

**IOPE UV DEFENSE SUN PROTECTOR EX- avobenzone, homosalate, octocrylene, octisalate lotion lotion**

**Amorepacific Corporation**

*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.*

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**IOPE UV DEFENSE SUN PROTECTOR EX**

***Drug Facts***

**ACTIVE INGREDIENTS**

Avobenzone 2.5%

Homosalate 9%

Octocrylene 9%

Octisalate 4.5%

**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 a doctor if*** rash occurs.
- ***Keep out of reach of children.*** If swallowed, call a poison control centre or get medical help right away.

**DIRECTIONS**

- 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.

**OTHER INFORMATION**

- 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.

**INACTIVE INGREDIENTS**

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

**Questions?**

[support@us.amorepacific.com](mailto:support@us.amorepacific.com)

**PRINCIPAL DISPLAY PANEL****IOPE****UV DEFENSE****SUN PROTECTOR EX****SUNSCREEN****BROAD SPECTRUM SPF39****60 ml / 2.02 FL. OZ.**

## Drug Facts

Active ingredients	Purpose
Avobenzone 2.5%	Sunscreen
Homosalate 9%	Sunscreen
Octocrylene 9%	Sunscreen
Octisalate 4.5%	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

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**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.

### Directions

•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.

### Other information

•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.

### Inactive ingredients

Water / Aqua / Eau, Propanediol, Butylacetyl salicylate, Glycerin, Butylene glycol diacrylate/dioacrylate, Diphenylsilyloxy phenyl trimethicone, Dimethicone, Trisiloxane, Silica, Cyclopentasiloxane, Trimethylsilyloxy silicate, VP/ Eicosene copolymer, 1,2-Hexanediol, Behenyl alcohol, Glyceryl stearate, PEG-100 stearate, C14-22 Alcohols, Polyacrylate-13, Cetyl alcohol, Potassium cetyl phosphate, Fragrance / Parfum, Polysobutene, C12-20 Alkyl glucoside, Butylene glycol, Disodium EDTA, Ethylhexyl glycerin, Polysorbate 20, Sorbitan isostearate, Gossypium herbaceum (cotton) extract, Glucose, Tocopherol

### Questions?

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IOPE

UV DEFENSE

SUN PROTECTOR EX

IOPE  
UV DEFENSE  
SUN PROTECTOR EX  
SUNSCREEN  
BROAD SPECTRUM SPF39

DERMATOLOGIST TESTED

AMOREPACIFIC US INC.  
DIST NEW YORK, NY 10018  
MADE IN KOREA (0288)

SUNSCREEN  
BROAD SPECTRUM SPF39

60 ml / 2.02 FL.OZ.

## IOPE UV DEFENSE SUN PROTECTOR EX

avobenzone, homosalate, octocrylene, octisalate lotion lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43419-418
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 mg in 60 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	2.7 mg in 60 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5.4 mg in 60 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	5.4 mg in 60 mL

## Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYISOBUTYLENE (1100000 MW) (UNII: FLT10CH37X)	
C12-20 ALKYL GLUCOSIDE (UNII: K67N5Z1RUA)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPANEDIOL (UNII: 5965N8W85T)	
DOCOSANOL (UNII: 9G1OE216XY)	
C14-22 ALCOHOLS (UNII: B1K89384RJ)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
TRIMETHYLSILOXYLSILICATE (M/Q 1.0-1.2) (UNII: 78GX033D7I)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LEVANT COTTON SEED (UNII: 550E4N439V)	
ANHYDROUS DEXTROSE (UNII: 5SLOG7R0OK)	
TOCOPHEROL (UNII: R0ZB2556P8)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: 75D21FL1PI)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43419-418-18	1 in 1 CARTON	04/27/2020	
1		60 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	04/27/2020	

**Labeler** - Amorepacific Corporation (631035289)

**Establishment**

Name	Address	ID/FEI	Business Operations
Amorepacific Corporation		694894112	manufacture(43419-418)

Revised: 3/2020

Amorepacific Corporation