

**ORANGE GEL- avobenzone octisalate octocrylene homosalate gel
Vacation Inc.**

Vacation Orange Gelee

Dosage and Administration

Apply liberally 15 minutes before sun exposure

Reapply at least every 2 hours

Use a water resistant sunscreen if swimming or sweating

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

Indications and Usage

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

Keep out of reach of children

Keep out of reach of children

In case of ingestion, get medical help or contact a Poison Control Center right away

Purpose

Sunscreen

Inactives

Behenyl Behenate, Butyloctyl Salicylate, Butyrospermum Parkii (Shea) Butter, Calophyllum Inophyllum Seed Oil, Cetyl Esters, Citrus Aurantium Bergamia (Bergamot) Peel Oil, Cocos Nucifera (Coconut) Oil, Crocus Sativus Flower Extract, Euphorbia Cerifera (Candelilla) Wax, Fragrance, Glyceryl Stearate, Helianthus Annuus (Sunflower) Seed Oil, Hydrogenated Castor Oil, Isododecane

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ORANGE GEL

avobenzone octisalate octocrylene homosalate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80641-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.9 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	6.9 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.9 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80641-016-30	88 g in 1 TUBE; Type 0: Not a Combination Product	03/08/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/08/2024	

Labeler - Vacation Inc. (117644631)

Revised: 3/2024

Vacation Inc.