

**HERBAL UV DEFENSE SPF40- homosalate, octisalate, avobenzone,  
octocrylene gel  
COSMAX USA, CORPORATION**

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**SEKKISEI HERBAL UV DEFENSE GEL BROAD SPECTRUM SPF40**

***Active Ingredients***

Homosalate 9.5%

Octisalate 5%

Avobenzone 3.0%

Octocrylene 2.6%

***Purpose***

Sunscreen

**USES**

***Uses***

- Helps prevent sunburn

**WARNINGS**

***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 a doctor** if rash occurs.

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

**DIRECTIONS**

***Directions***

- Apply liberally 15 minutes before sun exposure
- 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: Ask a doctor

### ***Inactive Ingredients***

Water, Isoamyl Laurate, Glycerin, Caprylic/Capric Triglyceride, Butyloctyl Salicylate, Polyglyceryl-10 Stearate, Poly C10-30 Alkyl Acrylate, Polyhydroxystearic Acid, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Cetearyl Olivatate, Sorbitan Olivatate, Hydroxyacetophenone, Phenoxyethanol, Polyglyceryl-10 Laurate, Microcrystalline Cellulose, Limonene, Rubus Idaeus (Raspberry) Seed Oil, Xanthan Gum, Glycine Soja (Soybean) Oil, Cellulose Gum, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Polyglyceryl-3 Diisostearate, Citrus Limon (Lemon) Peel Oil, Linalool, Citrus Aurantium Dulcis (Orange) Peel Oil, Oryza Sativa (Rice) Extract, Oryza Sativa (Rice) Germ Extract, Lavandula Angustifolia (Lavender) Oil, Propanediol, Ocimum Basilicum (Basil) Oil, Pelargonium Graveolens Flower Oil, Citral, Centella Asiatica Extract

### **OTHER INFORMATION**

#### ***Other information***

Protect this product from excessive heat and direct sun

#### **Packaging Label**



HERBAL UV DEFENSE GEL

Broad Spectrum  
SPF40  
Sunscreen

KOSÉ





## HERBAL UV DEFENSE SPF40

homosalate, octisalate, avobenzene, octocrylene gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68577-199
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	9.5 mg in 100 mg
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 100 mg
<b>AVOBENZENE</b> (UNII: G63QQF2NOX) (AVOBENZENE - UNII:G63QQF2NOX)	AVOBENZENE	3 mg in 100 mg
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	2.6 mg in 100 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>METHYL TRIMETHICONE</b> (UNII: S73ZQI0GXM)	
<b>BETAINE</b> (UNII: 3SCV180C9W)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CAESALPINIA SPINOSA FRUIT POD</b> (UNII: EXY4496LWD)	
<b>ORANGE OIL, COLD PRESSED</b> (UNII: AKN3KSD11B)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CITRUS BIOFLAVONOIDS</b> (UNII: BD70459I50)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW)</b> (UNII: J2S07SB0YL)	
<b>AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER</b> (UNII: W59H9296ZG)	
<b>KAPPAPHYCUS ALVAREZII</b> (UNII: T479H08K2O)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>BROCCOLI</b> (UNII: UOI4FT57BZ)	
<b>TROPAEOLUM MAJUS FLOWERING TOP</b> (UNII: RGT30824HY)	
<b>DIBUTYL ETHYLHEXANOYL GLUTAMIDE</b> (UNII: OIAF2L30VS)	
<b>GLYCYRRHIZA GLABRA</b> (UNII: 2788Z9758H)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>ANGELICA GIGAS ROOT</b> (UNII: 32766B2FHX)	
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)	
<b>BASIL OIL</b> (UNII: Z129UMU8LE)	
<b>AMINOMETHYLPROPANOL</b> (UNII: LU49E6626Q)	
<b>LEMON OIL, COLD PRESSED</b> (UNII: I9GRO824LL)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>COIX LACRYMA-JOBI VAR. MA-YUEN SEED</b> (UNII: 8DW238I7ZI)	
<b>BIOSACCHARIDE GUM-4</b> (UNII: 9XRL057X90)	
<b>DIBUTYL LAUROYL GLUTAMIDE</b> (UNII: 3V7K3IA58X)	
<b>PELARGONIUM GRAVEOLENS FLOWER OIL</b> (UNII: 3K0J1S7QGC)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED)</b> (UNII: K6MOM3T5YL)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68577-199-00	1 in 1 CARTON	01/03/2024	
1		30 mg 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 Drug	M020	01/03/2024	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
COSMAX USA, CORPORATION		010990210	manufacture(68577-199)

Revised: 12/2024

COSMAX USA, CORPORATION