

## **5299 SUNSCREEN- avobenzene, 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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### **5299 SUNSCREEN**

#### ***Drug Facts***

#### ***Active Ingredients***

Avobenzene 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

### **Broad Spectrum SPF30**

Product # X5299W

Made in China for Innovation Line  
Culver City, CA 90230

Questions or Comments?

Call:1-855-755-5346

### **Packaging**

<b>Broad Spectrum SPF30 Sunscreen Lotion</b> (NetWt 0.67FL OZ/20ML)	
<b>Drug Facts</b>	
<b>Active Ingredients</b> Avobenzone 3% Homosalate 10% Octocrylene 10% Octisalate 5%	<b>Purpose</b> } Sunscreen
<b>Uses</b> •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.	
<b>Warnings</b> For external use only Do not use on damaged or broken skin. When using this product keep out of eyes,	
PEEL HERE FOR CONTINUED DRUG FACTS ►	

<b>Drug Facts</b> (continued)
Rinse with water to remove. <b>Stop use and ask a doctor if rash occurs.</b> <b>Keep out of Reach of Children.</b> If product swallowed, get medical help or contact a Poison Control Center right away.
<b>Directions</b> •Apply liberally 15 minutes exposure. •reapply: •after 40 minutes of swimming or sweating •immediately after towel drying •at least every 2 hours.
<b>Sun Protection Measure.</b> 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
PEEL HERE FOR CONTINUED DRUG FACTS ►

<b>Drug Facts</b> (continued)
a.m-2 p.m. •wear long-sleeve shirts, pants, hats and sunglasses •children under 6 months: Ask a doctor.
<b>Inactive ingredients</b> 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
<b>Other information</b> •Protect this product from excessive heat and direct sun
0.67FL OZ(20ML) Product # X5299W Made in China for Innovation Line Culver City ,CA 90230 Questions or Comments? Call:1-855-755-5346

## **5299 SUNSCREEN**

avobenzone, homosalate, octocrylene, octisalate lotion

### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76138-221(NDC:70412-238)	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
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	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
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)				
VINYLPIRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)				
LEVOMENOL (UNII: 24WE03BX2T)				
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				
TROLAMINE (UNII: 9O3K93S3TK)				
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76138-221-06	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2022	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph final	part352	05/10/2022		

**Labeler** - Innovation Specialties (030837314)

## Establishment

Name	Address	ID/FEI	Business Operations
Innovation Specialties		030837314	relabel(76138-221) , repack(76138-221)

