

**INVISIBLE SUNSCREEN SPF 40- homosalate, octisalate, avobenzone,  
octocrylene cream  
COSMAX USA, CORPORATION**

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**PARTICLE FOR MEN INVISIBLE SUNSCREEN SPF 40**

***Active ingredients***

Homosalate 10%

Octisalate 5%

Avobenzone 3%

Octocrylene 2.6%

***Purpose***

Sunscreen

***Uses***

- Helps prevent sunburn
- If used as directed with other Sun Protection Measures (see **Directions**) decrease the risk of skin cancer and early skin aging damaged by the sun

***Warnings***

**For external use only**

**Do not use** on damaged or broken skin

**When you use 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**

***Directions***

- Apply liberally 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water-resistant sunscreen if swimming or sweating
- Reapply 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 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

## Other information

### Other information

- Protect this product from excessive heat and direct sun

### Inactive Ingredients:

Isodecane, Ethylhexyl Pamatate, Dimethicone/Bis-Isobutyl PPG-20 Crosspolymer, Butyloctyl Salicylate, Caprylyl Methicone, Polymethylsilsesquioxane, Dimethicone/Vinyl Dimethicone Crosspolymer, Caprylic/Capric Triglyceride, Tocopheryl Acetate, Sesamum Indicum(Sesame) Seed Extract, Tocopherol, Vitis Vinifera (Grape) Fruit Cell Extract, Isomalt, Lecithin, Fragrance, Silica, Water, PEG-12 Dimethicone/PPG-20 Crosspolymer, Dimethyl Isosorbide, Sodium Benzoate



## INVISIBLE SUNSCREEN SPF 40

homosalate, octisalate, avobenzone, octocrylene cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68577-196
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 mg in 100 mg
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 100 mg
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.6 mg in 100 mg
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 100 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>PEG-12 DIMETHICONE/PPG-20 CROSSPOLYMER</b> (UNII: 965K72OQXO)	
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)	
<b>ISOMALT</b> (UNII: S870P55O2W)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>DIMETHICONE/BIS-ISOBUTYL PPG-20 CROSSPOLYMER</b> (UNII: O4I3UFO6ZF)	
<b>SESAME SEED</b> (UNII: 7Y1255HVXR)	
<b>VITIS VINIFERA FRUIT RIND</b> (UNII: 653OHN32Q1)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:68577-196-01	1 in 1 CARTON	06/28/2024	
1		50 mg in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M020	06/28/2024	

**Labeler** - COSMAX USA, CORPORATION (010990210)

**Establishment**

Name	Address	ID/FEI	Business Operations
COSMAX USA		010990210	manufacture(68577-196)

Revised: 12/2024

COSMAX USA, CORPORATION