

**5414 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.*

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**5414 Sunscreen**

***Drug Facts***

***Active ingredient:***

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 before sun 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?**

HOTLINE # 1-855-755 5346

NPN# 80062390

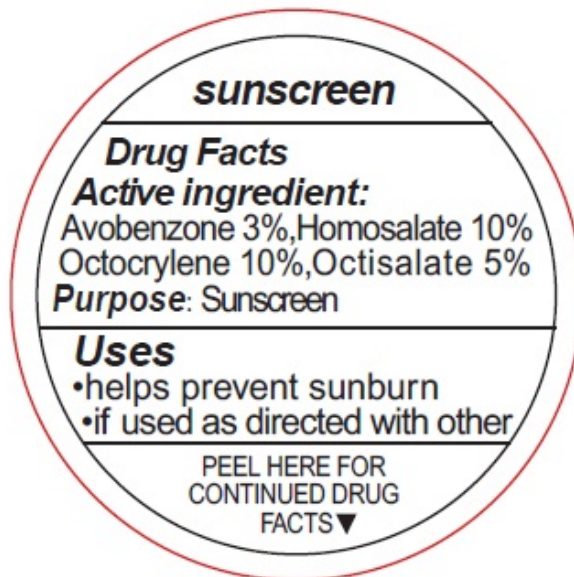
1FL OZ (30ML)

Made in China For Innovation Line Los Angeles, CA 90066

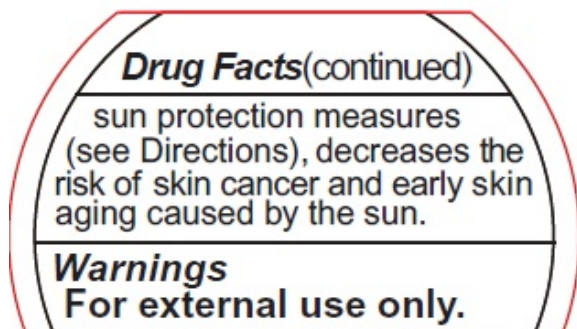
Product # 5414

**Packaging**

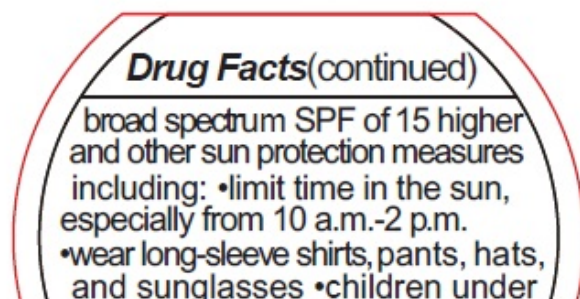
first layer-front side



second layer-front side



second layer-back side



**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 before sun 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 ▼

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

**third layer-front side**

**Drug Facts**  
(continued)

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**Questions?**

HOTLINE # 1-855-755 5346  
NPN# 80062390  
1FL OZ (30ML)  
Made in China For Innovation  
Line Los Angeles,  
CA 90066  
Product # 5414

**5414 SUNSCREEN**

avobenzone, homosalate, octocrylene, octisalate lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76138-218
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL

<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>VINYLPYRROLIDONE/HEXADECENE COPOLYMER</b> (UNII: KFR5QEN0N9)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MM307FC)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76138-218-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/20/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/20/2018	

**Labeler** - Innovation Specialties (030837314)