

# CIELE FILTER AND PROTECT- titanium dioxide, zinc oxide powder

## Ciele

*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.*

### Ciele Filter and Protect

**WL-AAI-ZT-P-1910**



## CIELE FILTER AND PROTECT

titanium dioxide, zinc oxide powder

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83103-1910
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.125 g in 1 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.225 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYMETHYLSILSESQUIOXANE (11 MICRONS)</b> (UNII: Z570VEV8XK)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>PHYSALIS ANGULATA</b> (UNII: W4TKW9D5GG)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	
<b>TRIDECYL SALICYLATE</b> (UNII: AZQ08K38Z1)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>ISODECYL SALICYLATE</b> (UNII: S7097PPF4C)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>METHICONE (20 CST)</b> (UNII: 6777U11MKT)	
<b>ISOCETETH-10</b> (UNII: 1K92T9919H)	
<b>OCTYLDODECANOL</b> (UNII: 461N1O614Y)	
<b>PHENYLPROPANOL</b> (UNII: 0F897O3O4M)	

## Product Characteristics

<b>Color</b>	brown	<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:83103-1910-2	1 in 1 CARTON	07/25/2023	
1	NDC:83103-1910-1	10 g in 1 JAR; 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

07/25/2023

**Labeler** - Ciele (105041170)

Revised: 8/2023

Ciele