

WL-AAB-Z-W-1001- 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-AAB-Z-W-1001

WL-AAB-Z-W-1001 GHS Label



***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.

LOT Number:

Net Weight: G

UN# *Not Regulated by DOT

Solesence WL-AAB-Z-W-1001

Zinc Oxide CAS# 1314-13-2 Dispersion with Additives (CS FLEX FAIR (SD))

Manufacturer Address: Nanophase Technologies Corporation - 1319 Marquette Drive Romeoville, IL 60446 (530)-771-6700 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.
P233 Keep container tightly closed.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.

*P391: Collect spillage.
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.

P405; Store locked up

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

KEEP CONTAINER TIGHTLY CLOSED. For FDA regulated products only.



Prod Code: EXF4438

WL-AAB-Z-W-1001

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63931-4438
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	135.6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MYRISTYL TRISILOXANE (UNII: J7960S4R1T)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
SODIUM MYRISTOYL GLUTAMATE (UNII: AYU7QD893W)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
DIMETHYLMETHOXY CHROMANOL (UNII: XBH432G01F)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ISODODECANE (UNII: A8289P68Y2)	
NIACINAMIDE (UNII: 25X51I8RD4)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW) (UNII: 9KB5R958PB)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M)	
ISOCETETH-10 (UNII: 1K92T9919H)	
CAESALPINIA SPINOSA FRUIT POD (UNII: EXY4496LWD)	
HELIANTHUS ANNUUS SPROUT (UNII: 4P26HG1S5W)	
MICA (UNII: V8A1AW0880)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	

ZEIN (UNII: 80N308T1NN)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63931-4438-1	150000 mL in 1 DRUM; Type 0: Not a Combination Product	05/06/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/06/2021	

Labeler - Nanophase Technologies Corporation (623502044)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(63931-4438)

Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(63931-4438) , manufacture(63931-4438) , pack(63931-4438)

Establishment

Name	Address	ID/FEI	Business Operations
Amcol Health & Beauty Solutions		872684803	api manufacture(63931-4438)