REEF BABIES SPF 50 OXYBENZONE FREE- octocrylene, octisalate, and avobenzone spray Tropical Seas, Inc.

Reef Babies SPF 50 Spray

Drug Facts

Active Ingredients

Octocrylene 10.0%

Octisalate 5.0%

Avobenzone 3.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- 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

Flammable: Do not use near heat, flame, or while smoking

Do not use on damaged or broken skin

When using this product:

- Keep out of eyes. Rinse with water to remove.
- Do not puncture or incinerate. Contents under pressure.
- Do not store at temperatures above 120° F

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- do not spray directly on face spray into hands and apply to face
- hold approximately 4 6 inches from skin to spray
- rub into skin evenly to ensure appropriate coverage

- use in a well-ventilated area
- avoid inhaling or exposing others to spray
- do not apply in windy conditions
- 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 a broad spectrum SPF 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. 2 p.m.
 - wear long-sleeve shirts, pants, hats and sunglasses
- children under 6 months: Ask a doctor

Inactive Ingredients

sd alcohol 40-b, deionized water, lauryl lactate, cyclopentasiloxane, c12-15 alcohols benzoate, acrylates octylacrylamide copolymer, octyldodecyl neopentanoate, octyl dodecyl citrate crosspolymer, phenethyl benzoate, and fragrance.

Other Information

- protect this product from excessive cold, heat, and direct sun.
- store at temp below 90° F and avoid long term storage
- may stain fabrics or surfaces

Questions or comments?

Call toll free 1-800-368-7327

Principal Display Panel - Bottle Label

180ml NDC 52854-558-02



REEF BABIES SPF 50 OXYBENZONE FREE

octocrylene, octisalate, and avobenzone spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52854-558
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL	

Inactive Ingredients

Ingredient Name	Strength	
PHENETHYL BENZOATE (UNII: 0C143929GK)		
CYCLOMETHICONE 5 (UNII: 0THT5PCIOR)		
LAURYL LACTATE (UNII: G5SU0BFK7O)		
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)		
OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: X323T6QO4M)		
ALCOHOL (UNII: 3K9958V90M)		
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)		
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)		

Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52854-558- 02	180 mL in 1 CAN; Type 0: Not a Combination Product	12/07/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	12/07/2020	

Labeler - Tropical Seas, Inc. (627865660)

Establishment					
Name	Address	ID/FEI	Business Operations		
Tropical Seas, Inc.		627865660	manufacture(52854-558)		

Revised: 10/2023 Tropical Seas, Inc.