

TOTAL SUNCARE SUNSCREEN SPF 15 - avobenzene, octisalate, octinoxate, oxybenzone spray

Total Suncare 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.

Sunscreen SPF 15

Active Ingredients

Avobenzene 2 percent
Octisalate 2 percent
Octinoxate 1 percent
Oxybenzone 2 percent

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Provides moderate protection against sunburn
- Retains SPF after 40 minutes of activity in the water

Warnings

- For External Use Only
- Flammable: Keep away from fire or flame
- UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.
- 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
- Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 degrees F.
- Keep out of reach of children.

Directions

- Apply evenly before sun exposure and as needed.
- Hold can about 6in away from body and spray onto skin.
- Do not spray onto face - spray into palm and smooth over face and neck.
- Children under 6 months of age: ask a doctor.
- Reapply as needed or after towel drying, swimming, or perspiring.

Other Information

- Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.
- May stain some fabrics
- Avoid long term storage above 104 degrees F
- For your protection, this bottle has an imprinted seal around the neck. Do not use if tamper evident seal is missing, tampered, broken, or destroyed.

Inactive Ingredients

Acrylates / Octylacrylamide Copolymer, Alcohol Denat, Alkyl Benzoate, Fragrance, Glycerin

Total SunCare
SUN
SCREEN
SPF 15

Contininuous Spray
Water Resistant

BROAD SPECTRUM
UVA/UVB PROTECTION

Clear rub-free free formula
fast and easy coverage

Net Contents 6 fl oz (177 ml)
Expiration Date?

Lot Number?

Distributed By:
Total Suncare LLC, 100 S. Washington Ave.
Dunellen, NJ 08812, United States
www.sunscreenus.com

Product of China



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SPF 15

Continuous Spray

Water Resistant

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Drug Facts

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Apply evenly before sun exposure and as needed. Hold can about 6in away from body and spray onto skin. Do not spray directly onto face - spray into palm and smooth over face and neck. Children under 6 months of age: ask a doctor. Reapply as needed or after towel drying, swimming, or perspiring.

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Product Information

Table with 4 columns: Product Type (HUMAN OTC DRUG), Item Code (Source), NDC:49893-100, Route of Administration (TOPICAL)

Active Ingredient/Active Moiety

Table with 3 columns: Ingredient Name, Basis of Strength, Strength. Lists Avobenzone, Octisalate, and Octinoxate with their respective strengths.

OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49893-100-01	177 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/25/2009	

Labeler - Total Suncare LLC (831945980)

Establishment

Name	Address	ID/FEI	Business Operations
Athena (Guangzhou) Cosmetics Manufacturer Co., Ltd		527326663	manufacture

Revised: 11/2009

Total Suncare LLC