

COSRX- vitamin e vitalizing sunscreen lotion
COSRX inc.

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.

Avobenzone 2.5%

Homosalate 9.0%

Octisalate 4.5%

Octocrylene 9.0%

Sunscreen

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.

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.

Apply liberally 15 minutes before sun exposure

Children under 6 months of age : Ask a doctor.

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.

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

Sun alert : Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Water / Aqua / Eau, Propanediol, Butyloctyl salicylate, Diphenylsiloxy phenyl trimethicone, Dimethicone, VP/Eicosene copolymer, Silica, Trisiloxane, Cyclopentasiloxane, Trimethylsiloxysilicate, 1,2-Hexanediol, Behenyl alcohol, Glyceryl stearate, PEG-100 stearate, C14-22 alcohols, Cetyl alcohol, Potassium cetyl phosphate, Polyacrylate-13, Polyisobutene, Fragrance / Parfum, C12-20 Alkyl glucoside, Butylene glycol, Disodium EDTA, Ethylhexylglycerin, Polysorbate 20, Sorbitan isostearate, Dextrin, Theobroma cacao (cocoa) extract, Gossypium herbaceum (cotton) extract, Glucose, Tocopherol

global@cosrx.co.kr

Vitamin E

Vitalizing Sunscreen

Tocopherol

SPF 50+ sunscreen contains Vitamin E to protect your skin from light (UV rays) and heat (Aging signs) leaving your skin healthy and moisturized.

SPF50+ BROAD SPECTRUM

50mL / 1.69 fl. oz.

