

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

## Milk Makeup LLC

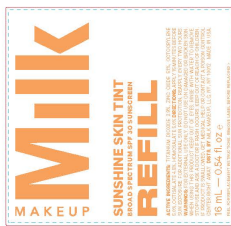
*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

### SUNSHINE SKIN TINT BROAD SPECTRUM SPF 30 REFILL Page 1

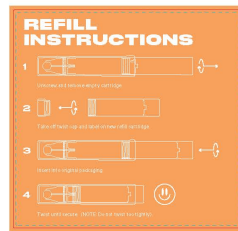


SUNSHINE SKIN TINT REFILL (US)  
REGULATORY ARTWORK REVIEW

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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 mg in 100 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 mg in 100 mL

<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 mg in 100 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.9 mg in 100 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.1 mg in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>MANDARIN OIL</b> (UNII: NJO720F72R)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES</b> (UNII: XO45V955LT)	
<b>TRIBEHENIN</b> (UNII: 8OC9U7TQZ0)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
<b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>HYDROGENATED OLIVE OIL UNSAPONIFIABLES</b> (UNII: B8MIX97W95)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYGLYCERYL-3 PENTARICINOLEATE</b> (UNII: 7Q0OK5DOT4)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>BETAINE</b> (UNII: 3SCV180C9W)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>CRAMBE HISPANICA SUBSP. ABYSSINICA SEED OIL</b> (UNII: 0QW9S92J3K)	
<b>LONICERA JAPONICA FLOWER</b> (UNII: 4465L2WS4Y)	
<b>GLYCERYL OLEATE</b> (UNII: 4PC054V79P)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85KORA)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TREMELLA FUCIFORMIS FRUITING BODY</b> (UNII: GG8N28393G)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>HYDROGENATED JOJOBA OIL, RANDOMIZED</b> (UNII: Q47ST02F58)	
<b>STEARALKONIUM HECTORITE</b> (UNII: OLV698AH5P)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>DIISOSTEARYL MALATE</b> (UNII: QBS8A3XZGQ)	
<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)	

## Product Characteristics

<b>Color</b>	white (LIGHT MEDIUM)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80778-008-03	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