

HAMPTON SUN- octinoxate, oxybenzone gel
Inspec Solutions LLC.

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.

HAMPTON SUN SPF 4 SUNSCREEN OIL

Active Ingredients:

Octinoxate – 4.00%

Oxybenzone - 2.00%

Octinoxate – 4.00%.....Sunscreen

Oxybenzone - 2.00%.....Sunscreen

Uses • Helps prevent sunburn☐

Warnings

Skin cancer/Skin Aging alert

For external use only

Do not use on Damage 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 immediately.

DIRECTIONS

- Apply liberally 15 minutes before sun exposure.
- Use water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- ☐ Children under 6 months of age: ask a doctor

Inactive Ingredients:

Aloe Barbadosis Leaf Extract, Benzotriazolyl Dodecyl p-Cresol, C12-15 Alkyl Benzoate, Cyclohexasiloxane, Cyclopentasiloxane

Dimethicone Crosspolymer, Ethylhexyl Palmitate, Fragrance, Hydrogenated Polyisobutene, Hydrolyzed Jojoba Esters, Jojoba Esters, Juglans Regia (Walnut) Seed Oil, Mineral Oil, Sorbitan Olivatate, Tocopheryl Acetate, Water

SPF 4 SUNSCREEN OIL

Our SPF 4 SUNSCREEN OIL is a luxurious formula that hydrates and improves the health of skin with natural Aloe Vera and Vitamin E. Advanced active ingredients protect skin from the sun's harmful rays while natural Walnut Oil imparts a sunkissed glow.

This product is best used with a healthy base tan.

Drug Facts

Active Ingredients	Purpose
Oxibenzonate 4.0%	Sunscreen
Cyberzone 2.0%	Sunscreen
Use - helps prevent sunburn	
Warnings	
Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. • This product has been shown only to prevent sunburn, not skin cancer or early skin aging. • 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 product is swallowed, get medical help or contact Poison Control Center right away.	
Directions	
• apply liberally 15 minutes before sun exposure • use a water resistant sunscreen if swimming or sweating • reapply at least every 2 hours • children under 6 months of age, ask a doctor.	
Inactive Ingredients Aloe Barbadensis Leaf Extract, Benzocaine, Dodecyl p-Cresyl, C12-15 Alkyl Benzoate, Cyclohexylsiloxane, Cyclopentasiloxane, Dimethylsiloxane, Crosspolymer, Ethylhexyl Palmitate, Fragrance, Hydrogenated Polyisobutene, Hydrolyzed Jojoba Esters, Jojoba Esters, Juglans Regia (walnut) Seed Oil, Mineral Oil, Gethan Olivata Tocopheryl Acetate, Water	
Other information	
• protect this product from excessive heat and direct sun	
Components Active	Function
Oxibenzonate 4.0%	Protectant Solaire
Cyberzone 2.0%	Protection Solaire
Utilisation • Prévention des coups de soleil.	
Avertissements	
Mise en garde concernant les cancers/sécheresses de la peau: Une exposition prolongée au soleil augmente le risque de vieillissement prématuré et de cancer de la peau. • D'après les études, ce produit prévient uniquement les coups de soleil. Il ne prévient pas le cancer de la peau ni le vieillissement cutané. • Usage externe uniquement. • Ne pas appliquer sur une peau abîmée ou écorchée. • Éviter le contact avec les yeux. En cas de contact rincer abondamment à l'eau. • En cas de rougeur, cesser l'utilisation et demander conseil à un médecin. • Tenir hors de portée des enfants. En cas d'ingestion du produit, consulter immédiatement un médecin ou contacter le centre Anti-Poison le plus proche.	
Conseils d'utilisation	
• Appliquer généreusement 15 minutes avant l'exposition au soleil. • En cas de baignade ou de transpiration, utiliser une crème solaire qui résiste à l'eau. • Renouveler l'application au moins toutes les 2 heures. • Enfants de moins de 6 mois, demander conseil à un médecin.	
Composants Inactifs Extrait de feuille d'Aloe Barbadensis, benzocaine, dodécyl p-crésyl, C12-15 alkyl benzoate, cyclohexylsiloxane, cyclopentasiloxane, polymère croisé de diméthylsiloxane, éthylhexyl palmate, parfum, polyisobutène hydrogéné, esters de jojoba hydrolysés, esters de jojoba, huile de graines de Juglans Regia (noyer), huile minérale, arbutane oléate, acétate de tocophérol, eau	
Autres informations	
• Ne pas exposer ce produit à une chaleur excessive ni à la lumière du soleil.	
Questions or comments? Call toll free 888-3-PRIVET (774836)	

HAMPTON SUN®



SMART
SERIOUS
SUNBATHING®

SPF 4 OIL

WITH ALOE AND VITAMIN E
HYPOALLERGENIC

CONTIENT DE L'ALOE VERA
ET DE LA VITAMINE E
HYPOALLERGENIQUE

(118 ML)
4 FL. OZ.

Made in the USA • Distributed by:
S&G Hampton Sun, LLC • Southampton, NY 11968
RP, MSL, BLY SNB, UK
RP, MSL, Suite 5385, 27 Upper Pembroke St, Dublin, IE
www.hampton sunscreen.com 1-866-9-PRIVET (774836)



octinoxate, oxybenzone gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72667-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE (UNII: V5VD430YW9)	
BENZOTRIAZOLYL DODECYL P-CRESOL (UNII: 298PX4M11X)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
WALNUT OIL (UNII: Y0P3555R51)	
MINERAL OIL (UNII: T5L8T28FGP)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
C12-15 ALCOHOLS (UNII: 2C8M6XLB5C)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
HYDROLYZED JOJOBA ESTERS (POTASSIUM SALTS) (UNII: CH428W5O62)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72667-012-01	118 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/01/2019	

Labeler - Inspec Solutions LLC. (081030372)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC.		081030372	manufacture(72667-012)

