

SPF30 SUNSCREEN- avobenzone, homosalate, octocrylene, octisalate lotion
Zhejiang Ayan Biotech Co., Ltd.

SPF30 Sunscreen Lotion

Drug Facts

Active Ingredients

Avobenzone 3%,
Homostate 10%,
Octocrylene 10%,
Octisalate 5%

Purpose

Sunscreen

Uses

- Helps prevent sunburn

WARNINGS:

Spending time in the sun increases your risk of skin cancer or early skin aging. This product has been shown only to prevent sunburn skin cancer or early skin aging. This product is water resistant or sweat resistant. **Skin Cancer/Skin Aging Alert:NOTNOT**

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

Directions

Non-Water Resistant Product

- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months: Ask a doctor
- 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 Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m. to 2 p.m.
 - Wear long sleeve shirts, pants, hats and sunglasses.

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?

Call toll free

Label

First layer front side

Drug Facts	
Active ingredients	Purpose
Avobenzone 3%	} Sunscreen
Homosalate 10%	
Octocrylene 10%	
Octisalate 5%	
Uses •Helps prevent sunburn• Higher SPF gives more sunburn protection	
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.

Peel here for continued drug facts ▼



(back side, no glue)

First layer back side

Drug Facts
(continued)

Directions

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- Children under 6 months: Ask a doctor.

• **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

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

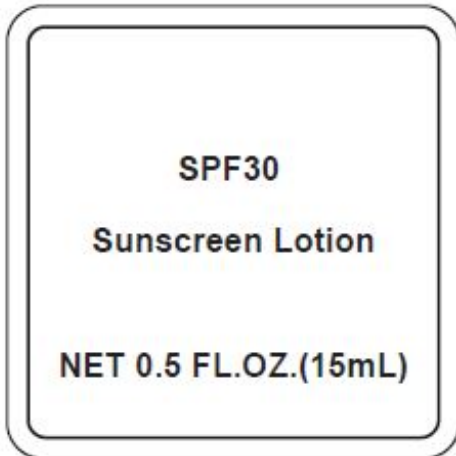
Second layer front side

Other information

- Protect from excessive heat and direct sun

0.68 FL.OZ.

Made in China



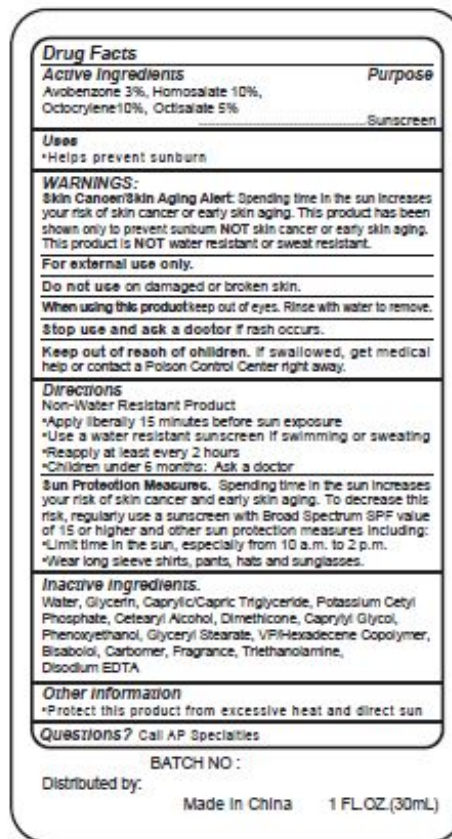
Front

Drug Facts	
Active Ingredients Avobenzone 3%, Homosalate 10%, Octocrylene 10%, Octisalate 5%	Purpose Sunscreen
Uses *Helps prevent sunburn	
WARNINGS: Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer or early skin aging. This product has been shown only to prevent sunburn NOT skin cancer or early skin aging. This product is NOT water resistant or sweat resistant. 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 swallowed, get medical help or contact a Poison Control Center right away.	
Directions Non-Water Resistant Product *Apply liberally 15 minutes before sun exposure *Use a water resistant sunscreen if swimming or sweating *Reapply at least every 2 hours *Children under 6 months: Ask a doctor	
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Other information *Protect this product from excessive heat and direct sun	
QUESTIONS? Call AP Specialties	
BATCH NO :	
Distributed by: Made In China 0.5 FL.OZ.(15mL)	

