

ALLSWELL MINERAL SUNSCREEN SPF 30- zinc oxide 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.

ALLSWELL MINERAL SUNSCREEN SPF 30

Active ingredient

Zinc Oxide 22%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (**See Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.

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 occurs.
- **Keep out of reach of children.** If product 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 two hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad-spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10am - 2pm
 - wear long-sleeve shirts, pants, hats and sunglasses
 - **Children under 6 months: Ask a doctor**

Inactive Ingredients

Helianthus Annus (Sunflower) Seed Oil, Persea Gratissima (Avocado) Oil, Caprylic Capric

Triglycerides, Butyrospermum Parkii (Shea) Butter, Beeswax, Helianthus Annus (Sunflower) Seed Wax, Polyhydroxystearic Acid, Glyceryl Caprylate (and) Glyceryl Undecylenate, Non-GMO Corn Starch, Acrylates Copolymer, Vitamin E

Other Information

- Protect this product from excessive heat and direct sun

Questions or comments?

- Visit allswellgoods.com

Allswell Mineral Sunscreen Spf 30-NDC 69555-043-01-Tube label

MINERAL SUNSCREEN

BEST FOR
FACE & SHOULDERS

Broad Spectrum SPF 30

ALLSWELL

GOODS

Water Resistant 80 min

**Non
Nano
Zinc**


Recyclable
Aluminum

**Reef
Friendly**

1.8 OZ (51g)

MARINE SPORT BALM

Drug Facts

Active Ingredients	Purpose
Zinc Oxide 22%	Sunscreen

Uses

- * Helps prevent sunburn
- * If used as directed with other sun protection measures (see Directions) decreases the risk of skin cancer and early skin ageing caused by the sun

Warnings

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- * Do not use on damaged or broken skin
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- * Stop use and ask doctor if rash occurs
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Directions

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 - * limit time in the sun, especially from 10am - 2pm
 - * wear long-sleeve shirts, pants, hats, and sunglasses
 - * children under 6 months: Ask a doctor

Inactive Ingredients

Helianthus Annuus (Sunflower) Seed Oil, Persea Gratissima (Avocado) Oil, Caprylic Capric Triglycerides, Butyrospermum Parkii (Shea) Butter, Beeswax, Helianthus Annuus (Sunflower) Seed Wax, Polyhydroxystearic Acid, Glyceryl Caprylate (and) Glyceryl Undecylenate, Non-GMO Corn Starch, Acrylates Copolymer, Vitamin E

Other Information

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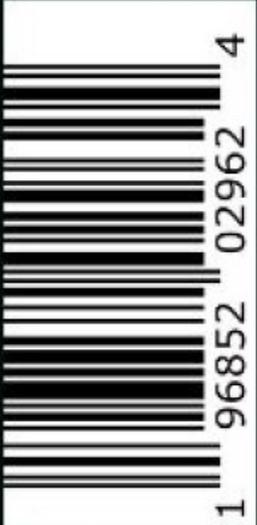
Questions or Comments?

* Visit allswellgoods.com



Formulated and Manufactured in U.S.A.
Distributed by ALLSWELLGOODS LLC
Cape Elizabeth, ME. 04107

NDC 82970-008-18



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ALLSWELL MINERAL SUNSCREEN SPF 30

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69555-043
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	22 g

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SHEA BUTTER (UNII: K49155WL9Y)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
STARCH, CORN (UNII: O8232NY3SJ)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69555-043-01	51 in 1 TUBE; Type 0: Not a Combination Product	03/28/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/28/2023	

Labeler - Stream2Sea, LLC (052920828)

Establishment

Name	Address	ID/FEI	Business Operations
Stream2Sea, LLC		052920828	manufacture(69555-043)

Revised: 4/2023

Stream2Sea, LLC