

**REFRESHING WATER HYDRATION STICK SPF 50- avobenzone octisalate
homosalate octocrylene 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 Refreshing Water Hydration Stick SPF 50

Drug Facts

Active Ingredients

Avobenzone 2.5%, Homosalate 3.5%, Octisalate 2.15%, Octocrylene 5.0%

Purpose

Sunscreen

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 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.
- reapply: ● after swimming or sweating ● immediately after towel drying ● at least every 2 hours

● **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 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-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

Inactive Ingredients

Aloe Barbadensis Leaf Juice (ORGANIC), Glycerin (ORGANIC), Sodium Stearate, Carthamus Tinctorius (Safflower) Oleosomes (ORGANIC), Polyglyceryl-10 Caprylate/Caprates, Butyloctyl Salicylate, Copernicia Cerifera (Carnauba) Wax (ORGANIC), Sorbitan Olivates, VP/Hexadecene Copolymer, Cocos Nucifera (Coconut) Fruit Water (ORGANIC), Jasminum Sambac (Jasmine) Leaf Cell Extract, Melia Azadirachta Leaf Extract, Melia Azadirachta Flower Extract, Coralline Officinalis Extract, Solanum Melongena (Eggplant) Fruit Extract, Theobroma Cacao (Cocoa) Seed Extract, Aloe Barbadensis Flower Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Hyaluronic Acid, Coccinia Indica Fruit Extract, Curcuma Longa (Turmeric) Root Extract, Ocimum Basilicum (Basil) Flower/Leaf Extract, Ocimum Sanctum Leaf Extract, Schinus Molle Extract, Propanediol, Butylene Glycol, 1,2-Hexanediol, Caprylyl Glycol, Water, Tropolone, Fragrance (Natural)

Other information

- may stain fabrics
- protect this product from excessive heat and direct sun

Questions or comments?

Call 760-940-2125

COOLA Label

SPF

50

70%+

Organic

COOLA®

Refreshing Water

Hydration Stick

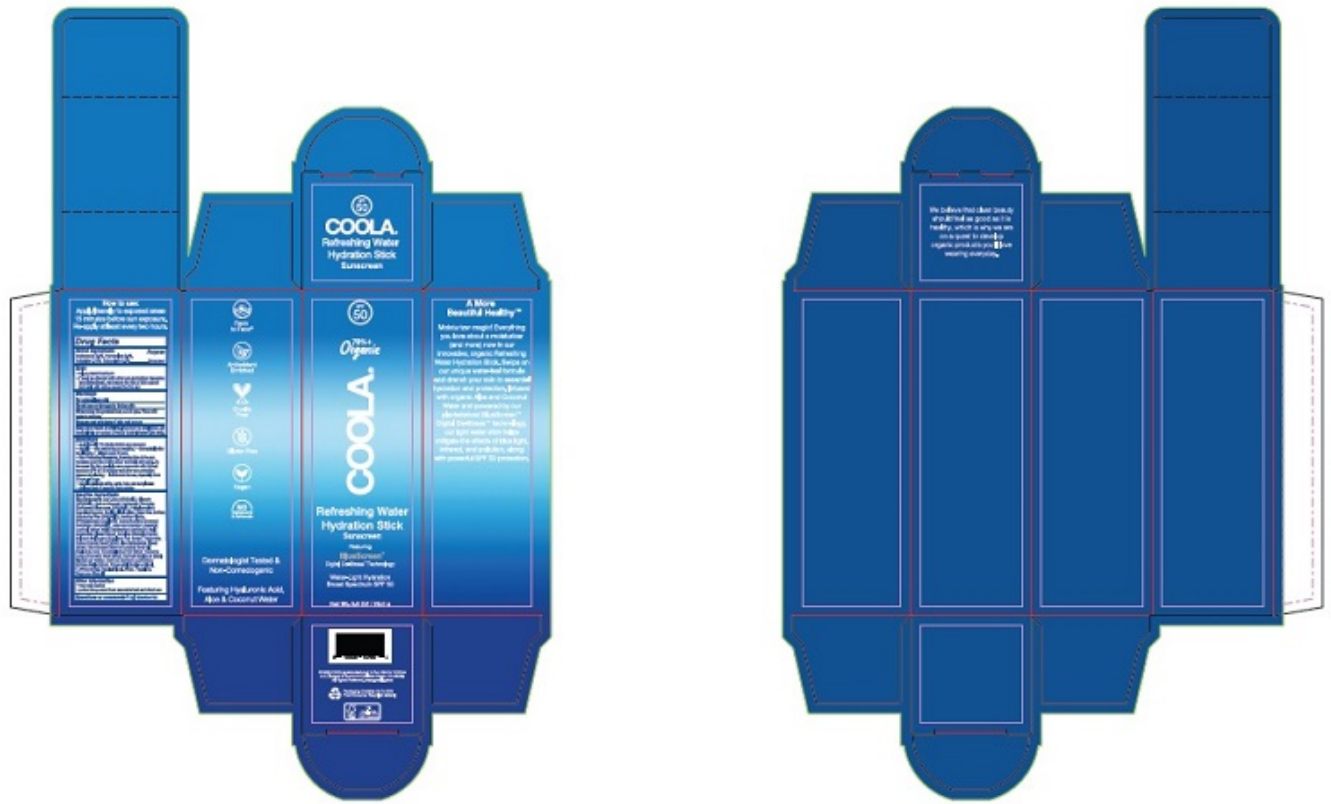
Sunscreen

Net Wt. 0.8 OZ / 22.0 g

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LLC, located in Sunny & Cool San Diego, CA 92010.

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REFRESHING WATER HYDRATION STICK SPF 50			
avobenzone octisalate homosalate octocrylene stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-035
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.15 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	3.5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5.0 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
POLYGLYCERYL-10 CAPRYLATE (UNII: YS396CQX5C)	
POLYGLYCERYL-10 CAPRATE (UNII: TL8V5BW2HC)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
PROPANEDIOL (UNII: 5965N8W85T)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
WATER (UNII: 059QF0KO0R)	
JASMINUM OFFICINALE LEAF (UNII: 6OG06384ID)	
AZADIRACHTA INDICA LEAF (UNII: HKY915780T)	
AZADIRACHTA INDICA FLOWER (UNII: 3TE8A92UPM)	
CORALLINA OFFICINALIS (UNII: 4004498D06)	
COCCINIA GRANDIS FRUIT (UNII: VLJ6WOT3K5)	
TROPOLONE (UNII: 7L6DL16P1T)	
EGGPLANT (UNII: W5K7RAS4VK)	
COCOA (UNII: D9108TZ9KG)	
ALOE VERA FLOWER (UNII: 575DY8C1ER)	
COCONUT WATER (UNII: 267F5Y81NT)	
JOJOBA OIL (UNII: 724GKU717M)	
TURMERIC (UNII: 856YO1Z64F)	
OCIMUM BASILICUM FLOWERING TOP (UNII: 7SAB275FP2)	
HOLY BASIL LEAF (UNII: SCJ765569P)	
SCHINUS MOLLE FRUITING TOP (UNII: T8L6O1KSB4)	
HYALURONIC ACID (UNII: S270N0TRQY)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-035-01	1 in 1 CARTON	01/16/2023	
1		22.0 g in 1 CANISTER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/16/2023	

Labeler - COOLA LLC (956990290)

Revised: 1/2023

COOLA LLC