

**OCEAN SAFE SUNSCREEN- titanium dioxide cream**  
**Naturally Uncommon, 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.*

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**OCEAN SAFE SUNSCREEN**

***Broad Spectrum UVA/UVB Water-Resistant 80 Minutes***

**SAFE FOR FACE & BODY**

**SENSITIVE SKIN FORMULA**

**SWEAT RESISTANT**

**FRAGRANCE FREE**

**HIGH PERFORMANCE MINERAL BASED SUNSCREEN**

**3 FL OZ/ 88 ML**

**DRUG FACTS**  
**Active Ingredients**

8.8% Titanium Dioxide

**Purpose**

(Non-Nano).....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.

## **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.

## **OTHER INFO**

Protect this product from excessive heat and sunlight.

## **INACTIVE INGREDIENTS**

Deionized Water, Aqueous Extracts of Camellia Sinenis (Green Tea) Leaf\*, Ocimum Tenuiflorum (Tulsi) Leaf\*, Alaria Esculenta (Wakame Seaweed)\*, Olea Europa (Olive) Leaf\*, Caprylic/Capric Triglyceride, Aloe Barbadensis (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 Aluminum Silicate, Sorbitan Palmitate, Tocopherol, Xanthan Gum, Alumina, Benzyl Alcohol, Salicylic Acid and Sorbic Acid.

\*Organic Ingredients.

## **MANUFACTURED FOR**

NATURALLY UNCOMMON, LLC  
ATKINSON, NH03811

[fishermanhandscrub.com](http://fishermanhandscrub.com)

## **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**OCEAN SAFE SUNSCREEN-88 ML - NDC-80325-003-01- TUBE LABEL.**



## OCEAN SAFE SUNSCREEN

titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80325-003
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	88 mg in 88 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>HOLY BASIL LEAF</b> (UNII: SCJ765569P)	

<b>ALARIA ESCULENTA</b> (UNII: EJ9JK8J58D)
<b>OLEA EUROPAEA LEAF</b> (UNII: MJ95C3OH47)
<b>ALOE</b> (UNII: V5VD430YW9)
<b>TRICAPRIN</b> (UNII: O1PB8EU98M)
<b>COCO-GLYCERIDES</b> (UNII: ISE9I7DNUG)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)
<b>POLYHYDROXYSTEARIC ACID STEARATE</b> (UNII: 8KQ7I65XZE)
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)
<b>METHYLCELLULOSE, UNSPECIFIED</b> (UNII: Z944H5SN0H)
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>LUVISET 360</b> (UNII: 05BG6GY6YK)
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)
<b>SORBITAN MONOPALMITATE</b> (UNII: 77K6Z421KU)
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ)
<b>SORBIC ACID</b> (UNII: X045WJ989B)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80325-003-01	88 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** - Naturally Uncommon, LLC (044473410)

### Establishment

Name	Address	ID/FEI	Business Operations
Stream2Sea, LLC		052920828	manufacture(80325-003)