

TROPICAL OTTERS GLITTER SUNSCREEN SPF-50 - SUGAR SPARKLE-
homosalate, octisalate, octocrylene, zinc oxide cream
6174 INDUSTRIES, LLC

TROPICAL OTTERS Glitter Sunscreen SPF-50 - Sugar Sparkle

Drug Facts

Active Ingredients

Homosalate 10.00%
Octisalate 5.00%
Octocrylene 5.00%
Zinc Oxide 4.00%

Purpose

Sunscreen

Uses:

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Retains SPF after 80 minutes of swimming or sweating.
- 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 or irritation develops and lasts.

Keep out of reach of children.

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

If pregnant or breast-feeding,

ask a health professional before use.

Directions

- Apply liberally 15 minutes before sun exposure and as needed.
- Children under 6 months of age: ask a doctor.
- Reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying.
 - at least every 2 hours.
- **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 broad spectrum SPF 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.

Other Information:

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

Inactive Ingredients:

Acrylates Copolymer, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Butyloctyl Salicylate, Calendula Officinalis Extract, Camellia sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Safflower) Oil, Cetearyl Oliviate, Cetyl Alcohol, Citric Acid, Cocos Nucifera (Coconut) Oil, Cosmetic Glitter (Polyethylene Terephthalate, Polymethyl Methacrylate, Polyurethane 33), Daucus Carota Sativa (Carrot) Extract, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, Parfum (Fragrance), Phenoxyethanol, Polysorbate-20, Sorbitan Oliviate, Styrene/Acrylates Copolymer, Tocopheryl Acetate (Vitamin E), Zemea (Corn) Propanediol, FD&C Blue #1, FD&C Red #40

Questions?

1-980-202-1769

Package Labeling:

TROPICAL OTT3RS
GLITTER SUNSCREEN
BROAD SPECTRUM SPF 50
SUGAR SPARKLE

UVA + UVB PROTECTION | WATER RESISTANT 80 MINUTE | BIODEGRADABLE GLITTER

4.5 FLOZ (133 ML)

Drug Facts	
Active Ingredients	Purpose
Homosalate 10.00%	Sunscreen
Octisalate 5.00%	Sunscreen
Octocrylene 5.00%	Sunscreen
Zinc Oxide 4.00%	Sunscreen
Uses:	
<ul style="list-style-type: none"> Helps prevent sunburn. Higher SPF gives more sunburn protection. Retains SPF after 80 minutes of swimming or sweating. 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 or irritation develops and lasts.	
Keep out of reach of children.	
If swallowed, get medical help or contact a Poison Control Center right away.	
If pregnant or breast-feeding, ask a health professional before use.	
Directions:	
<ul style="list-style-type: none"> Apply liberally 15 minutes before sun exposure and as needed. Children under 6 months of age: ask a doctor. Reapply: <ul style="list-style-type: none"> after 80 minutes of swimming or sweating immediately after towel drying at least every 2 hours Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> Limit time in the sun, especially from 10 a.m. - 2 p.m. Wear long-sleeved shirts, pants, hats, and sunglasses. 	
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Questions? 1-980-202-1769	
<p>Made in the USA www.ott3rs.com Manufactured for 6174 Industries, LLC Huntersville, NC 28078</p>	
<p>1 98168 48175 2</p>	

TROPICAL OTTERS GLITTER SUNSCREEN SPF-50 - SUGAR SPARKLE

homosalate, octisalate, octocrylene, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84164-460
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CARROT (UNII: L56Z1JK48B)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CORN (UNII: 0N8672707O)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84164-460-00	133 mL in 1 TUBE; Type 0: Not a Combination Product	03/04/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/04/2024	

Labeler - 6174 INDUSTRIES, LLC (110191799)