

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

Milk Makeup LLC

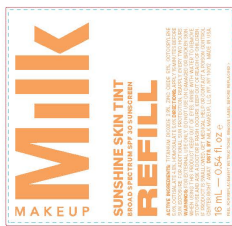
Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

SUNSHINE SKIN TINT BROAD SPECTRUM SPF 30 REFILL Page 1

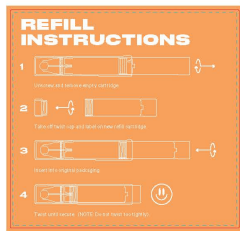


SUNSHINE SKIN TINT REFILL (US)
REGULATORY ARTWORK REVIEW

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

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| 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 |
|---|-------------------|------------------|
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 5 mg in 100 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 4.5 mg in 100 mL |

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

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| MAGNESIUM SILICATE (UNII: 9B9691B2N9) | |
| HYDROGENATED OLIVE OIL UNSAPONIFIABLES (UNII: B8MIX97W95) | |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G) | |
| JOJOBA OIL (UNII: 724GKU717M) | |
| GLYCERYL OLEATE (UNII: 4PC054V79P) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| BETAINE (UNII: 3SCV180C9W) | |
| SQUALANE (UNII: GW89575KF9) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58) | |
| STEARALKONIUM HECTORITE (UNII: O LX698AH5P) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| AVOCADO OIL (UNII: 6VNO72PFC1) | |
| TRIBEHENIN (UNII: 8OC9U7TQZ0) | |
| ISOSTEARIC ACID (UNII: X33R8U0062) | |
| GRAPE SEED OIL (UNII: 930MLC8XGG) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| CRAMBE HISPANICA SUBSP. ABYSSINICA SEED OIL (UNII: 0QW9S92J3K) | |
| LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |
| ACACIA (UNII: 5C5403N26O) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| 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) | |
| OLIVE OIL (UNII: 6UYK2W1W1E) | |

Product Characteristics

| | | | |
|-----------------|---------------|---------------------|--|
| Color | white (CAMEL) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:80778-008-09 | 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