

ISNTREE ONION NEWPAIR SUNSCREEN- avobenzone, homosalate, octinoxate, octisalate, octocrylene cream
ISNTREE Inc.

ISNTREE ONION NEWPAIR SUNSCREEN

Active ingredients

Avobenzone 2.7 %
Homosalate 9 %
Octinoxate 6.8 %
Octisalate 4.5 %
Octocrylene 4 %

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 skin aging caused by the sun

Warnings

For external use only.

Do not use

- on damaged skin 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.

Directions

■ apply liberally 15 minutes before sun exposure. 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 ■ reapply at least every 2 hours. ■ use a water-resistant sunscreen if swimming or sweating.

Other information

■ protect the product from excessive heat and direct sun ■ Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients

Water, Butyloctyl Salicylate, Butylene Glycol, Acrylates Copolymer, Niacinamide, Polymethylsilsesquioxane, C20-22 Alkyl Phosphate, C20-22 Alcohols, 1,2-Hexanediol, Glycerin, Pentylene Glycol, Caprylyl Methicone, Cetyl Alcohol, Dicaprylyl Carbonate, Glyceryl Stearate, Tromethamine, Poly C10-30 Alkyl Acrylate, Silica, Coco-Caprylate/Caprates, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Trisiloxane, Polyacrylate Crosspolymer-6, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polyisobutene, Allium Ceba (Onion) Bulb Extract, Ethylhexylglycerin, Kaolin, Adenosine, Polyhydroxystearic Acid, Xanthan Gum, Triethoxycaprylylsilane, Alumina, Sorbitan Oleate, Caprylyl/Capryl Glucoside, Tocopherol, Allantoin, Panthenol, Houttuynia Cordata Extract, Caprylic/Capric Triglyceride, Hydrogenated Lecithin, Polyglyceryl-10 Diisostearate, Glycoproteins, Menadione, Ultramarines(CI 77007), Titanium Dioxide(CI 77891)



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81100-502
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	4.5 g in 50 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.4 g in 50 mL

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.25 g in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 50 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.35 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
NIACINAMIDE (UNII: 25X51I8RD4)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
C20-22 ALCOHOLS (UNII: O4M0347C6A)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0)	
ALLANTOIN (UNII: 344S277G0Z)	
PANTHENOL (UNII: WW9CM0O67Z)	
HOULTTUYNIA CORDATA FLOWERING TOP (UNII: RH041UUZ22)	
C20-22 ALKYL PHOSPHATE (UNII: L4VKPOY7RP)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TROMETHAMINE (UNII: 023C2WHX2V)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
ONION (UNII: 492225Q21H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
ADENOSINE (UNII: K72T3FS567)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MP.A.S) (UNII: Q7UI015FF9)	
KAOLIN (UNII: 24H4NWX5CO)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MENADIONE (UNII: 723JX6CXY5)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81100-502-	1 in 1 BOX	01/17/2024	

02	1 III 1 BOX	01/17/2024	
1	NDC:81100-502-01	50 mL in 1 TUBE; Type 1: Convenience Kit of Co-Package	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/17/2024	

Labeler - ISNTREE Inc. (689043012)

Establishment			
Name	Address	ID/FEI	Business Operations
Kolmar Korea Co., Ltd		963271745	manufacture(81100-502)

Revised: 7/2024

ISNTREE Inc.