

MACKENZIES OCEAN SAFE SUNSCREEN- titanium dioxide cream
Naturally Uncommon, LLC

Mackenzies SPF 30 Sunscreen

DRUG FACTS

Active Ingredients

Titanium Dioxide (non-nano) 8.8%

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.

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 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

Acrylates Copolymer, Alaria Esculenta (Wakame Seaweed) Extract*, Aloe Barbadensis (Aloe) Leaf Juice*, Alumina, Benzyl Alcohol, Camellia Sinensis (Green Tea) Leaf Extract*, Caprylic/Capric Triglyceride, Cetearyl Oliviate, Cocoglycerides, Cocos Nucifera (Coconut Oil)*, Deionized Water, glycerin, Magnesium Aluminum Silicate, Methylcellulose, Ocimum

Tenuiflorum (Tulsi) Leaf Extract*, Olea Europea (Olive) Leaf Extract*, Polyhydroxystearic Acid, Salicylic Acid, Sorbic Acid, Sorbitan Oliviate, Sorbitan Palmitate, Stearic Acid, Tocopherol, Xanthan Gum.

*Certified Organic Ingredients

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



MACKENZIES OCEAN SAFE SUNSCREEN
 titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80325-030
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)	
ALOE (UNII: V5VD430YW9)	
TRICAPRIN (UNII: O1PB8EU98M)	
COCO-GLYCERIDES (UNII: ISE9I7DNUG)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	
COCONUT OIL (UNII: Q9L0O73W7L)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LUVISET 360 (UNII: 05BG6GY6YK)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
SORBITAN MONOPALMITATE (UNII: 77K6Z421KU)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80325-030-03	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 Drug	M020	07/01/2022	
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Labeler - Naturally Uncommon, LLC (044473410)

Registrant - Stream2Sea LLC (052920828)

Establishment			
Name	Address	ID/FEI	Business Operations
Stream2Sea, LLC		052920828	manufacture(80325-030)

Revised: 8/2024

Naturally Uncommon, LLC