

MACKENZIES SPF 40 OCEAN SAFE SUNSCREEN- zinc oxide cream
Naturally Uncommon LLC

Zinc Oxide 20%

Sunscreen.

Helps prevent sunburn.

- **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 or irritation develops and lasts.

If product is swallowed, get medical help or contact a Poison Control Center right away.

- 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.

Alaria Esculenta (Wakame Seaweed) Extract*, Camellia Sinensis (Green Tea) Leaf Extract*, Cera Alba (Beeswax), Cetearyl Alcohol, Cetyl Palmitate, Helianthus Annus (Sunflower) Seed Oil, Jojoba Esters, Mixed Tocopherols (Vitamin E), Ocimum Tenuiflorum (Tulsi) Leaf Extract*, Olea Europea (Olive) Leaf Extract*, Polyhydroxystearic Acid, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Silica, Sorbitan Oliviate, Squalene (Plant Based)

*Certified Organic Ingredients

OCEAN SAFE NON-NANO ZINC OXIDE FORMULA

DRUG FACTS

Active Ingredient	Purpose
Zinc Oxide 20% (Non-Nano EcoSafe Zinc™)	Sunscreen

Use ■ Helps prevent sunburn

Warnings

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 or irritation develops and lasts ■ **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 or immediately after towel drying and at least every 2 hours • For children under 6 months of age; ask a doctor

Other Information ■ Protect this product from excessive heat and sunlight.

Inactive Ingredients ■ Alaria Esculenta (Wakame Seaweed) Extract*, Camellia Sinensis (Green Tea) Leaf Extract*, Cera Alba (Beeswax), Cetearyl Alcohol, Cetyl Palmitate, Helianthus Annus (Sunflower) Seed Oil, Jojoba Esters, Mixed Tocopherols (Vitamin E), Ocimum Tenuiflorum (Tulsi) Leaf Extract*, Olea Europea (Olive) Leaf Extract*, Polyhydroxystearic Acid, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Silica, Sorbitan Oliviate, Squalene (Plant Based) *Certified Organic Ingredients

MANUFACTURED FOR NATURALLY UNCOMMON



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NATURALLY UNCOMMON, LLC
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MACKENZIES SPF 40 OCEAN SAFE SUNSCREEN

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80325-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
ALMOND OIL (UNII: 66YXD4DKO9)	
SQUALENE (UNII: 7QWM220FJH)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HOLY BASIL LEAF (UNII: SCJ765569P)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TOCOPHEROL (UNII: R0ZB2556P8)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
ALARIA ESCULENTA (UNII: EJ9JK8J58D)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80325-040-02	80 g in 1 JAR; Type 0: Not a Combination Product	07/17/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/17/2024	

Labeler - Naturally Uncommon LLC (044473410)

Registrant - Stream2Sea LLC (052920828)

Establishment

Name	Address	ID/FEI	Business Operations
Stream2Sea LLC		052920828	manufacture(80325-040)