CLEAN- zinc oxide lotion Clean, Know What's On Your Skin 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.

Clean Lotion

Drug Facts

Active Ingredients

Zinc Oxide 12%

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 the eyes. Rinse with water to remove.

Stop use and ask doctor

is skin rash occurs

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
- 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 the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:

• limit time in the sun, especially from 10 a.m. - 2 p.m.

- Wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: ask a Doctor

Inactive Ingredients

Alcohol, Aloe Barbadensis Leaf Juice Powder, Ascorbyl Palmitate, Bisabolol, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, C16 Alpha Olefin, Capryl Glycol, Caprylyl Methicone, Cetyl PEG/PPG-10/1 Dimethicone, Chamomilla Recutita (Matricaria) Flower Extract*, Citrus Aurantium Dulcis (Orange) Fruit Extract*, Citrus Aurantium Dulcis (Orange) Peel Extract*, Dimethiconol/Propylsilsesquioxane/Silicate Crosspolymer, Ethylhexylglycerin, Fucus Vesiculosus Extract, Simmondsia Chinensis (Jojoba) Seed Oil*, Glycerin*, Hexylene Glycol, Isododecane, Oenothera Biennis (Evening Primrose) Oil*, Palmaria Palmata Extract, Phenoxyethanol, Propanediol, Rosa Canina Fruit Oil*, Sodium Chloride, Tetrasodium Glutamate Diacetate, Tocopherol, Trilaureth-4 Phosphate, VP/ Eicosene Copolymer, Water, Zostera Marina Extract *=Organic

Other information

• protect this product from excessive heat and direct sun

Questions or comments?

Call 424-272-6522

Clean Lotion, 100mL (72394-000-01)

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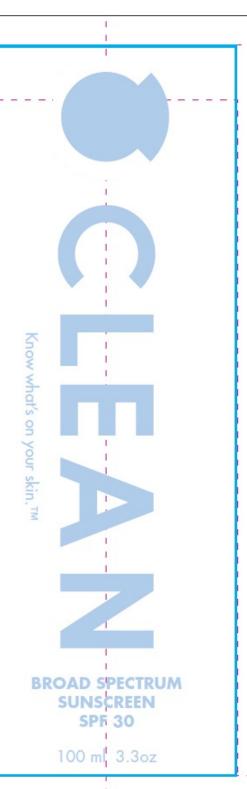
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Eye Mark 3X7mm

♦ 3<u>mm</u>

Active Ingredient.....Zinc Oxide 12%

Hello, Sunshine!
We created this sunscreen to empower you to know what's on your skin. Our ingredients are hand-selected—something you can trust, love and understand. It's not just suncare. It's skincare. It's a movement. It's transparent.

It's CLEAN:

ANTI-AGING
ANTIOXIDANT ENRICHED
CLINICALLY TESTED
GLUTEN-FREE
OXYBENZONE-FREE
ORGANIC INGREDIENTS
NON-GMO
NON-NANO
PARABEN-FREE
SYNTHETIC FRAGRANCE-FREE
VEGAN

DIRECTIONS Apply liberally to face, neck and chest at least 15 minutes prior to sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply at least every 2 hours. Children under 6 months ask a doctor.

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 out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

CLEANSPF.COM

Madelin USA

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LEFT SIDE 6.5" X 1.593"



FRONT 6.5" X 1.593"



Active Ingredient Zinc Oxide 12% Purpose.....Sunscreen



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

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QUESTIONS OR COMMENTS? CALL (424) 272-6522 CLEANSPE.COM

> Clean, Know What's On Your Skin LLC 405 West Superior Street, Chicago, Illinois 60654

BACK 6.5" X 1.593"

RIGHT SIDE BLANK 6.5" X 1.593"

CLEAN

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72394-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	120 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0 X)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
LEVOMENOL (UNII: 24WE03BX2T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8 D3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
CAPRYLYL TRISILO XANE (UNII: Q95M2P1KJL)	
CHAMO MILE (UNII: FGL3685T2X)	
ORANGE (UNII: 5EVU04N5QU)	
ORANGE PEEL (UNII: TI9T76 XD44)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)	
ISODO DECANE (UNII: A8289P68Y2)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
DULSE (UNII: 7832HOY4ZQ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPANEDIOL (UNII: 5965N8W85T)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TETRASO DIUM GLUTAMATE DIACETATE (UNII: 5EHL50 I4MY)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
WATER (UNII: 059QF0KO0R)	

]	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72394-000-00	100 mL in 1 TUBE; Type 0: Not a Combination Product	07/18/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/18/2018	

Labeler - Clean, Know What's On Your Skin LLC (081544845)

Revised: 3/2019

Clean, Know What's On Your Skin LLC