLES (UNII: B8MIX97W95)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
CRAMBE HISPANICA SUBSP. ABYSSINICA SEED OIL (UNII: 0QW9S92J3K)	
TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
JOJOBA OIL (UNII: 724GKU717M)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ACACIA (UNII: 5C5403N26O)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SQUALANE (UNII: GW89575KF9)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
MANDARIN OIL (UNII: NJO720F72R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
BETAINE (UNII: 3SCV180C9W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	white (MEDIUM TAN)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80778-008-08	1 in 1 CARTON	05/01/2021	
1		16 mL 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	part352	05/01/2021	

Labeler - Milk Makeup LLC (079817709)

Registrant - Milk Makeup LLC (079817709)

Establishment

Name	Address	ID/FEI	Business Operations
COSMAX USA, INC, (COSMAX USA, CORPORATION)		010990210	manufacture(80778-008)

Revised: 12/2022

Milk Makeup LLC