

**REEF SAFE SPF 45- homosalate, octocrylene, octinoxate, oxybenzone and octisalate spray
Tropical Seas, Inc.**

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.

Drug Facts

Active Ingredients

Homosalate 10.0%

Octylcrylene 10.0%

Octinoxate 7.5%

Oxybenzone 6.0%

Octisalate 5.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown to prevent sunburn, not skin cancer or early skin aging.

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 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
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- children under 6 months: Ask a doctor

Inactive Ingredients

ethanol, aqueous extracts of: aloe barbadensis leaf extract, algae extract (hawaiian seaplant), chamomilla recutita (matricaria) flower extract, symphytum officinale (comfrey) root & leaf extract, taraxacum

officinale (dandelion) leaf extract, echinacea purpurea (coneflower) extract, sambucus nigra (elder) flower extract, panax quinquefolium (ginseng) root extract, macrocystis pyrifera (kelp) extract, lavandula angustifolia (lavender) extract, cymbopogon schoenanthus (lemon grass) extract, althea officinalis (marshmallow) root extract, achillea millefolium (yarrow flower) extract, camellia sinensis (white tea) extract, acrylates octylacrylamide co-polymer, c12-15 alcohols benzoate, cyclopentasiloxane, octyldodecyl neopentanoate, and fragrance.

Other Information

- **WARNING: Flammable**
 - **do not** use near open flame or heat source
 - hold approximately 10 - 12 inches from skin to spray
 - spray into palm of hand, rub together, then apply to your face
 - **do not** spray directly into your face so that it won't get in your eyes.
 - rub into skin evenly to ensure appropriate coverage
 - protect this product from excessive heat and direct sun.
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Questions or comments?

Call toll free 1-800-368-7327

Principal Display Panel - Bottle Label

Biodegradable

Reef Safe®

BY TROPICAL SEAS

45

Original Formula SPF 45+

Water Resistant (80 minutes)

8.45 fl. oz. (250ml) **Sprayable Sunscreen**

Non-Toxic to Sealife

Biodegradable

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REEF SAFE SPF 45

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52854-046
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	6 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
CHAMOMILE (UNII: FGL3685T2X)	
SYMPHYTUM UPLANDICUM LEAF (UNII: D05HXK6R3G)	
COMFREY ROOT (UNII: M9VVZ08EKQ)	
TARAXACUM OFFICINALE LEAF (UNII: 0022LFFJ74Y)	
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX)	
SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)	
AMERICAN GINSENG (UNII: 8W75VCV53Q)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
CYMBOPOGON SCHOENANTHUS TOP (UNII: 9SJ1LW39W)	
ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H)	
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52854-046-01	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2013	

Labeler - Tropical Seas, Inc. (627865660)

Establishment

Name	Address	ID/FEI	Business Operations
Tropical Seas, Inc.		627865660	manufacture(52854-046)

Revised: 2/2020

Tropical Seas, Inc.