

**LANEIGE HYDRO UV DEFENSE- avobenzone, homosalate, octisalate, and octocrylene 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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**Laneige Hydro UV Defense Broad Spectrum SPF 50+**

**Drug Facts**

**Inactive ingredients**

WATER / AQUA / EAU, PROPANEDIOL, BUTYLOCTYL SALICYLATE, GLYCERIN, DIMETHICONE, SILICA, DIPHENYLSILOXY PHENYL TRIMETHICONE, BEHENYL ALCOHOL, TRISILOXANE, VP/EICOSENE COPOLYMER, CYCLOPENTASILOXANE, TRIMETHYLSILOXYSILICATE, C14-22 ALCOHOLS, 1,2-HEXANEDIOL, GLYCERYLSTEARATE, PEG-100 STEARATE, PHENYL TRIMETHICONE, CETYL ALCOHOL, POTASSIUM CETYL PHOSPHATE, CAPRYLYL METHICONE, POLYACRYLATE-13, FRAGRANCE / PARFUM, POLYISOBUTENE, C12-20 ALKYL GLUCOSIDE, ETHYLHEXYLGLYCERIN, DISODIUM EDTA, POLYSORBATE 20, SORBITAN ISOSTEARATE, LAVANDULA ANGUSTIFOLIA (LAVENDER) FLOWER WATER, BUTYLPHENYL METHYLPROPIONAL, HYDROXYCITRONELLAL, LIMONENE, BENZYL SALICYLATE, ALPHA-ISOMETHYL IONONE, GERANIOL, CITRONELLOL, BUTYLENE GLYCOL, GLUCOSE, ALOE BARBADENSIS LEAF EXTRACT, PENTYLENE GLYCOL, CENTELLA ASIATICA FLOWER/LEAF/STEM EXTRACT, BRASSICA OLERACEA ITALICA (BROCCOLI) EXTRACT, HIBISCUS ABELMOSCHUS EXTRACT, MAGNESIUM SULFATE, CALCIUM CHLORIDE, TOCOPHEROL, XANTHAN GUM, CITRIC ACID, SODIUM BENZOATE, POTASSIUM SORBATE, MANGANESE SULFATE, CHENOPODIUM QUINOA SEED EXTRACT, ZINC SULFATE, ASCORBYL GLUCOSIDE

**ACTIVE INGREDIENTS**

Avobenzone 2.5%  
Homosalate 9%  
Octisalate 4.5%  
Octocrylene 9%

**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, get medical help or contact a Poison Control Center right away.

## **DIRECTIONS**

- Apply liberally 15 minutes before sun exposure
- 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.
- Children under 6 months of age : Ask a doctor.

## **OTHER INFORMATION**

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

## **INACTIVE INGREDIENTS**

WATER / AQUA / EAU, DIMETHICONE, CYCLOPENTASILOXANE, BUTYLENE GLYCOL, PROPYLHEPTYL CAPRYLATE, CETYL PEG/PPG-10/1 DIMETHICONE, CAPRYLIC/CAPRIC TRIGLYCERIDE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, PROPANEDIOL, POLYSILICONE-11, DISTEARDIMONIUM HECTORITE, VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER, SYNTHETIC FLUORPHLOGOPITE, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, 1,2-HEXANEDIOL, MAGNESIUM SULFATE, POLYHYDROXYSTEARIC ACID, METHYL METHACRYLATE CROSSPOLYMER, ALUMINA, FRAGRANCE / PARFUM, STEARIC ACID, CAPRYLYL DIMETHICONE ETHOXY GLUCOSIDE, CAPRYLYL GLYCOL, GLYCERYL CAPRYLATE, SOLIDAGO VIRGAUREA (GOLDENROD) EXTRACT, EUGENIA CARYOPHYLLUS (CLOVE) BUD EXTRACT, ETHYLHEXYLGLYCERIN, DICAPRYLYL CARBONATE, MICA, SILICA, TOCOPHEROL, IRON OXIDES (CI 77491), TRIETHOXYCAPRYLYLSILANE

## **Questions?**

support@us.amorepacific.com

# PRINCIPAL DISPLAY PANEL

Laneige  
Hydro UV Defense  
Sunscreen  
Broad Spectrum  
SPF 50+  
Hypoallergenic Tested  
Dermatologist Tested  
No White Cast  
50 ml / 1.6 fl. oz.