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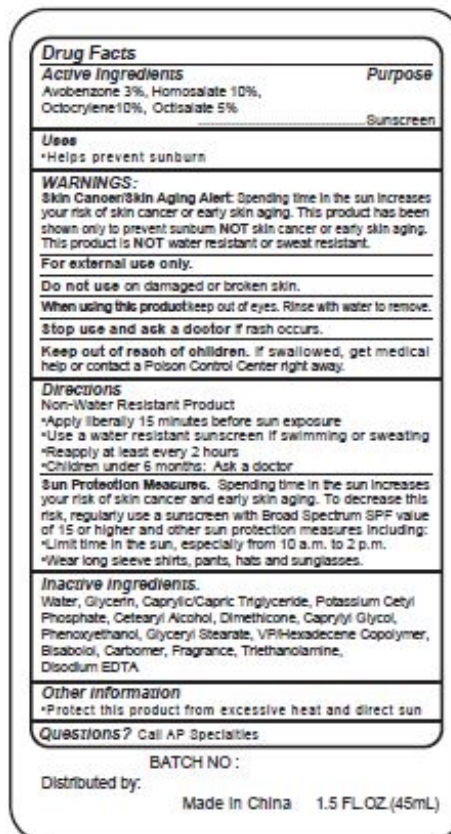
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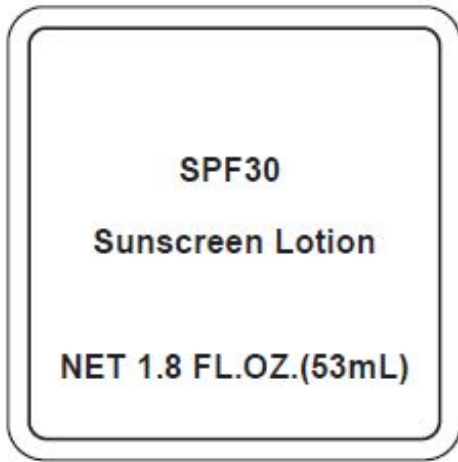
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Front



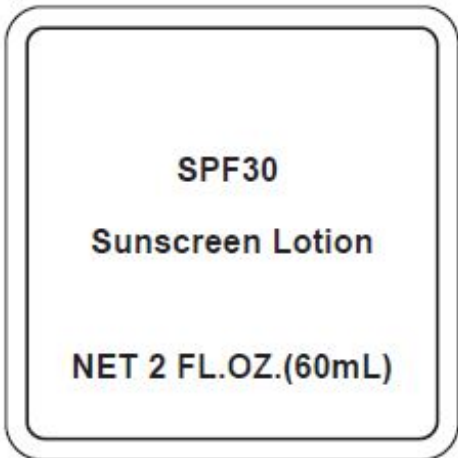
Back



Front

Drug Facts	
Active Ingredients Avobenzone 3%, Homosalate 10%, Octocrylene 10%, Octisalate 5%	Purpose Sunscreen
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Other information •Protect this product from excessive heat and direct sun	
QUESTIONS? Call AP Specialties	
BATCH NO :	
Distributed by: Made in China 1.8 FL.OZ.(53mL)	

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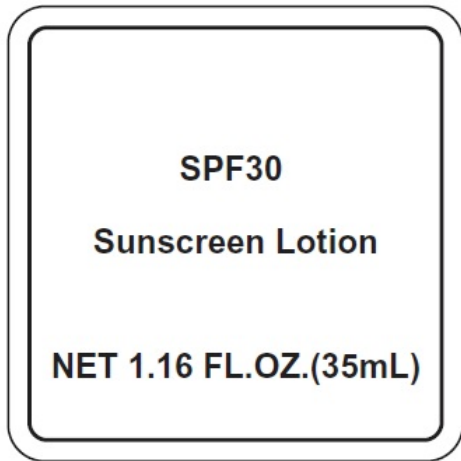


Front

Drug Facts	
Active Ingredients Avobenzone 3%, Homosalate 10%, Octocrylene 10%, Octisalate 5%	Purpose Sunscreen
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Other information •Protect this product from excessive heat and direct sun	
QUESTIONS? Call AP Specialties	
BATCH NO :	
Distributed by: Made in China 2 FL.OZ.(60mL)	

Back

Package Labeling: (35mL 70412-231-35)



Front

Drug Facts	
Active Ingredients	Purpose
Avobenzone 3%, Homosalate 10%, Octocrylene 10%, Octisalate 5%Sunscreen
Uses	
•Helps prevent sunburn	
WARNINGS:	
Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer or early skin aging. This product has been shown only to prevent sunburn NOT skin cancer or early skin aging. This product is NOT water resistant or sweat resistant.	
For external use only.	
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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 swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
Non-Water Resistant Product	
•Apply liberally 15 minutes before sun exposure	
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•Reapply at least every 2 hours	
•Children under 6 months: Ask a doctor	
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 Broad Spectrum SPF value of 15 or higher and other sun protection measures including:	
•Limit time in the sun, especially from 10 a.m. to 2 p.m.	
•Wear long sleeve shirts, pants, hats and sunglasses.	
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? Call toll free	

BATCH NO :

Distributed by:

Made in China 1.16 FL.OZ.(35mL)

SPF30 SUNSCREEN

avobenzone, homosalate, octocrylene, ocitsalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
LEVOMENOL (UNII: 24WE03BX2T)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
COCONUT (UNII: 3RT3536DHY)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70412-231-15	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2018	
2	NDC:70412-231-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2018	
3	NDC:70412-231-45	45 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2018	
4	NDC:70412-231-53	53 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	07/01/2018	
5	NDC:70412-231-30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2018	
6	NDC:70412-231-35	35 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2018	
7	NDC:70412-231-20	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/01/2018	

Labeler - Zhejiang Ayan Biotech Co., Ltd. (544377996)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Ayan Biotech Co., Ltd.		544377996	manufacture(70412-231)

Revised: 11/2023

Zhejiang Ayan Biotech Co., Ltd.