

**ORGANYS OPEN FORMULA TINTED- zinc oxide lotion**  
**Organys Beauty**

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**Organys Open Formula Tinted**

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- Directions**
- Apply liberally 15 minutes before sun exposure
  - Reapply:
    - 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 10pm-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, Propylendiol, Caprylyl Methicone, Dimethicone, Niacinamide, Lauryl PEG-10 Tris(trimethylsiloxy) silylethyl Dimethicone, Triureth-4 Phosphate, Dimethiconol/Propylsilsesquioxane/Silicate Crosspolymer, Allantoin, Bisabolol, Sodium Chloride, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Phenylethanol, 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 Open Formula Tinted

DRUG FACTS	
Active Ingredients	Purpose
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 Open Formula Tinted



OPEN  
FORMULA

**spf 50 tinted  
moisturizer**

100% mineral  
broad spectrum  
SPF 50 sunscreen  
water resistant (80 min)

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) 612-9698, or  
Email: ask@openformula.com  
Distributed by: Open Formula  
Des Plaines, IL 60018



# ORGANYS OPEN FORMULA TINTED

zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83612-1330
<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>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>NIACINAMIDE</b> (UNII: 25X5118RD4)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW)</b> (UNII: 9KB5R958PB)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>TETRASODIUM GLUTAMATE DIACETATE</b> (UNII: 5EHL50I4MY)	
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>PALMITOYL TRIPEPTIDE-1</b> (UNII: RV743D216M)	
<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>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	

## 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>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83612-1330-1	45 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/29/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/29/2021	

**Labeler** - Organys Beauty (077820778)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(83612-1330)

## Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(83612-1330) , pack(83612-1330)

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Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(83612-1330) , manufacture(83612-1330)

Revised: 10/2024

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