

LIPLUX SPF 30 LIP BALM- classic stick
COOLA LLC

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.

COOLA Classic Liplux Lip Balm SPF30 0.15oz - Original

Active Ingredients

Avobenzone 2.9%, Octisalate 4.9%, Octocrylene 7.6%

Purpose

Sunscreens

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.

Stop use and ask doctor if skin rash occurs.

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

Directions

Apply liberally 15 minutes before sun exposure & again after 80 minutes of swimming or sweating. Apply at least every 2 hours. Sun Protection Measures - to decrease your risk of cancer and early skin aging, 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. to 2 p.m. and wear long-sleeved shirts, pants, hats, and sunglasses. Children under 6 months: ask a doctor.

Inactive ingredients

Aloe Barbadensis Leaf Extract, Astrocaryum Vulgare Kernel Oil (ORGANIC), Behenyl Behenate, Bisabolol, Butyloctyl Salicylate, Caprylic/Capric Triglyceride, Carthamus Tinctorius (Safflower) Seed Oil, Cocos Nucifera (Coconut) Oil (ORGANIC), Copernicia Cerifera (Carnauba) Wax (ORGANIC), Euphorbia Cerifera (Candelilla) Wax, Flavor, Helianthus Annuus (Sunflower) Seed Oil (ORGANIC), Linoleic Acid, Persea Gratissima (Avocado) Oil (Organic), Phospholipids, Phytosterols, Polyhydroxstearic Acid, Rubus Idaeus (Raspberry) Seed Oil (ORGANIC), Simmondsia Chinensis (Jojoba) Seed Oil (ORGANIC), Stevia Rebaudiana Extract, Tetrahexyldecyl Ascorbate, Theobroma Grandiflorum Seed Butter (ORGANIC), Tocopherol (ORGANIC)

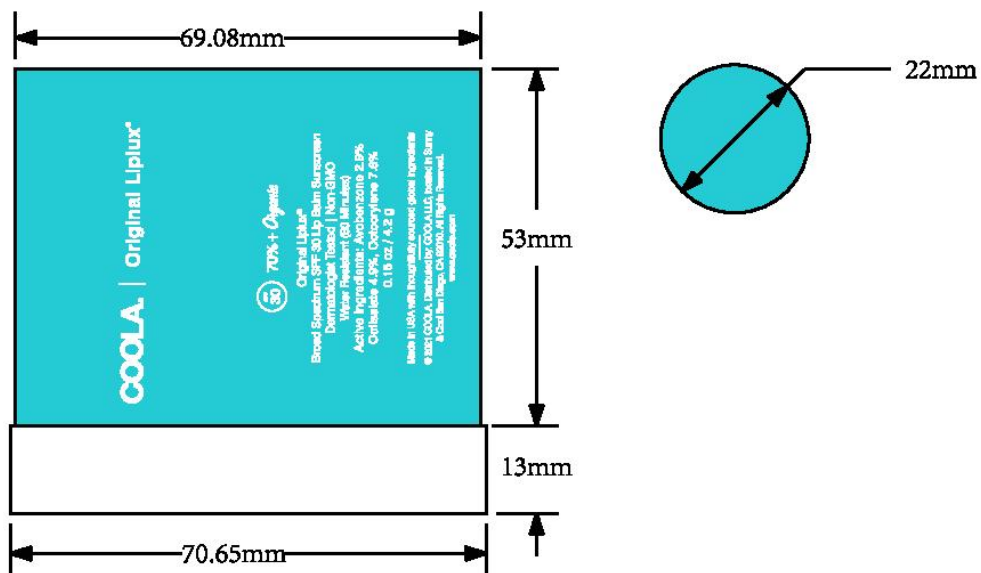
Other Information

Protect this product from excessive heat and direct sun.

Questions or Concerns?

Call 760-940-2125

Primary and secondary package labels





LIPLUX SPF 30 LIP BALM

classic stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	8 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
ASTROCARYUM VULGARE KERNEL OIL (UNII: 1IQY04O559)	
COCONUT OIL (UNII: Q9L0O73W7L)	
BEHENYL BEHENATE (UNII: K8NU647RJ0)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
CANDELILLA WAX (UNII: WL0328HX19)	
THEOBROMA GRANDIFLORUM SEED BUTTER (UNII: I711F13FXM)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TOCOPHEROL (UNII: R0ZB2556P8)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
REBAUDIOSIDE A (UNII: B3FUD0528F)	
JOJOBA OIL (UNII: 724GKU717M)	
CASTOR OIL (UNII: D5340Y2I9G)	
ROSEMARY (UNII: IJ67X351P9)	
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)	
LEVOMENOL (UNII: 24WE03BX2T)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-012-01	4.2 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2020	

