

**WL-AAB-Z-W-1819- zinc oxide lotion**  
**Nanophase Technologies Corporation**

*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.*

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**WL-AAB-Z-W-1819**

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**Solesence WL-AAB-Z-W-1819**

Zinc Oxide CAS# 1314-13-2 Dispersion with Additives (Ciele's Tint + Protect SPF 50 Shade 11 (Rich))

Manufacturer Address: Nanophase Technologies Corporation - 1319 Marquette Drive Romeoville, IL 60446 (800)-771-8700 www.nanophase.com  
Emergency Telephone Numbers:  
INFOTRAC emergency phone number: (800) 535-5053  
INFOTRAC international emergency phone number: 1-352-323-3500



\*P273: Avoid release to the environment.  
P261: Avoid breathing dust/fume/gas/mist/vapors/spray  
P272: Contaminated work clothing should not be allowed out of the workplace.  
P233 Keep container tightly closed.  
P264 Wash skin thoroughly after handling  
P280 Wear protective gloves/ eye protection/ face protection.

\*P391: Collect spillage.  
P302+352: IF ON SKIN: Wash with plenty of soap and water.;  
P332+313: If skin irritation occurs: Get medical advice/ attention.  
P333+313: If skin irritation or rash occurs: Get medical advice/attention  
P331: Do NOT induce vomiting.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
foam to extinguish.  
P405: Store locked up.  
P501: Dispose of contents/container to approved TSDF in accordance with local / regional / national / international regulations.

**Warning**

\*H410: Very toxic to aquatic life with long lasting effects.  
H315: Causes skin irritation  
H317: May cause an allergic skin reaction  
H319: Causes serious eye irritation  
H302: Harmful if Swallowed  
H384: May be fatal if swallowed and enters airways.

LOT Number:

Item Number: WL-4291-144-030-5030-ID

Net Weight: g

UN# \*Not Regulated by DOT

Counter: 1

KEEP CONTAINER TIGHTLY CLOSED.  
For FDA regulated  
cosmetics only



Prod Code: EXP6034

LABEL ID 4285

**WL-AAB-Z-W-1819**

zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63931-1819
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ALLANTOIN (UNII: 344S277G0Z)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
LAURYL PEG-8 DIMETHICONE (300 CPS) (UNII: ELL2U7K8T8)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
WATER (UNII: 059QF0KO0R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
ISODODECANE (UNII: A8289P68Y2)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (45000000 MW) (UNII: 9KB5R958PB)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	

## Product Characteristics

<b>Color</b>	brown	<b>Score</b>	
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<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:63931-1819-1	150000 mL in 1 DRUM; Type 0: Not a Combination Product	06/02/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/02/2023	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(63931-1819)

### Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(63931-1819) , manufacture(63931-1819)

### Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	manufacture(63931-1819) , pack(63931-1819)

Revised: 7/2023

Nanophase Technologies Corporation