COSRX

<p>COSRX Vitamin E Vitalizing Sunscreen SPF 50+</p> <table border="1"><tr><th colspan="2">Drug Facts</th></tr><tr><th>Active ingredients</th><th>Purpose</th></tr><tr><td>Avobenzone 2.5%</td><td>Sunscreen</td></tr><tr><td>Homosalate 9%</td><td>Sunscreen</td></tr><tr><td>Octisalate 4.5%</td><td>Sunscreen</td></tr><tr><td>Octocrylene 9%</td><td>Sunscreen</td></tr></table> <p>Uses</p> <ul style="list-style-type: none">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. <p>Warnings <i>For external use only</i></p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none">Apply liberally 15 minutes before sun exposure.Children under 6 months of age : Ask a doctor.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 :<ul style="list-style-type: none">Limit time in the sun, especially from 10 a.m. - 2 p.m.Wear long-sleeved shirts, pants, hats, and sunglasses. <p>SUNSCREEN BROAD SPECTRUM SPF 50+</p>	Drug Facts		Active ingredients	Purpose	Avobenzone 2.5%	Sunscreen	Homosalate 9%	Sunscreen	Octisalate 4.5%	Sunscreen	Octocrylene 9%	Sunscreen	<table border="1"><tr><th>Drug Facts (continued)</th></tr><tr><th>Inactive ingredients</th></tr><tr><td>Water / Aqua / Eau, Prop- anediol, Butyloctyl salicyl- ate, Diphenylsiloxy phenyl trimethicone, Dimethicone, VP/Elcosene copolymer, Silica, Trisiloxane, Cyclop- entasiloxane, Trimethylsil- oxysilicate, 1,2-Hexandi- ol, Behenyl alcohol, Glyceryl stearate, PEG-100 stearate, C14-22 alcohols, Cetyl al- cohol, Potassium cetyl ph- osphate, Polyacrylate-13, Polyisobutene, Fragrance / Parfum, C12-20 Alkyl gl- ucoside, Butylene glycol, Disodium EDTA, Ethylhex- ylglycerin, Polysorbate 20, Sorbitan isostearate, Dex- trin, Theobroma cacao (c- ocoa) extract, Gossypium herbaceum (cotton) extr- act, Glucose, Tocopherol</td></tr><tr><th>Other information</th></tr><tr><td><ul style="list-style-type: none">Protect the product in this container from excessive heat and direct sun.Sun alert : Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.</td></tr><tr><th>Questions?</th></tr><tr><td>global@cosrx.co.kr</td></tr></table> <p>Distributed by COSRX INC. Gangnam-gu, Seoul, Korea (06142)</p>	Drug Facts (continued)	Inactive ingredients	Water / Aqua / Eau, Prop- anediol, Butyloctyl salicyl- ate, Diphenylsiloxy phenyl trimethicone, Dimethicone, VP/Elcosene copolymer, Silica, Trisiloxane, Cyclop- entasiloxane, Trimethylsil- oxysilicate, 1,2-Hexandi- ol, Behenyl alcohol, Glyceryl stearate, PEG-100 stearate, C14-22 alcohols, Cetyl al- cohol, Potassium cetyl ph- osphate, Polyacrylate-13, Polyisobutene, Fragrance / Parfum, C12-20 Alkyl gl- ucoside, Butylene glycol, Disodium EDTA, Ethylhex- ylglycerin, Polysorbate 20, Sorbitan isostearate, Dex- trin, Theobroma cacao (c- ocoa) extract, Gossypium herbaceum (cotton) extr- act, Glucose, Tocopherol	Other information	<ul style="list-style-type: none">Protect the product in this container from excessive heat and direct sun.Sun alert : Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.	Questions?	global@cosrx.co.kr	<p>Vitamin E Vitalizing Sunscreen</p> <p>Tocopherol</p> <p>SPF 50+ sunscreen contains Vitamin E to protect your skin from light (UV rays) and heat (Aging signs) leaving your skin healthy and moisturized.</p> <p>SPF 50+ BROAD SPECTRUM</p> <p>COSRX 50 mL / 1.69 fl. oz.</p>	<p>#Reef-Friendly : formulated without Octinoxate, Oxybenzone</p> <p>DERMATOLOGIST TESTED</p> <p>FSC MX Packaging FSC® C102823</p> <p>Reef friendly</p> <p>SPF 50+ sunscreen contains Vitamin E to protect your skin from light (UV rays) and heat (Aging signs) leaving your skin healthy and moisturized.</p> <p>MADE IN KOREA COSRX.COM</p>
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70319-220
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	4.5 mg in 50 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.25 mg in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.25 mg in 50 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	0.65 mg in 50 mL
TRISILOXANE (UNII: 9G1ZW13R0G)	0.6 mg in 50 mL
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	0.5 mg in 50 mL
TRIMETHYLSILOXYSILICATE (M/Q 1.0-1.2) (UNII: 78GX033D7I)	0.5 mg in 50 mL
PEG-100 STEARATE (UNII: YD01N1999R)	0.325 mg in 50 mL
CETYL ALCOHOL (UNII: 936JST6JCN)	0.25 mg in 50 mL
CETETH-18 (UNII: 9E0067TYQH)	0.0075 mg in 50 mL
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	0.04 mg in 50 mL
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	1 mg in 50 mL
DIMETHICONE (UNII: 92RU3N3Y1O)	0.9 mg in 50 mL
ECHINACEA PURPUREA FLOWERING TOP WATER (UNII: G72P70SL42)	22.26195 mg in 50 mL
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	0.0008 mg in 50 mL
1,3-PROPANEDIOL BIS(4-AMINOBENZOATE) (UNII: 8860R9ORQR)	5 mg in 50 mL
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	0.85 mg in 50 mL
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	0.5 mg in 50 mL
DOCOSANOL (UNII: 9G1OE216XY)	0.35 mg in 50 mL
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	0.325 mg in 50 mL
C14-22 ALCOHOLS (UNII: B1K89384RJ)	0.318 mg in 50 mL
POLYISOBUTYLENE (45000 MW) (UNII: YR8AQ94O31)	0.108 mg in 50 mL
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.025 mg in 50 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.024975 mg in 50 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.018 mg in 50 mL
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	0.016 mg in 50 mL
COCOA (UNII: D9108TZ9KG)	0.0075 mg in 50 mL
LEVANT COTTON SEED (UNII: 550E4N439V)	0.00225 mg in 50 mL
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	0.000025 mg in 50 mL
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	0.25 mg in 50 mL
C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	0.1 mg in 50 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70319-220-01	1 in 1 CARTON	01/09/2023	
1		50 mL in 1 TUBE; 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	06/01/2022	

Labeler - COSRX inc. (689516893)

Registrant - COSRX inc. (689516893)

Revised: 1/2023

COSRX inc.