

**PAVISE LIP DEFENSE TINTED HYDRATING OIL (HUE 774)- 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 774)**

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<b>PAVISE LIP DEFENSE TINTED HYDRATING OIL (HUE 774)</b>			
zinc oxide lotion			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83100-1763
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	100 mg in 1 mL	

## Inactive Ingredients

Ingredient Name	Strength
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>HYDROLYZED JOJOBA ESTERS (ACID FORM)</b> (UNII: UDR641JW8W)	
<b>DIAMOND</b> (UNII: 6GRV67N0U2)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE</b> (UNII: 687U3PEB2Y)	
<b>PHENYLPROPANOL</b> (UNII: 0F897O3O4M)	
<b>FERROSOFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>DIISOSTEARYL MALATE</b> (UNII: QBS8A3XZGQ)	
<b>TRIDECYL TRIMELLITATE</b> (UNII: FY36J270ES)	
<b>.ALPHA.-BISABOLOL, (+)-</b> (UNII: 105S6I733Z)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>TRIHYDROXYSTEARIN</b> (UNII: 06YD7896S3)	
<b>POLYGLYCERYL-2 ISOSTEARATE</b> (UNII: 7B8OE71MQC)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83100-1763-2	1 in 1 CARTON	02/17/2023	
1	NDC:83100-1763-1	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(83100-1763)

## Establishment

Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		118812921	pack(83100-1763)

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Name	Address	ID/FEI	Business Operations
Nanophase Technologies Corporation		623502044	api manufacture(83100-1763) , manufacture(83100-1763)

Revised: 2/2023

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