

TRIPLE DEFENSE SUNSCREEN BROAD SPECTRUM SPF 40- sunscreen lotion
Rothschild Beauty Group 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.

Rothschild Sunscreen SPF40

Active Ingredients

Titanium Dioxide 3.3%

Zinc Oxide 8.8%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Provides high protection against sunburn

Warnings

For external use only

Do not use

on damaged or broken skin

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

if rash or irritation develops and lasts.

Keep out of reach of children

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply liberally 15 minutes before sun exposure

- Use a water-resistant sunscreen if swimming or sweating.
- Reapply
 - o Immediately after towel drying
 - o At least every 2 hours
- Children under 6 months of age: ask a 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, especially from 10 am to 2 pm
- wear long-sleeved shirts, pants, hats and sunglasses

Other Information

Protect this product from excessive heat and direct sun

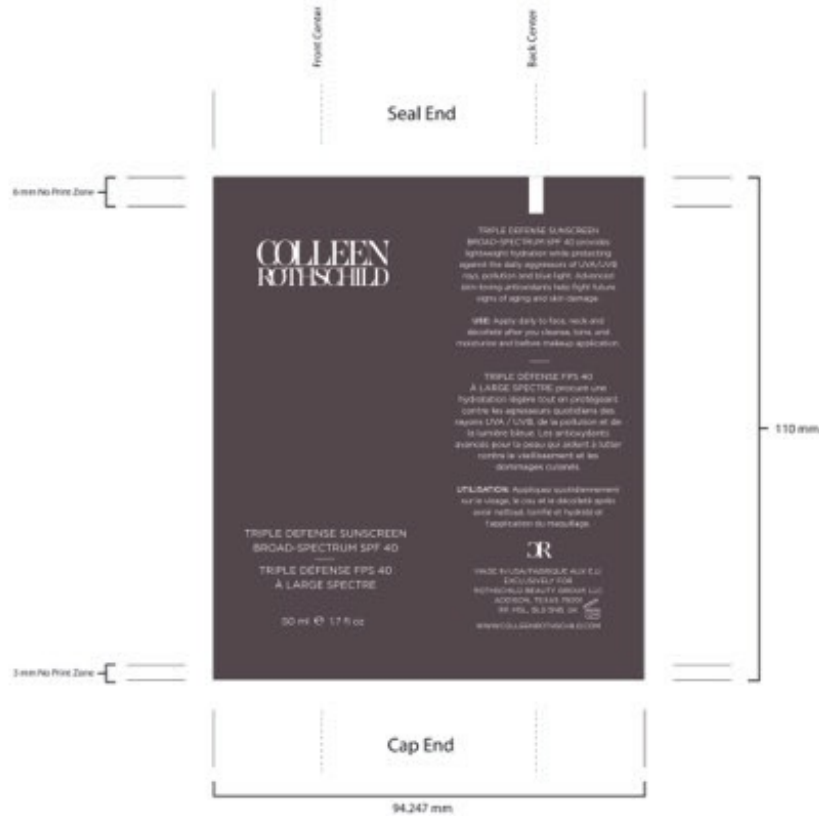
Inactive Ingredients

Alkyl (C12-15) Benzoate, Alpha Lipoic Acid, Artemisia Capillaris Flower, Butylene Glycol, Caprylyl Glycol, Chia Seed, Cyclomethicone, Diatomaceous Earth, Dimethicone, Dunaliella Salina, Ethylhexylglycerin, Fragrance, Glycerin, Haematococcus Pluvialis, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Galactoarabinan, Green Tea Leaf, Karum Seed Oil, Mannitol, Matricaria Chamomilla Whole, Oleth-10, Phenoxyethanol, Phymatolithon Calcareum, Polyacrylate Crosspolymer-6, Polyhydroxystearic Acid (2300 MW), Polysorbate 20, Polysorbate 60, Propanediol, Propanediol Dicaprylate, Silicon Dioxide, Sodium Phosphate, Sorbitol, Tetrahexyldecyl Ascorbate, Trehalose, Triethoxycaprylylsilane, Water, Xylitol, Zinc Sulfate

Tube and Carton label

All text must be outlined.

Acceptable artwork formats are:
Adobe Illustrator (.ai) or Encapsulated Post Script (.eps)



Width = Diameter x 11

8655 South 208th Street, Kent, WA 98031 • 1-800-365-4080

TRIPLE DEFENSE SUNSCREEN BROAD SPECTRUM SPF 40

sunscreens lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73040-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	88 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	33 mg in 1 mL

Inactive Ingredients

	Ingredient Name	Strength
	HAEMATO COCCUS PLUVIALIS (UNII: 31T0FF0472)	
	ZINC SULFATE (UNII: 89DS0H96TB)	
	TREHALOSE (UNII: B8WCK70T7I)	
	WATER (UNII: 059QF0KO0R)	
	XYLITOL (UNII: VCQ006KQ1E)	
	KARUM SEED OIL (UNII: 62160PU6FJ)	
	ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
	DIMETHICONE (UNII: 92RU3N3Y1O)	
	GLYCERIN (UNII: PDC6A3C0OX)	
	HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%) (UNII: 86FQE96TZ4)	
	GALACTOARABINAN (UNII: SL4SX1O487)	
	PROPANEDIOL (UNII: 5965N8W85T)	
	PROPANEDIOL DICAPRYLATE (UNII: C577OMC6UH)	
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
	MANNITOL (UNII: 3OWL53L36A)	
	MATRICARIA CHAMOMILLA WHOLE (UNII: G0R4UBI2ZZ)	
	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
	POLYSORBATE 60 (UNII: CAL22UVI4M)	
	OLETH-10 (UNII: JD797EF70J)	
	SODIUM PHOSPHATE (UNII: SE337SVY37)	
	SORBITOL (UNII: 506T60A25R)	
	TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
	TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
	ARTEMISIA CAPILLARIS FLOWER (UNII: KG4724BPZG)	
	CYCLOMETHICONE (UNII: NMQ347994Z)	
	DIATOMACEOUS EARTH (UNII: 2RF6EJ0M85)	
	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
	ALPHA LIPOIC ACID (UNII: 73Y7P0K73Y)	
	CHIA SEED (UNII: NU0OLX06F8)	
	DUNALIELLA SALINA (UNII: F401DKI9A6)	
	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
	GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
	AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPAS) (UNII: Q7UI015FF9)	
	POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
	PHYMATOLITHON CALCAREUM (UNII: 6J1M3WA0ZK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73040-001-01	1 in 1 CARTON	11/13/2020	
1		60 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	11/13/2020	

Labeler - Rothschild Beauty Group LLC (062783354)

Establishment

Name	Address	ID/FEI	Business Operations
TAKA USA Inc. dba Cosmetic Innovations		802860515	manufacture(73040-001)

Revised: 11/2020

Rothschild Beauty Group LLC