

WL-AAD-Z-W-1386- 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-AAD-Z-W-1386

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AN ISO 9001 AND ISO14001 REGISTERED COMPANY

We Make NanoTechnology Work! ®

Prod Code: EXP4528

Solesence WL-AAD-Z-W-1386

Product Description: Zinc Oxide CAS# 1314-13-2 Dispersion with Additives

Manufacturer Address: Nanophase Technologies Corporation · 1319 Marquette Drive
Romeoville, IL 60446 (630)-771-6700 www.nanophase.com

Emergency Telephone Numbers:
INFOTRAC emergency phone number: (800) 535-5053
INFOTRAC International emergency phone number: 1-352-323-3500

UN# Not Regulated



Danger

*H410: Very toxic to aquatic life with long lasting effects.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H304: May be fatal if swallowed and enters airways.

*P273: Avoid release to the environment.
P264: Wash hands, face thoroughly after handling.
P280: Wear protective gloves/ eye protection/ face protection.

P405: Store locked up.

*P391: Collect spillage.
P306+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P302+P362: IF ON SKIN: Wash with plenty of soap and water.
P332+P313: If skin irritation occurs: Get medical advice/ attention.
P337+P313: If eye irritation persists: Get medical advice/attention.
P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P331: Do NOT induce vomiting.

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

Supplemental Information

KEEP CONTAINER TIGHTLY CLOSED. For FDA regulated products only.



LOT Number:

Net Weight: g

Nanophase makes no warranties concerning this product which extend beyond the description contained in the accompanying SDS pertaining to the product's material characteristics. SPECIFICALLY, SOLESENCE MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, CONCERNING THIS PRODUCT. Solesence has no knowledge of or control over the use of this product by the customer, and therefore disclaims any liability in connection with or arising out of that use. This product should be handled by trained personnel only as described in the SDS. Please refer to the SDS for important additional information.

WL-AAD-Z-W-1386

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63931-4529
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	110 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
RUTIN (UNII: 5G06TVY3R7)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
ALLANTOIN (UNII: 344S277G0Z)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
C13-15 ALKANE (UNII: 114P5I43UJ)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63931-4529-1	150000 mL in 1 DRUM; Type 0: Not a Combination Product	04/26/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/26/2022	

Labeler - Nanophase Technologies Corporation (623502044)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(63931-4529)

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Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(63931-4529) , manufacture(63931-4529) , pack(63931-4529)

Revised: 4/2022

Nanophase Technologies Corporation