

PLANET PROTECTING SUNSCREEN 30- titanium dioxide lotion **Stream2Sea, 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.

Planet Protecting Sunscreen 30+

DRUG FACTS

ACTIVE INGREDIENTS

8.8% Titanium dioxide (Non-Nano)

PURPOSE

Sunscreen

USES

- Helps prevent sunburn

WARNINGS

- For external use only.
- Do not use on damaged or broken skin.
- Stop use and ask a doctor if rash occurs.
- When using this product, keep out of eyes, Rinse with water to remove.
- Keep babies and young children out of direct sunlight.

DIRECTIONS

- Apply liberally 15 minutes before sun exposure.
- Reapply after 80 minutes of swimming or sweating or immediately after towel drying and at least every 2 hours.
- For children under 6 months of age; ask a doctor.
- Wear UPF clothing and apply to exposed skin in small amounts to start.

OTHER INFORMATION

- Protect this product from excessive heat and sunlight
- **REEF-LEGAL SUNSCREEN TO PROTECT PALAU AND THE FUTURE OF THE PLANET**
 - Many sunscreens contain chemicals that damage the planet's reefs and wildlife when you wear it in the water. This one doesn't. So you can save your skin and the Earth's.

INACTIVE INGREDIENTS

Deionized Water, Aqueous Extracts of Camellia sinensis (Green Tea) Leaf*, Ocimum Tenuiflorum (Tulsi) Leaf*, Alaria Esculenta (Wakame Seaweed)* and Olea Europa (Olive) Leaf*, Caprylic/Capric Triglyceride, Aloe Barbedensis (Aloe) Leaf juice*, Cocoglycerides, Glycerin, Cetearyl Alcohol, Cetyl Palmitate, Polyhydroxystearic Acid, Sorbitan Oliviate, Cetearyl Oliviate, Methylcellulose, Cocos Nucifera (Coconut) Oil*, Stearic acid, Acrylates Copolymer, Magnesium Aluminium Silicate, Sorbitan Palmitate, Tocopherol, Xanthum

Gum, Alumina, Benzyl Alcohol, Salicylic Acid, Sorbic Acid, Iron Oxides *ORGANIC INGREDIENTS

OUR PACKAGE IS MADE USING SUGARCANE RESIN, PLEASE RECYCLE

Manufactured in the USA by: Stream2Sea | Bowling Green, FL 33834 Questions: 866-960-9513 | Stream2Sea.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

PLANET PROTECTING SUNSCREEN 30+ NDC 69555-037-30 - 3 FL OZ/90 ML - Label

The image shows a blue product label for Planet Protecting Sunscreen 30+. The label features the product name and SPF 30+ in large white text. Below this is a white box with a horizontal line and a dot, labeled 'PALAU PLEDGE'. The label also includes a large yellow circle and the Stream2Sea logo with '3 FL OZ. 90 ML'. On the left side, there is a 'DRUG FACTS' section with sub-sections for Active Ingredients, Inactive Ingredients, Purpose, Warnings, Directions, and Other Info. Below this is a 'REEF-LEGAL' section and a recycling notice. At the bottom left is a barcode with the number 8 51061 00634 6. At the bottom center are logos for 'Protect Land x Sea CERTIFIED', a recycling symbol, and 'UVA'. At the bottom right is the Stream2Sea logo.

DRUG FACTS

ACTIVE INGREDIENTS • 8.8% Titanium Dioxide (Non-Nano)

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Protect Land x Sea CERTIFIED

UVA

STREAM2SEA®
3 FL OZ. 90 ML

PLANET PROTECTING SUNSCREEN 30

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69555-037
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	8.8 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
HOLY BASIL LEAF (UNII: SCJ765569P)	
ALARIA ESCULENTA (UNII: EJ9JK8J58D)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALOE (UNII: V5VD430YW9)	
COCO-GLYCERIDES (UNII: ISE9I7DNUG)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	
COCONUT OIL (UNII: Q9L0O73W7L)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
SORBITAN MONOPALMITATE (UNII: 77K6Z421KU)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SORBIC ACID (UNII: X045WJ989B)	
FERROUS OXIDE (UNII: G7036X8B5H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69555-037-30	90 mL in 1 TUBE; Type 0: Not a Combination Product	07/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/01/2022	

Labeler - Stream2Sea, LLC (052920828)

Establishment

Name	Address	ID/FEI	Business Operations
Stream2Sea, LLC		052920828	manufacture(69555-037)

Revised: 6/2022

Stream2Sea, LLC