5298 SUNSCREEN- avobenzone, homosalate, octocrylene, octisalate lotion
Innovation Specialties

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.

5298 SUNSCREEN

Drug Facts

Active Ingredients

Avobenzone 3%
Homosalate 10%
Octocrylene 10%
Octisalate 5%

Purpose

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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

• Apply liberally 15 minutes exposure. • reapply: • after 40 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours.

Sun Protection Measure.

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 of 15 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: Ask a doctor.

Inactive ingredients

Water, Glycerin, Caprylic/Capric Triglyceride, Potassium Cetyl Phosphate, Cetearyl Alcohol, Dimethicone, Caprylyl Glycol, Phenoxyethanol, Glyceryl Stearate, VP/Hexadecene Copolymer, Bisabolol, Carbomer, Fragrance, Triethanolamine, Disodium EDTA

Other Information

• Protect this product from excessive heat and direct sun

Questions or Comments?

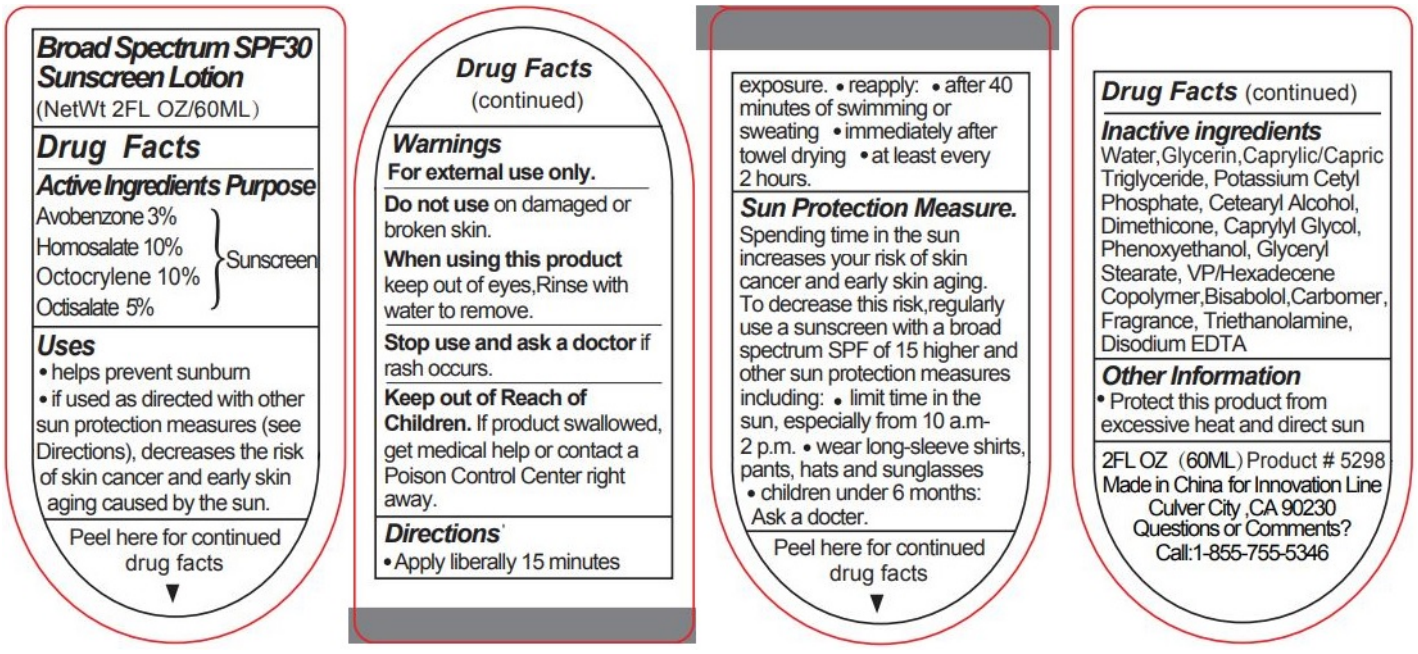
Call:1-855-755-5346

Broad Spectrum SPF30

Product # 5298

Made in China for Innovation Line
Culver City, CA 90230

Packaging



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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76138-220(NDC:70412-231)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
LEVOMENOL (UNII: 24WE03BX2T)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76138-220-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/10/2022	

Labeler - Innovation Specialties (030837314)

Establishment

Name	Address	ID/FEI	Business Operations
Innovation Specialties		030837314	relabel(76138-220) , repack(76138-220)

Revised: 12/2022

Innovation Specialties