

LIFEGUARD- sunscreen cream
SPHERE 8 INC

SPHERE 8- Sunscreen 50 SPF

Active Ingredient(s)

Octisalate 4% Sunscreen

Octocrylene 5% Sunscreen

Zinc Oxide 17.18% Sunscreen

Purpose

Sunscreen

Use

Helps prevent sunburn and photo damage by UV/UVB exposure 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

- When using this product keep out of eyes. Rinse with water to remove Stop use and ask doctor if rash or irritation occurs Do not use on damaged or broken skin or if allergic to any ingredient If swallowed, get medical help or contact a Poison Control Center

Rinse with water to remove Stop use and ask doctor if rash or irritation occurs

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- Shake well prior to use • Apply liberally to dry skin 15 minutes before sun exposure • For topical use only .Keep out of reach of children. For children under 6 months, ask doctor
- 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 value of 15 or higher and other sun protection measures including: Limit time in sun, especially from 10am - 2pm
- Wear long-sleeved shirts, pants, hats, and sunglasses, Reapply to dry skin at least every 2 hours. Use water resistant sunscreen if swimming or sweating.

Other information

Protect from excessive heat.

Inactive ingredients

Water(Aqua), Boyle* Glycol DicaorylateXicarxete, C12-15 Alkyl Benzoate, Propanedi01, Elutyloctyi Salicylat, CvryliciCapric Triglyteride, Glycerin, Lally PEG-10 Tris(Trimethylsilm) ilyiettyil Dimethiccne, C15-19 Mane, Niaciriamide, Polyglycenii-2 Triisosbearate, Magnesium Stitata-Heolatrydraie, Meleafied Soy can Oil GlycenfIOctyklooecanol Polymer, Propylheptyl Caprylata, Silica, Dlabserdirnohlurn Hed01149, Dirnerlipme, Triethoxycaorytylsilane, 1,2-Hexanaciol, Pentlienol, Polyglycerk3 PolydlmeNsfoxyethyl Dinethicone, Propylene Carbonate, Aloe Berbadensis Leaf Juice, DirnethiconelPEG-1015 Crosspolymer, Cactityl Gycol, Glycerii Capritare, Ethyl Ferulate, Tocopherol, tsostearic Acid, Dipropylene Gird, Sodium Citrate

Package Label - Principal Display Panel



LIFEGUARD

sunscreen cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85527-111
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17.18 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ETHYL FERULATE (UNII: 5B8915UELW)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
SOYBEAN OIL (UNII: 241ATL177A)	
PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: 75D21FL1PI)	
PROPANEDIOL (UNII: 5965N8W85T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
C15-19 ALKANE (UNII: CI87N1IM01)	
NIACINAMIDE (UNII: 25X51I8RD4)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PANTHENOL (UNII: WW9CM0O67Z)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
ALOE VERA LEAF JUICE (UNII: RUE8E6T4NB)	
CETYL DIGLYCERYL TRIS(TRIMETHYLSILOXY)SILYLETHYL DIMETHICONE (3500 MM2/S) (UNII: KB7T6C99UP)	
POLYGLYCERYL-2 TRIISOSTEARATE (UNII: 68DUY2D39A)	
SILICA (UNII: ETJ7Z6XBU4)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85527-111-11	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/01/2025	

Labeler - SPHERE 8 INC (119448828)

Establishment

Name	Address	ID/FEI	Business Operations
HK Kolmar USA LLC		809172885	manufacture(85527-111)

Revised: 4/2025

SPHERE 8 INC