

WL-AAS-Z-A-348- 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-348

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AN ISO 9001 AND ISO14001 REGISTERED COMPANY

We Make NanoTechnology Work! ®

Prod Code: EXP4302

Solesence WL-AAS-Z-A-348

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

Manufacturer Address: Nanophase Technologies Corporation · 1319 Marquette Drive
 Romeoville, IL 60448 (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 by DOT



Warning

***H410: Very toxic to aquatic life with long lasting effects.**
H319: Causes serious eye irritation
H302: Harmful if Swallowed
H304: May be fatal if swallowed and enters airways.

***P273:** Avoid release to the environment.
P233 Keep container tightly closed.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.

P405: Store locked up

***P391:** Collect spillage.
P331: Do NOT induce vomiting.
P306 + P361 + P353 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.

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

Supplemental Information

KEEP CONTAINER TIGHTLY CLOSED, For PC evaluation only.



LOT Number:

Net Weight:

KG

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, NANOPHASE MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, CONCERNING THIS PRODUCT. Nanophase 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-AAS-Z-A-348

zinc oxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63931-4302

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	95 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PROPANEDIOL (UNII: 5965N8W85T)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIMETHICONOL/PROPYLSILSESQUOXANE/SILICATE CROSSPOLYMER (45000000 MW) (UNII: 9KB5R958PB)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ISODODECANE (UNII: A8289P68Y2)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SQUALANE (UNII: GW89575KF9)	

Product Characteristics			
Color	pink	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63931-4302-1	7000 mL in 1 PAIL; Type 0: Not a Combination Product	07/24/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/24/2019	

Labeler - Nanophase Technologies Corporation (623502044)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(63931-4302)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(63931-4302) , manufacture(63931-4302) , pack(63931-4302)

Establishment

Name	Address	ID/FEI	Business Operations
Amcol Health & Beauty Solutions		872684803	api manufacture(63931-4302)

Revised: 7/2019

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