

**SPF30 SUNSCREEN AND SPF15- avobenzene, homosalate, octocrylene, octisalate**  
**Zhejiang Ayan Biotech Co.,Ltd.**

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**SPF30 Sunscreen Lotion and SPF15 Lip Balm**

***Drug Facts***

***Active Ingredients***

Avobenzene 3%, Homosalate 10%, Octocrylene10%, 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

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. **Sun Protection Measures.**

### ***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 AP Specialties

### ***Drug Facts***

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

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Homostate 10%,  
Octocrylene 10%,  
Octisalate 5%

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***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
  - 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: **Sun Protection Measures.**
- 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

## ***Drug Facts***

### ***Active Ingredients***

Avobenzone 2% Octocrylene 8% Octisalate 5.5% Homosalate 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 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, Ozokerite, Cera Microcristallina, Polyisobutene, Cocos Nucifera (Coconut) Oil, Ethylhexyl Palmitate, Polyethylene, Tridencyl Trimellitate, Butyrospermum Parkii (Shea Butter), BHT, Tocopheryl Acetate, Fragrance.

### ***Other Information***

- Protect from excessive heat and direct sun.

**Questions?**

Call AP Specialties

BATCH NO:

Distributed by:

**Package Labeling:**

SPF30  
Sunscreen Lotion  
NET 1FL.OZ.(30mL)

SPF15  
LIP BALM  
NET 2g /0.07 OZ

**SPF30 Sunscreen Lotion**

| <b>Drug Facts</b>   | <b>Purpose</b> |
|---|----------------|
| <b>Active Ingredients</b><br>Avobenzone 3%, Homosalate 10%,<br>Octocrylene 10%, Octisalate 5%   | Sunscreen      |
| <b>Uses</b><br>•Helps prevent sunburn   |                |
| <b>WARNINGS:</b><br><b>Skin Cancer/Skin Aging Alert:</b> Spending time in the sun increases your risk of skin cancer or early skin aging. This product has been shown only to prevent sunburn <b>NOT</b> skin cancer or early skin aging. This product is <b>NOT</b> water resistant or sweat resistant.  |                |
| <b>For external use only.</b>   |                |
| <b>Do not use</b> on damaged or broken skin.  |                |
| <b>When using this product</b> keep out of eyes. Rinse with water to remove.  |                |
| <b>Stop use and ask a doctor</b> if rash occurs.  |                |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.   |                |
| <b>Directions</b><br>Non-Water Resistant Product<br>•Apply liberally 15 minutes before sun exposure<br>•Use a water resistant sunscreen if swimming or sweating<br>•Reapply at least every 2 hours<br>•Children under 6 months: Ask a doctor  |                |
| <b>Sun Protection Measures.</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 Broad Spectrum SPF value of 15 or higher and other sun protection measures including:<br>•Limit time in the sun, especially from 10 a.m. to 2 p.m.<br>•Wear long sleeve shirts, pants, hats and sunglasses. |                |
| <b>Inactive ingredients.</b><br>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><br>•Protect this product from excessive heat and direct sun  |                |
| <b>Questions?</b> Call AP Specialties   |                |

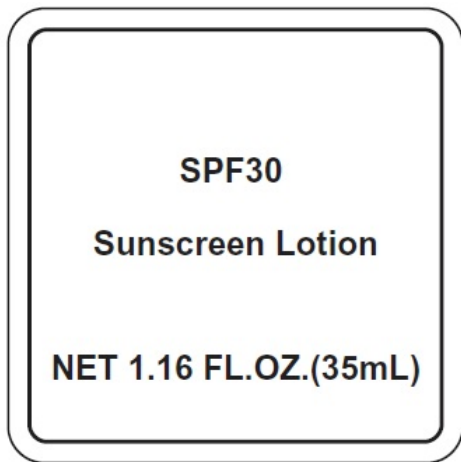
BATCH NO :

Distributed by: Made in China    1 FL.OZ.(30mL)

**SPF15 LIP BALM**

| <b>Drug Facts</b>   | <b>Purpose</b> |
|---|----------------|
| <b>Active Ingredients</b><br>Avobenzone 2%<br>Homosalate 8%<br>Octocrylene 5.5%<br>Octisalate 2%  | Sunscreen      |
| <b>Uses</b> • Helps prevent sunburn.  |                |
| <b>Warnings</b><br><b>For external use only.</b><br><b>Do not use</b> on damaged or broken skin.<br><b>When using this product</b> keep out of eyes. Rinse with water to remove.<br><b>Stop use and ask a doctor</b> if rash occurs.                          |                |
| <b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact a Poison Control Center right away.  |                |
| <b>Directions</b><br>• Apply liberally 15 minutes before sun exposure.    • Use a water resistant sunscreen if swimming or sweating.<br>• Reapply at least every 2 hours.<br>• Children under 6 months: Ask a doctor.   |                |
| <b>Inactive Ingredients</b><br>Mineral Oil, Ozokerite, Cera Microcrystallina, Polyisobutene, Cocos Nucifera (Coconut) Oil, Ethylhexyl Palmitate, Polyethylene, Tridecyl Trimellitate, Butyrospermum Parkii (Shea Butter), BHT, Tocopheryl Acetate, Fragrance. |                |
| <b>Other Information</b><br>• Protect from excessive heat and direct sun.<br>Made in China  |                |
| <b>Questions?</b> Call AP Specialties<br>BATCH NO :<br>Distributed by:  |                |

