

**ORGANYS DERMA MADE- zinc oxide lotion**  
**Organys Beauty**

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**Directions**

- Apply liberally 15 minutes before sun exposure
- Reapply:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 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 your time in the sun, especially from 10am-2pm
  - wear long-sleeved shirts, pants, hats, and sunglasses
  - Children under 6 months of age: ask a doctor.

**Inactive Ingredients**

Water, C12-15 Alkyl Benzoate, Butyloctyl Salicylate, Isododecane, Lauryl PEG-8 Dimethicone, Polymethylsilsesquioxane, Octyldodecyl Neopentanoate, Propanediol, Caprylyl Methicone, Dimethicone, Niacinamide, Lauryl PEG-10 Tris(trimethylsiloxy) silyl ethyl Dimethicone, Triurethane Phosphate, Dimethiconol Propylsilsesquioxane/ Silicate Crosspolymers, Allantoin, Bisabolol, Sodium Chloride, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Phenoxethanol, Triethoxycaprylylsilane, Tetrasodium Glutamate Diacetate, PEG-10, Sodium Hydroxide, Iron Oxides.

**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.

# Organys Derma Made

<b>DRUG FACTS</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Zinc Oxide 12%	Sunscreen

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**Warning**

- 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 skin rash occurs.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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# Organys Derma Made

## DERMA MADE

Dermatologist Developed    *Unscented*

### SPF 50+ Moisturizer Tinted Mineral

Broad spectrum SPF 50+  
sunscreen

Infrared & blue light  
protection

Water resistant  
(80 minutes)

100% mineral

1.5 fl oz (45 ml)

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#### Other Information

Protect the product in this container from excessive heat and direct sun.

Question or Comments?

Call (312) 620-9240, or

Email: [support@dermamade.com](mailto:support@dermamade.com)

Distributed by: Derma Made

Des Plaines, IL 60018



# ORGANYS DERMA MADE

zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83612-0403
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	132 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>NIACINAMIDE</b> (UNII: 25X5118RD4)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW)</b> (UNII: 9KB5R958PB)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>TETRASODIUM GLUTAMATE DIACETATE</b> (UNII: 5EHL50I4MY)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>.BETA.-TOCOPHEROL</b> (UNII: 9U6A490501)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>PALMITOYL TETRAPEPTIDE-7</b> (UNII: Q41S464P1R)	
<b>TRILAURETH-4 PHOSPHATE</b> (UNII: M96W2OLL2V)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>.ALPHA.-BISABOLOL, (+)-</b> (UNII: 105S6I733Z)	
<b>LAURYL PEG-8 DIMETHICONE (300 CPS)</b> (UNII: ELL2U7K8T8)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	

## Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	

<b>Flavor</b>		<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83612-0403-1	45 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/07/2022	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	06/07/2022		

**Labeler** - Organys Beauty (077820778)

**Registrant** - Nanophase Technologies Corporation (623502044)

### Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(83612-0403)

### Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	pack(83612-0403) , manufacture(83612-0403)

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Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(83612-0403) , manufacture(83612-0403)

Revised: 11/2023

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