

**TROPICAL OTTERS GLITTER SUNSCREEN SPF-50 - FRAGRANCE FREE-  
homosalate, octisalate, octocrylene, zinc oxide cream  
6174 INDUSTRIES, LLC**

-----  
**TROPICAL OTTERS Glitter Sunscreen SPF-50 - Fragrance Free**

***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, Lactobacillus Ferment, Phenoxyethanol, Polysorbate-20, Punica Granatum (Pomegranate) Extract, Rubus Idaeus (Raspberry) Extract, Sorbitan Oliviate, Styrene/Acrylates Copolymer, Tocopheryl Acetate (Vitamin E), Zemea (Corn) Propanediol, FD&C Blue #1, FD&C Yellow #5.

**Questions?**

1-980-202-1769

**Package Labeling:**

**Drug Facts**

Active Ingredients	Purpose
Homosalate 10.00%	Sunscreen
Octisalate 5.00%	Sunscreen
Octocrylene 5.00%	Sunscreen
Zinc Oxide 4.00%	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 the 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, Lactobacillus Ferment, Phenoxyethanol, Polysorbate-20, Punica Granatum (Pomegranate) Extract, Rubus Idaeus (Raspberry) Extract, Sorbitan Oliviate, Styrene/Acrylates Copolymer, Tocopheryl Acetate (Vitamin E), Zemea (Corn) Propanediol, FD&C Blue #1, FD&C Yellow #5.

**Questions?** 1-980-202-1769

Made in the USA  
www.ott3rs.com  
Manufactured for  
6174 Industries, LLC  
Huntersville, NC 28078

1 98168 55077 9

## TROPICAL OTTERS GLITTER SUNSCREEN SPF-50 - FRAGRANCE FREE

homosalate, octisalate, octocrylene, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:84164-461
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

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

## Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>SAFFLOWER</b> (UNII: 4VBL71TY4Y)	
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>CARROT</b> (UNII: L56Z1JK48B)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>POMEGRANATE</b> (UNII: 56687D1Z4D)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CORN</b> (UNII: 0N8672707O)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84164-461-00	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)