

**TOTAL SUNCARE SUNSCREEN SPF 30 - avobenzone, 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 30**

Active Ingredients

Avobenzone 3 percent  
Octisalate 2 percent  
Octinoxate 5 percent  
Oxybenzone 3 percent

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Provides high 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 15

Continuous Spray  
Water Resistant

BROAD SPECTRUM  
UVA/UVB PROTECTION

Clear rub-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

	<b>Drug Facts</b>				
	<table border="1"><thead><tr><th>Active Ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Avobenzone 3% Octisalate 2% Octinoxate 5% Oxybenzone 3%</td><td>Sunscreen</td></tr></tbody></table>	Active Ingredients	Purpose	Avobenzone 3% Octisalate 2% Octinoxate 5% Oxybenzone 3%	Sunscreen
	Active Ingredients	Purpose			
	Avobenzone 3% Octisalate 2% Octinoxate 5% Oxybenzone 3%	Sunscreen			
	<b>Uses</b> ▪ Helps prevent sunburn ▪ Higher SPF gives more sunburn protection ▪ Provides high protection against sunburn ▪ Retains SPF after 40 minutes of activity in the water				
<b>Warnings</b> ▪ <b>For External Use Only</b> ▪ <b>Flammable: Keep away from fire or flame</b> ▪ 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°F. ▪ Keep out of reach of children.					
<b>Directions</b> ▪ 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.					
<b>Other information</b> ▪ <b>Sun Alert:</b> 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°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.					
<b>Inactive Ingredients</b> Acrylates / Octylacrylamide Copolymer, Alcohol Denat, Alkyl Benzoate, Aloe Barbadosensis Leaf extract, Fragrance, Mineral oil.					
Clear rub-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			

# TOTAL SUNCARE SUNSCREEN SPF 30

avobenzone, octisalate, octinoxate, oxybenzone spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49893-200
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	2 mL in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 mL in 100 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	3 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958 V90 M)	
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	
MINERAL OIL (UNII: T5L8 T28 FGP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49893-200-01	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