

CIELE SPF 45 FLUSH PROTECT- sunscreen 45 powder
LÚE COSMETICS INC

DRUG FACTS

Active Ingredients

Zinc Oxide 21.37%

Homosalate 5.0%

Titanium Dioxide 4.25%

Ethylhexyl Salicylate 3.0%

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure and as needed
- reapply at least every 2 hours.
- use a water resistant sunscreen if swimming or sweating
- Sun Protection Measures. Spending time in the sun

increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses
- children under 6 months of age: Ask a doctor

Inactive ingredients

Synthetic Fluorophlogopite, Mica, Boron Nitride, Zinc Stearate, Dimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Silica, Triethoxycaprylylsilane, Diisostearyl

Malate, Ethylhexylglycerin, Caprylyl Glycol, Tocopherol, Red 7 Lake (CI 15850), Iron Oxides (CI 77492), Iron Oxides (CI 77499), Yellow 5 Lake (CI 19140), Ultramarines (CI 77007)

Other Information

Protect the product in this container from excessive heat and direct sun.

Questions?

1-866-860-0811

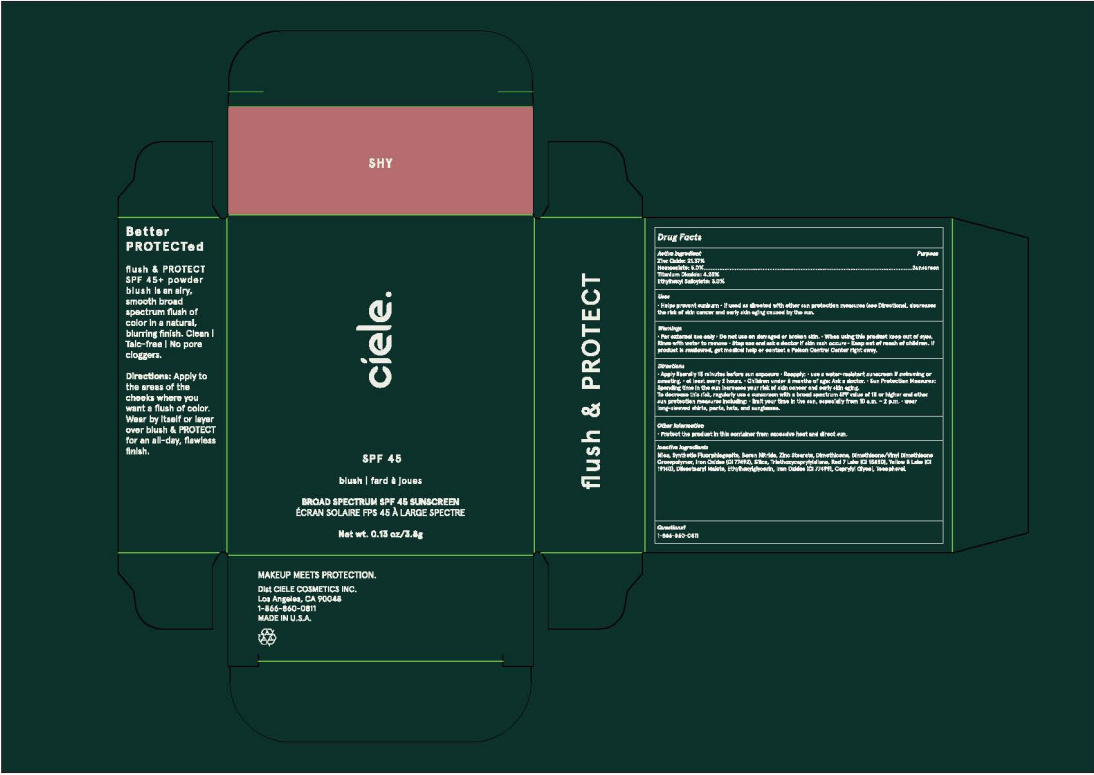
Purpose

Sunscreen

Keep out of reach of children

Keep out of reach of children

Principal Display Panel



CIELE SPF 45 FLUSH PROTECT

sunscreen 45 powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83103-1001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)		HOMOSALATE	5 mg in 100 mg
ETHYLHEXYL SALICYLATE (UNII: 4X49Y0596W) (ETHYLHEXYL SALICYLATE - UNII:4X49Y0596W)		ETHYLHEXYL SALICYLATE	3 mg in 100 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	21.372 mg in 100 mg
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	4.25 mg in 100 mg

Inactive Ingredients	
Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
ZINC STEARATE (UNII: H92E6QA4FV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
RED 7 (UNII: ECW0LZ41X8)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
YELLOW 5 (UNII: I753WB2F1M)	
ULTRAMARINE VIOLET (UNII: 1YZ11D167R)	
SILICON (UNII: Z4152N8IUI)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83103-1001-1	1 in 1 PACKAGE	01/30/2025	
1		100 mg in 1 TRAY; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/30/2025	

Labeler - LÚE COSMETICS INC (105041170)