

**SPF 15 LIP AND SPF 30 SUNSCREEN- avobenzone, homosalate, octocrylene, octisalate
Zhejiang Ayan Biotech 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.

SPF 15 Lip Balm and SPF 30Sunscreen Stick

Drug Facts

Active Ingredients

Homosalate 2%
Avobenzone 8%
Octocrylene 5.5%
Octisalate 2%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

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. • Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- Children under 6 months: Ask a doctor.

Inactive Ingredients

Mineral Oil, Beeswax(Cera Alba), Cera Microcristallina, Ozokerite, Polyisobutene, Cocos

Nucifera (Coconut) Oil, Ethylhexyl Palmitate, Polyethylene, Tridecyl Trimellitate, Butyrospermum Parkii (Shea Butter), BHT, Tocopheryl Acetate, Fragrance.

Other Information

- Protect from excessive heat and direct sun.

Questions?

Call AP Specialties

Drug Facts

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- Children under 6 months: Ask a doctor.

Inactive Ingredients

Mineral Oil, Cera Microcrystallina, Polyisobutene, Cocos Nucifera (Coconut) Oil, Ethylhexyl Palmitate, Polyethylene, Hydroxystearic Acid, Butyrospermum Parkii (Shea Butter), Tridecyl Trimellitate, Ozokerite, Synthetic Wax, Dextrin Palmitate, BHT, Tocopheryl Acetate, Fragrance.

Other Information

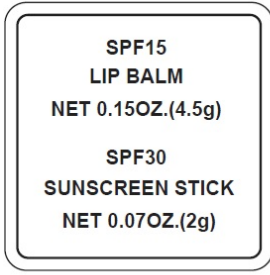
- Protect from excessive heat and direct sun.

Questions?

Call AP Specialties

Package Labeling:

25x25mm



Front

SPF15 LIP BALM	
Drug Facts	
Active Ingredients	Purpose
Avobenzone 2%	} Sunscreen
Homosalate 8%	
Octocrylene 5.5%	
Octisalate 2%	
Uses • Helps prevent sunburn.	
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. • Use a water resistant sunscreen if swimming or sweating.	
• Reapply at least every 2 hours.	
• Children under 6 months: Ask a doctor.	
Inactive Ingredients	
Mineral Oil, Beeswax(Cera Alba), Cera Microcrystallina, Ozokerite, Polyisobutene, Cocos Nucifera (Coconut) Oil, Ethylhexyl Palmitate, Polyethylene, Tridecyl Trimellitate, Butyrospermum Parkii (Shea Butter), BHT, Tocopheryl Acetate, Fragrance.	
Other Information	
• Protect from excessive heat and direct sun.	
Made in China	4.5g / 0.15 OZ
Questions? Call AP Specialties	
BATCH NO :	
Distributed by:	

SPF30 SUNSCREEN STICK	
Drug Facts	
Active Ingredients	Purpose
Avobenzone 3%	} Sunscreen
Homosalate 10%	
Octocrylene 10%	
Octisalate 5%	
Uses • Helps prevent sunburn.	
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. • Use a water resistant sunscreen if swimming or sweating.	
• Reapply at least every 2 hours.	
• Children under 6 months: Ask a doctor.	
Inactive Ingredients	
Mineral Oil, Beeswax(Cera Alba), Cera Microcrystallina, Ozokerite, Polyisobutene, Cocos Nucifera (Coconut) Oil, Ethylhexyl Palmitate, Polyethylene, Tridecyl Trimellitate, Butyrospermum Parkii (Shea Butter), BHT, Tocopheryl Acetate, Fragrance.	
Other Information	
• Protect from excessive heat and direct sun.	
Made in China	2g / 0.07 OZ
Questions? Call AP Specialties	
BATCH NO :	
Distributed by:	

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Back

SPF 15 LIP AND SPF 30 SUNSCREEN

avobenzone, homosalate, octocrylene, octisalate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70412-816
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70412-816-10	1 in 1 KIT	06/01/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	4.5 g
Part 2	1 TUBE	2 g

Part 1 of 2

SPF15

avobenzone, homosalate, octocrylene, octisalate lipstick

Product Information

Item Code (Source)	NDC:70412-316
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	55 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CERESIN (UNII: Q1LS2UJO3A)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
SHEA BUTTER (UNII: K49155WL9Y)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70412-316-15	4.5 g 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	06/01/2018	

Part 2 of 2**SPF30 SUNSCREEN**

avobenzene, homosalate, octocrylene, octisalate stick

Product Information

Item Code (Source)	NDC:70412-211
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 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CERESIN (UNII: Q1LS2UJO3A)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
SHEA BUTTER (UNII: K49155WL9Y)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70412-211-15	2 g 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	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2018	

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

Revised: 5/2018

Zhejiang Ayan Biotech Co.,Ltd.