**Package Labeling:**



Front

|  |                |
|--|----------------|
| <b>Drug Facts</b>  |                |
| <b>Active Ingredients</b>  | <b>Purpose</b> |
| Avobenzone 3%, Homosalate 10%,<br>Octocrylene 10%, Octisalate 5%   | Sunscreen      |
| <b>Uses</b>  |                |
| •Helps prevent sunburn   |                |
| <b>WARNINGS:</b>   |                |
| <b>Skin Cancer/Skin Aging Alert:</b> Spending time in the sun increases your risk of skin cancer or early skin aging. This product has been shown only to prevent sunburn <b>NOT</b> skin cancer or early skin aging. This product is <b>NOT</b> water resistant or sweat resistant. |                |
| <b>For external use only.</b>  |                |
| <b>Do not use</b> on damaged or broken skin.   |                |
| <b>When using this product</b> keep out of eyes. Rinse with water to remove.   |                |
| <b>Stop use and ask a doctor</b> if rash occurs.   |                |
| <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.  |                |
| <b>Directions</b>  |                |
| Non-Water Resistant Product  |                |
| <ul style="list-style-type: none"> <li>•Apply liberally 15 minutes before sun exposure</li> <li>•Use a water resistant sunscreen if swimming or sweating</li> <li>•Reapply at least every 2 hours</li> <li>•Children under 6 months: Ask a doctor</li> </ul>                         |                |
| <b>Sun Protection Measures.</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 Broad Spectrum SPF value of 15 or higher and other sun protection measures including:                        |                |
| <ul style="list-style-type: none"> <li>•Limit time in the sun, especially from 10 a.m. to 2 p.m.</li> <li>•Wear long sleeve shirts, pants, hats and sunglasses.</li> </ul>   |                |
| <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   |                |
| <b>Questions?</b> Call toll free   |                |

BATCH NO :

Distributed by: Made in China 1.16 FL.OZ.(35mL)

**SPF30 SUNSCREEN AND SPF15**

avobenzone, homosalate, octocrylene, octisalate kit

**Product Information**

|                     |                |                           |               |
|---------------------|----------------|---------------------------|---------------|
| <b>Product Type</b> | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70412-818 |
|---------------------|----------------|---------------------------|---------------|

## Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:70412-818-01 | 1 in 1 KIT          | 12/01/2018           |                    |

## Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 1 BOTTLE         | 30 mL                  |
| Part 2 | 1 TUBE           | 2 g                    |

## Part 1 of 2

### SPF30 SUNSCREEN

avobenzene, homosalate, octocrylene, ocitsalate lotion

## Product Information

|                         |               |
|-------------------------|---------------|
| Item Code (Source)      | NDC:70412-231 |
| Route of Administration | TOPICAL       |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength       |
|---|-------------------|----------------|
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE        | 30 mg in 1 mL  |
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE        | 100 mg in 1 mL |
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM) | OCTOCRYLENE       | 100 mg in 1 mL |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE        | 50 mg in 1 mL  |

## Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <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)            |          |
| <b>COCONUT</b> (UNII: 3RT3536DHY)                               |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                                 |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                              |          |

**MEDIUM-CHAIN TRIGLYCERIDES** (UNII: C9H2L21V7U)

**POTASSIUM CETYL PHOSPHATE** (UNII: 03KCY6P7UT)

## Packaging

| # | Item Code        | Package Description                                  | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70412-231-30 | 30 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 12/01/2018           |                    |

## Part 2 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     |
|---|-------------------|--------------|
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE        | 20 mg in 1 g |
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE        | 80 mg in 1 g |
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 55 mg in 1 g |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE        | 20 mg in 1 g |

## Inactive Ingredients

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



## Packaging

| # | Item Code        | Package Description                              | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70412-316-07 | 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 Drug | M020                                     | 12/01/2018           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 12/01/2018           |                    |

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

## Establishment

| Name                           | Address | ID/FEI    | Business Operations               |
|--------------------------------|---------|-----------|-----------------------------------|
| Zhejiang Ayan Biotech Co.,Ltd. |         | 544377996 | manufacture(70412-818, 70412-231) |

Revised: 11/2023

Zhejiang Ayan Biotech Co.,Ltd.