VACATION SPF 30 CHARDONNAY OIL- avobenzone, homosalate, octisalate, octocrylene oil Vacation Inc.

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.

Vacation - SPF 30 Chardonnay Oil

Avobenzone (2.9%) Homosalate (9.8%) Octisalate (4.9%) Octocrylene (9.5%) 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

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

Directions

- Apply liberally 15 minutes before sun exposure.
- Reapply: after 80 minutes of swimming or sweating immediately after towel drying
- 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 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 10 a.m. - 2 p.m. wear long-sleeve shirts, pants, hats, and sunglasses • Children under 6 months of age: ask a physician.

Bisabolol, Butyloctyl Salicylate, Butyrospermum Parkii (Shea) Oil, Caprylic/Capric Triglyceride, C12-15 Alkyl Benzoate, Fragrance, Isopropyl Myristrate, Methyl Dihydroabietate, Passiflora Edulis (Passionfruit) Seed Oil, Polyester-8, Sclerocarya Birrea (Marula) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol (Vitamin E),Trimethylpentanediol/Adipic Acid/Glycerin Crosspolymer, Vitis Vinifera (Chardonnay Grape) Seed Oil

Other Information

• Protect this product from excessive heat and direct sun.



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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80641-008
Route of Administration	TOPICAL		

Active Ingred	lient/Active Moiety		
	Ingredient Name	Basis of Strengt	h Strength
HOMOSALATE (UI	NII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	9.8 g in 100 mL
OCTISALATE (UNI	I: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.9 g in 100 mL
AVOBENZONE (UI	NII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	2.9 g in 100 mL
OCTOCRYLENE (U	JNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9.5 g in 100 mL
Inactive Ingr	adianta		
mactive mgro	Ingredient Name		Strength
LEVOMENOL (UNI	-		
BUTYLOCTYL SAI	LICYLATE (UNII: 2EH13UN8D3)		
ALKYL (C12-15)	BENZOATE (UNII: A9EJ3J61HQ)		
TRIMETHYLPENT 587WKM3S9Q)	ANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER (2	25000 MPA.S) (UNII:	
MEDIUM-CHAIN T	RIGLYCERIDES (UNII: C9H2L21V7U)		
METHYL DIHYDRO	DABIETATE (UNII: 7666FJ0J9F)		
POLYESTER-8 (14	400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UN	III: T9296U138P)	
JOJOBA OIL (UNII:	724GKU717M)		
TOCOPHEROL (UI	NII: ROZB2556P8)		
ISOPROPYL MYRI	STATE (UNII: ORE8K4LNJS)		
SHEANUT OIL (UN	III: 088E196QRF)		
PASSIFLORA EDU	LIS SEED OIL (UNII: F3VOA31UHQ)		
SCLEROCARYA B	IRREA SEED OIL (UNII: WDO4TLS35F)		
GRAPE SEED OIL	(UNII: 930MLC8XGG)		
Packaging			
# Item Code	Package Description	Marketing Start M Date	Marketing End Date

#	ltem Code	Package Description	Date	Date
1	NDC:80641- 008-01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2023	
2	NDC:80641- 008-02	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2023	
Marketing Information				

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	M020	01/01/2023	

Labeler - Vacation Inc. (117644631)

Revised: 3/2023

Vacation Inc.