

TOTAL SUNCARE SUNSCREEN SPF 50 - avobenzone, homosalate, octinoxate, octisalate, 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 50

Active Ingredients

Avobenzone	3 percent
Homosalate	10 percent
Octinoxate	3 percent
Octyl Salicylate	3 percent
Oxybenzone	4 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.

Acrylates / Octylacrylamide Copolymer, Alcohol Denat, Alkyl Benzoate, Aloe Barbadensis Leaf

extract, Fragrance, Mineral oil

Total SunCare

SUN

SCREEN

SPF 50

Continuous 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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- Apply evenly before sun exposure and as needed.
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Other information

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Inactive Ingredients

Acrylates / Octylacrylamide Copolymer, Alcohol Denat, Alkyl Benzoate, Aloe Barbadosensis Leaf extract, Fragrance, Mineral oil.

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avobenzene, homosalate, octinoxate, octisalate, oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49893-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 mL in 100 mL

OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	3 mL in 100 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	4 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
MINERAL OIL (UNII: T5L8 T28 FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49893-300-01	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