

**LIGHT HEARTED BROAD SPECTRUM SPF 30 SUNSCREEN- octisalate,
octocrylene, zinc oxide lotion
Sunday Riley Modern Skincare, 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.

LIGHT HEARTED BROAD SPECTRUM SPF 30 SUNSCREEN LOTION

Active Ingredients

Octisalate 5%
Octocrylene 3.5%
Zinc Oxide 16.32%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (**see Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

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 occurs

Keep out of reach of Children

Directions

- Apply generously 15 minutes before sun exposure
- 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 a.m-2 p.m
 - Wear long-sleeved shirts, pants, hats, and sunglasses

- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating

Inactive Ingredients

Water/Eau/Aqua, Octyldodecanol, Dimethicone, Alcohol Denat., Polypropylsilsesquioxane, C12-C15 Alkyl Benzoate , Cyclopentasiloxane, Polyhydroxystearic Acid, Cetyl Diglyceryl Tris (Trimethylsiloxy) silylethyl Dimethicone, Isododecane, PPG-24-Glycereth-24, Curcuma Longa (Turmeric) Root Extract, Xanthophyll, Melia Azadirachta Leaf Extract, Melia Azadirachta Flower Extract, Corallina Officinalis Extract, Betaine, Coccinia Indica Fruit extract, Dimethicone/Vinyl Dimethicone Crosspolymer, Octyldodecyl Xyloside, PEG-30 Dipolyhydroxystearate, Magnesium stearate, Triethoxycaprylsilane, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinamate, Dimethicone Crosspolymer, Carthamus Tinctorius (Safflower) seed oil, Methylpropanediol, Caprylyl Glycol, Polyquaternium-80, Didecyldimonium Chloride, Magnesium Sulphate, Sodium Chloride, Magnesium Myristate

Other Information

Protect the product in this container from excessive heat and direct sun

Distributed By

Sunday Riley Modern Skincare, LLC
Houston, Texas (TX) 77027, USA

PACKAGE LABEL



LIGHT HEARTED BROAD SPECTRUM SPF 30 SUNSCREEN

octisalate, octocrylene, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73001-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octisalate (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	Octisalate	5 g in 100 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	3.5 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	16.32 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Octyldodecanol (UNII: 461N1O614Y)	
Dimethicone (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
PROPYLSILSESQUIOXANE, HYDROGEN TERMINATED (UNII: 2PDG9JR76G)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ISODODECANE (UNII: A8289P68Y2)	
PPG-24-GLYCERETH-24 (UNII: V341SPY84U)	
TURMERIC (UNII: 856YO1Z64F)	
LUTEIN (UNII: X72A60C9MT)	
AZADIRACHTA INDICA LEAF (UNII: HKY915780T)	
AZADIRACHTA INDICA FLOWER (UNII: 3TE8A92UPM)	
CORALLINA OFFICINALIS (UNII: 4004498D06)	
BETAINE (UNII: 3SCV180C9W)	
COCCINIA GRANDIS FRUIT (UNII: VLJ6WOT3K5)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
OCTYLDODECYL XYLOSIDE (UNII: 8Z6VNR46QM)	
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
DIMETHICONE/DIENE DIMETHICONE CROSSPOLYMER (UNII: RSA9I561OK)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIDECYLDIMONIUM CHLORIDE (UNII: JXN4009Y9B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73001-005-45	1 in 1 BOX	04/16/2021	
1		45 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph not final	part352	04/16/2021	

Labeler - Sunday Riley Modern Skincare, LLC (012302640)

Revised: 11/2021

Sunday Riley Modern Skincare, LLC