

**PAVISE LIP DEFENSE TINTED HYDRATING OIL (HUE 616)- zinc oxide lotion
B.A.I. Biosciences INC.**

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.

pavise Lip Defense tinted hydrating oil (hue 616)

pavise Lip Defense tinted hydrating oil (hue 616)



PAVISE LIP DEFENSE TINTED HYDRATING OIL (HUE 616)

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83100-1762
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)	
FERROSOFERRIC 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:83100-1762-2	1 in 1 CARTON	02/17/2023	
1	NDC:83100-1762-1	5 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

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

Labeler - B.A.I. Biosciences INC. (083612207)

Registrant - Nanophase Technologies Corporation (623502044)

Establishment			
Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		050383046	api manufacture(83100-1762)

Establishment			
Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(83100-1762) , manufacture(83100-1762)

Establishment			
Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	pack(83100-1762)

Revised: 2/2023

B.A.I. Biosciences INC.