

IM SPORTS AQUA SUNGEL- octyl methoxycinnamate, homosalate, octyl salicylate lotion
Normalest Co., Ltd.

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.

180131 SUNTIQUE I'M SPORTS AQUA SUNGEL_BOX



I'M SPORTS AQUA SUNGEL

Drug Facts

Active ingredients	Purpose
Homosalate (6.0%) Octyl Methoxycinnamate (7.0%) Octyl Salicylate (4.5%)	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. If product is 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 in this container from excessive heat and direct sun

Inactive ingredients

1,2-hexanediol, achillea millefolium extract, acrylates/C10-30 alkyl acrylate copolymer, alchemilla vulgaris extract, alcohol, aloe barbadensis leaf extract, ammonium acryloyldimethylsulfate/VP copolymer, butylene glycol, cardiospermum halicacabum flower leaf/vine extract, clematis asiatica extract, diethylamino hydroxybenzoyl/henyl benzoate, dimethicone crosspolymer, echium plantagineum seed oil, ethylhexylglycerin, fragrance, fructooligosaccharides, glycerin, helianthus annuus (sunflower) seed oil unsaponifiables, houttuynia cordata extract, malva sylvestris (mallow) extract, melissa officinalis leaf extract, mentha piperita (peppermint) leaf extract, octyldodecanol, pentylene glycol, phenylethanol, primula veris extract, propargenediol, pullulan, saccharide hydrolysate, salvia hispanica seed extract, sodium hydroxide, tocoopherol, triethanolamine, veronica officinalis extract, water

Manufactured for Normalest Co., Ltd.
 5F 297-1, Yeonseo-ro, Eunpyeong-gu, Seoul, Korea

MADE IN KOREA WWW.SUNTIQUE.NET



SUNTIQUE

SUNTIQUE

I'M SPORTS
AQUA SUNGEL

50 SUNSCREEN
 BROAD SPECTRUM SPF 50

SUNCARE A TO Z

50ml

1.69 FL. OZ.

www.suntique.net





Active ingredients

Octyl Methoxycinnamate 7%

Homosalate 6%

Octyl Salicylate 4.5%

Inactive ingredients

Water, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Propanediol, Dimethicone Crosspolymer, Pentylene Glycol, Ammonium Acryloyldimethyltaurate/VP Copolymer, Salvia Hispanica Seed Extract, Centella Asiatica Extract, Houttuynia Cordata Extract, Phenoxyethanol, Fragrance, Fructooligosaccharides, Saccharide Hydrolysate, Pullulan, Acrylates/C10-30 Alkyl Acrylate, Crosspolymer, Ethylhexylglycerin, Triethanolamine, Octyldodecanol, 1,2-Hexanediol, Echium Plantagineum Seed Oil, Butylene Glycol, Glycerin, Alcohol, Cardiospermum Halicacabum Flower/Leaf/Vine Extract, Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables, Achillea Millefolium Extract, Alchemilla Vulgaris Extract, Malva Sylvestris (Mallow) Extract, Melissa Officinalis Leaf Extract, Mentha Piperita (Peppermint) Leaf Extract, Primula Veris Extract, Veronica Officinalis Extract, Aloe Barbadensis Leaf Extract, Tocopherol, Sodium Hydroxide

IM SPORTS AQUA SUNGEL

octyl methoxycinnamate, homosalate, octyl salicylate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72284-0006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.5 g in 50 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	3 g in 50 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.25 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PROPANEDIOL (UNII: 5965N8W85T)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
HOUTTUYNIA CORDATA WHOLE (UNII: O3E12ZLW5T)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	

AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)
SALVIA HISPANICA SEED (UNII: NU0OLX06F8)
CENTELLA ASIATICA (UNII: 7M867G6T1U)
FOSEFRUCTOSE (UNII: M7522JYX1H)
INVERT SUGAR (UNII: ED959S6ACY)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
OCTYLDODECANOL (UNII: 461N1O614Y)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
ECHIUM PLANTAGINEUM SEED OIL (UNII: PIB7XBU8XW)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
MENTHA PIPERITA LEAF (UNII: A389O33LX6)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
TOCOPHEROL (UNII: R0ZB2556P8)
WATER (UNII: 059QF0K00R)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PULLULAN (UNII: 8ZQ0AYU1TT)
TROLAMINE (UNII: 9O3K93S3TK)
GLYCERIN (UNII: PDC6A3C0OX)
ALCOHOL (UNII: 3K9958V90M)
CARDIOSPERMUM HALICACABUM WHOLE (UNII: 185RQ97K0V)
MALVA SYLVESTRIS WHOLE (UNII: I01732476C)
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK)
MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219)
PRIMULA VERIS (UNII: W6LFQ57E4M)
VERONICA OFFICINALIS WHOLE (UNII: 9EHR580PSP)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72284-0006-1	1 in 1 BOX	03/06/2019	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/06/2019	

Labeler - Normalest Co., Ltd. (694812877)

Registrant - Normalest Co., Ltd. (694812877)

Establishment

Name	Address	ID/FEI	Business Operations
Normalest Co., Ltd.		694812877	manufacture(72284-0006)

Revised: 3/2019

Normalest Co., Ltd.