WL-AAD-Z-W-1062- 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-1062

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Solesence WL-AAD-Z-W-1062

Zinc Oxide CAS# 1314-13-2 Dispersion with Additives (SHADE V2)

AN ISO 9001 AND ISO14001 REGISTERED COMPANY We Make NanoTechnology Work! ®



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.

Supplemental Information

KEEP CONTAINER TIGHTLY CLOSED. For FDA regulated products only.

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 hands, face thoroughly after handling.

P280: Wear protective gloves/ eye protection/ face protection.

*P391: Collect spillage.
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P302+352: IF ON SKIN: Wash with plenty of soap and water.

P332+P313: If skin irritation occurs: Get medical advice/ attention. P337+313: If ske irritation persists: Get medical advice/attention.

P301+310: IF ŚWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P331: Do NOT induce vomiting.

P405: Store locked up.

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: EXP4475

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63931-4475

Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	132 mg in 1 mL

SQUALANE (UNII: GW89575KF9) RUTIN (UNII: 5G06TVY3R7) GLYCERIN (UNII: PDC6A3C0OX) ISOSTEARIC ACID (UNII: X33R8U0062)	
GLYCERIN (UNII: PDC6A3C0OX)	
· · · · · · · · · · · · · · · · · · ·	
ISOSTEARIC ACID (UNII: X33R8U0062)	
1000117/11/10 / CHAIN / ASSISTED COULTY	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
JOJOBA OIL (UNII: 724GKU717M)	
ORYZA SATIVA WHOLE (UNII: 84IVV0906Z)	
TRIDECYL SALICYLATE (UNII: AZ Q08K38Z 1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
NYLON-12 (UNII: 446U8J075B)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
METHYLHEPTYL ISOSTEARATE (UNII: 981F40Q9FF)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
ALLANTOIN (UNII: 344S277G0Z)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ROSMARINUS OFFICINALIS FLOWER (UNII: NR1A27F290)	
.ALPHABISABOLOL, (+)- (UNII: 105S6I733Z)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics		
Color	brown	Score
Shape		Size
Flavor		Imprint Code
Contains		

ı	Packaging			
	# Item Code Package Description		Date	Marketing End Date
	1 NDC:63931- 4475-1	150000 mL in 1 DRUM; Type 0: Not a C Product	Combination 04/12/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/12/2022	

Labeler - Nanophase Technologies Corporation (623502044)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment			
Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(63931-4475)

Establishment			
Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(63931-4475), manufacture(63931-4475), pack(63931-4475)

Revised: 4/2022 Nanophase Technologies Corporation