

SUMMER GELEE SPF-30- homosalate, octisalate, octocrylene gel
SUMMER GELEE LLC

SUMMER GELEE SPF-30

Drug Facts

Active Ingredients

Homosalate 10.00%, Octisalate 5.00%, Octocrylene 5.00%

Purpose

Sunscreen

Uses:

Helps prevent sunburn.

- Higher SPF gives more sunburn protection.
- If used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early 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 or irritation develops and lasts.

Keep out of reach of children.

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

If pregnant or breast-feeding,

ask a health professional before use.

Directions:

Apply liberally 15 minutes before sun exposure and as needed.

- 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 the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10am-2pm.
- Wear long-sleeved shirts, pants, hats, & sunglasses.

Other Information:

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

Inactive Ingredients:

Cinnamomum Cassia Oil, Hydrogenated Vegetable Oil, Iron Oxides (CI 77492), Isopropyl Myristate, Mineral Oil, Ozokerite Wax, Paraffin, Parfum (Fragrance), Petrolatum, Tocopheryl Acetate (Vitamin E), Tridecyl Salicylate, D&C Red #17.

Package Labeling:



SUMMER
TANNING GELÉE
Superior Quality

THE LUXURIOUS FORMULA OF SUMMER GELÉE ENHANCES THE SKIN'S NATURAL TANNING PROCESS WITH ITS EMOLLIENT-RICH FORMULA, GIVING A DEEP SUN-KISSED GLOW WHILE MOISTURIZING YOUR SKIN.



BROAD SPECTRUM SPF 30
SUNSCREEN
 3.12 FL OZ (92.26 mL)

Printing Area

Drug Facts

Active Ingredients Homosalate 10.00%, Octisalate 5.00%, Octocrylene 5.00%	Purpose Sunscreen
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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 or irritation develops and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. • **If pregnant or breast-feeding**, ask a health professional before use.

Directions: Apply liberally 15 minutes before sun exposure and as needed. • 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 the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
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SUMMER • 1228 SNOWDEN RD.
 WHITE SALMON, WA • 98672

SUMMER GELEE SPF-30

homosalate, octisalate, octocrylene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84281-477
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CHINESE CINNAMON OIL (UNII: A4WO0626T5)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MINERAL OIL (UNII: T5L8T28FGP)	
CERESIN (UNII: Q1LS2UJO3A)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
D&C RED NO. 17 (UNII: ND733RX3JN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84281-477-00	92.26 mL in 1 TUBE; Type 0: Not a Combination Product	05/06/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/06/2024	

Labeler - SUMMER GELEE LLC (119209761)

Revised: 4/2024

SUMMER GELEE LLC