

COOLA REFRESHING WATER MIST SPF 18- avobenzene, homosalate, octisalate, octocrylene spray
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 Mist Sunscreen SPF 18

Drug Facts

Active Ingredients

Avobenzene 2.0%. Homosalate 10.0%

Octisalate 5.0%, Octocrylene 5.5%

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

- shake well • 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 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-sleeved shirts, pants, hats, and sunglasses

- children under 6 months: Ask a doctor

Inactive Ingredients

Aloe Barbadensis Leaf Extract (ORGANIC), Undecane, Tridecane, Water, Cocos Nucifera (Coconut) Water (ORGANIC), Sodium Hyaluronate, Jasminum Sambac (Jasmine) Leaf Cell Extract, Theobroma Cacao (Cocoa) Seed Extract, Schinus Molle Extract, Heliotropine*, Juniperus Mexicana*, Propanediol, Butylene Glycol, Methypropanediol, Caprylic/Capric Triglyceride, Caprylyl Glycol, Polyquaternium-80, Sodium Phytate, Didecyldimonium Chloride, Anisaldehyde*, Benzyl acetate*, Delta-Decalactone*, Gamma-Nonalactone*, Gamma Octalactone*, Methyl benzoate*, Nerolidol*, Ethyl Butyrate*, Triethyl citrate*, Vanillin

* Plant-derived scent constituent.

Other information

- protect this product from excessive heat and direct sun

Questions or comments? Call 760-940-2125

Product Label - COOLA Refreshing Water Mist Sunscreen SPF 18

SPF

18

COOLA®

Refreshing Water Mist

Sunscreen

Broad Spectrum SPF 18

0.85 FL OZ / 25 mL

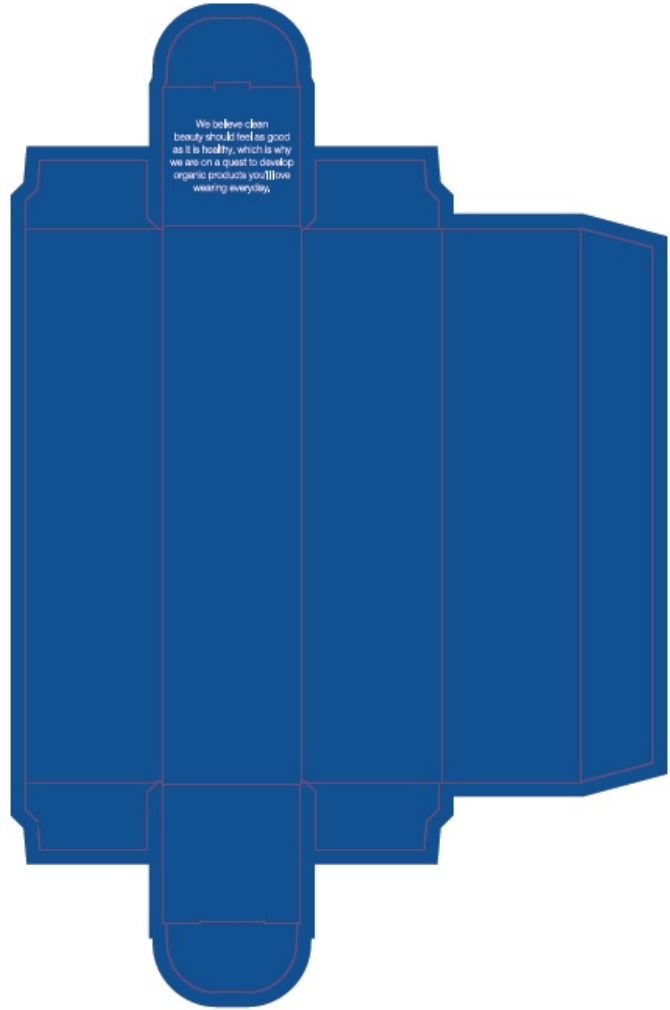
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COOLA REFRESHING WATER MIST SPF 18

avobenzone, homosalate, octisalate, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79753-079
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.0 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10.0 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
UNDECANE (UNII: JVOQT00NUE)	
TRIDECANE (UNII: A3LZF0L939)	

WATER (UNII: 059QF0KO0R)
COCONUT WATER (UNII: 267F5Y81NT)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
JASMINUM OFFICINALE LEAF (UNII: 6OG06384ID)
COCOA (UNII: D9108TZ9KG)
SCHINUS MOLLE FRUITING TOP (UNII: T8L6O1KSB4)
PIPERONAL (UNII: KE109YAK00)
JUNIPERUS DEPPEANA WOOD OIL (UNII: 4739QA5686)
PROPANEDIOL (UNII: 5965N8W85T)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
POLYQUATERNIUM-80 (UNII: 3N8LGV97HR)
PHYTATE SODIUM (UNII: 88496G1ERL)
DIDCYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B)
P-ANISALDEHYDE (UNII: 9PA5V6656V)
BENZYL ACETATE (UNII: 0ECG3V79ZJ)
.DELTA.-DECALACTONE (UNII: CNA0S5T234)
.GAMMA.-NONALACTONE (UNII: I1XGH66S8P)
.GAMMA.-OCTALACTONE (UNII: UHD6M52X0K)
METHYL BENZOATE (UNII: 6618K1VJ9T)
NEROLIDOL (UNII: QR6IP857S6)
ETHYL BUTYRATE (UNII: UFD2LZ005D)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
VANILLIN (UNII: CHI530446X)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79753-079-02	1 in 1 CARTON	02/01/2023	
1		25 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	02/01/2023	

Labeler - COOLA LLC (956990290)

Registrant - Bentley Laboratories, LLC (068351753)

