

WL-AAS-Z-A-1762- 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.

WL-AAS-Z-A-1762

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AN ISO 9001 AND ISO14001 REGISTERED COMPANY
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Warning

*H410: Very toxic to aquatic life with long lasting effects.

H319: Causes serious eye irritation

Supplemental Information
KEEP CONTAINER TIGHTLY CLOSED. For FDA regulated products only.

Counter: 1

Solesence WL-AAS-Z-A-1762

Zinc Oxide CAS# 1314-13-2 Dispersion with Additives (Lip Shade Medium- BAI)

Manufacturer Address: Nanophase Technologies Corporation -
1319 Marquette Drive Romeoville, IL 60446 (630)-771-61700 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.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.

*P391: Collect spillage.
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.

*P501: Dispose of contents/container to approved TSDF in accordance with local / regional / national / international regulations.



Lot Number:

Net Weight: g
UN# Not Regulated

Prod Code: EXP4573
Item Number:

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63931-4573
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
DIAMOND (UNII: 6GRV67N0U2)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TOCOPHEROL (UNII: ROZB2556P8)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
PROPANEDIOL (UNII: 5965N8W85T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
POLYGLYCERYL-2 ISOSTEARATE (UNII: 7B8OE71MQC)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63931-4573-1	150000 mL in 1 DRUM; Type 0: Not a Combination Product	02/17/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/17/2023	

Labeler - Nanophase Technologies Corporation (623502044)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(63931-4573)

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Nanophase Technologies Corporation		623502044	api manufacture(63931-4573) , manufacture(63931-4573) , pack(63931-4573)

Revised: 2/2023

Nanophase Technologies Corporation