<p><b>Drug Facts</b></p> <table border="1"><thead><tr><th>Active ingredients</th><th>Purpose</th></tr></thead><tbody><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></tbody></table> <p><b>Uses</b> •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> <p><b>Warnings</b> <b>For external use only</b> 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><b>Directions</b> •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.</p> <p><b>Other information</b> •Protect the product in this container from excessive heat and direct sun. ▶</p>	Active ingredients	Purpose	Avobenzone 2.5%	Sunscreen	Homosalate 9%	Sunscreen	Octisalate 4.5%	Sunscreen	Octocrylene 9%	Sunscreen	<p><b>Drug Facts</b> <i>(continued)</i></p> <p><b>Inactive ingredients</b> WATER / AQUA /EAU, PROPANEDIOL, BUTYLOCTYL SALICYLATE, GLYCERIN, DIMETHICONE, SILICA, DIPHENYLSILOXY PHENYL TRIMETHICONE, BEHENYL ALCOHOL, TRISILOXANE, VP/EICOSENE COPOLYMER, CYCLOPENTASILOXANE, TRIMETHYLSILOXY SILICATE, C14-22 ALCOHOLS, 1,2-HEXANEDIOL, GLYCERYL STEARATE, PEG-100 STEARATE, PHENYL TRIMETHICONE, CETYL ALCOHOL, POTASSIUM CETYL PHOSPHATE, CAPRYLYL METHICONE, POLYACRYLATE-13, FRAGRANCE / PARFUM, POLYISOBUTENE, C12-20 ALKYL GLUCOSIDE, ETHYLHEXYLGLYCERIN, DISODIUM EDTA, POLYSORBATE 20, SORBITAN ISOSTEARATE, LAVANDULA ANGUSTIFOLIA (LAVENDER) FLOWER WATER, BUTYLPHENYL METHYLPROPIONAL, HYDROXYCITRONELLAL, LIMONENE, BENZYL SALICYLATE, ALPHA-ISOMETHYL IONONE, GERANIOL, CITRONELLOL, BUTYLENE GLYCOL, GLUCOSE, ALOE BARBADENSIS LEAF EXTRACT, PENTYLENE GLYCOL, CENTELLA ASIATICA FLOWER/LEAF/STEM EXTRACT, BRASSICA OLERACEA ITALICA (BROCCOLI) EXTRACT, HIBISCUS ABELMOSCHUS EXTRACT, MAGNESIUM SULFATE, CALCIUM CHLORIDE, TOCOPHEROL, XANTHAN GUM, CITRIC ACID, SODIUM BENZOATE, POTASSIUM SORBATE, MANGANESE SULFATE, CHENOPodium QUINOA SEED EXTRACT, ZINC SULFATE, ASCORBYL GLUCOSIDE</p> <p><b>Questions?</b> support@us.amorepacific.com</p>	<p><b>LANEIGE</b></p> <p><b>HYDRO UV DEFENSE</b> <b>SUNSCREEN</b> <b>BROAD SPECTRUM</b></p> <p><b>SPF50+</b></p> <p>Hypoallergenic Tested Dermatologist Tested No White Cast</p> <p>50 mL / 1.6 fl.oz.</p> <p>A lightweight, daily SPF 50+ sunscreen that hydrates and soothes skin with an invisible finish.</p> <p><b>MAIN FEATURES</b> Centella Asiatica Extract</p> <p><b>SKIN TYPE</b> for all skin types</p> <p><b>DIRECTIONS</b> : Use as the last step of your routine, before makeup. Take a dime-size amount and spread evenly onto face. Reapply every two hours when exposed to sunlight.</p> <p><b>Soothing Hydration</b></p> <p><input checked="" type="checkbox"/> Centella Asiatica Extract : A plant derived-ingredient, to help soothe skin.</p> <p>AMOREPACIFIC CORPORATION AMOREPACIFIC US INC. Dist New York, NY 10018 MADE IN KOREA (2402)</p> <p></p>
Active ingredients	Purpose											
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Homosalate 9%	Sunscreen											
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## LANEIGE HYDRO UV DEFENSE

avobenzone, homosalate, octisalate, and octocrylene lotion lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43419-768
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZYL SALICYLATE</b> (UNII: WAO5MKN9TU)	
<b>ISOMETHYL-.ALPHA.-IONONE</b> (UNII: 9XP4LC555B)	
<b>GERANIOL</b> (UNII: L837108USY)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>MAGNESIUM SULFATE, UNSPECIFIED</b> (UNII: DE08037SAB)	
<b>ZINC SULFATE</b> (UNII: 89DS0H96TB)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>PHENYL TRIMETHICONE</b> (UNII: DROK5NOJ4R)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>.BETA.-CITRONELLOL, (R)-</b> (UNII: P01OUT964K)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CALCIUM CHLORIDE</b> (UNII: M410D6VV5M)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>ABELMOSCHUS MOSCHATUS SEED</b> (UNII: UN2QZ55I88)	
<b>POLYISOBUTYLENE (85000 MW)</b> (UNII: 7X53O5S2ZY)	
<b>C12-20 ALKYL GLUCOSIDE</b> (UNII: K67N5Z1RUA)	
<b>DIPHENYLSILOXY PHENYL TRIMETHICONE</b> (UNII: I445L28B12)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>MANGANESE SULFATE</b> (UNII: W00LYS4T26)	
<b>ASCORBYL GLUCOSIDE</b> (UNII: 2V52RONHXW)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>C14-22 ALCOHOLS</b> (UNII: B1K89384R)	
<b>BUTYLPHENYL METHYLPROPIONAL</b> (UNII: T7540GJV69)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	

<b>ANHYDROUS DEXTROSE</b> (UNII: 5SL0G7R0OK)
<b>CENTELLA ASIATICA FLOWERING TOP</b> (UNII: J02K2IV2PB)
<b>BROCCOLI SPROUT</b> (UNII: 128UH9LOAE)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)
<b>TRISILOXANE</b> (UNII: 9G1ZW13R0G)
<b>HYDROXYCITRONELLAL</b> (UNII: 8SQ0VA4YUR)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)
<b>VINYLPYRROLIDONE/EICOSENE COPOLYMER</b> (UNII: 035MV9S1C3)
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0)</b> (UNII: 25LXE464L2)
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43419-768-08	1 in 1 CARTON	12/31/2021	
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	12/31/2021	

**Labeler** - Amorepacific Corporation (631035289)

Revised: 1/2023

Amorepacific Corporation