

**INN BEAUTY SUN BALM SPF30 BROAD SPECTRUM LIP BALM - ROSY BROWN-  
zinc oxide cream  
COSMAX USA, CORPORATION**

-----  
**INN BEAUTY SUN BALM SPF30 BROAD SPECTRUM LIP BALM - ROSY BROWN**

***Active Ingredient***

Zinc Oxide 13.5%

***Purpose***

Sunscreen

**USES**

***Uses***

- helps protect against sunburn and chapped lips

**Do not use** on damaged or broken skin

**When using the 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**

***Directions***

- apply generously and evenly 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating

**Sun Protection Measures.** Spending time increases your risk of skin cancer and early aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF 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
- children under 6 months: Ask a doctor

***Inactive Ingredients:***

Diisostearyl Malate, Polybutene, Hydrogenated Polyisobutene, Butyloctyl Salicylate, Caprylic/Capric Triglyceride, Microcrystalline Wax, Silica Dimethyl Silylate, Bis-Diglyceryl Polyacyladipate-2, Sorbitan Olivatate, Isononyl Isononanoate, Squalane, Simmondsia Chinensis (Jojoba) Seed Oil, Mangifera Indica (Mango) Seed Butter, Butyrospermum Parkii (Shea) Butter, Tetrahexyldecyl Ascorbate, Rosa Canina Fruit Oil, Bisabolol, Sorbitan Isostearate, Isostearic Acid, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, VP/Hexadecene Copolymer, Dehydroxyacetic Acid, Lecithin, Titanium Dioxide (CI 77891), Iron Oxides (CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499), Yellow

5 Lake (CI 19140), Red 7 Lake (CI 15850), Tocopherol, Menthone Glycerin Acetal, Flavor.

## OTHER INFORMATION

### Other information

- protect this product from excessive heat and direct sun



## INN BEAUTY SUN BALM SPF30 BROAD SPECTRUM LIP BALM - ROSY BROWN

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68577-192
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.5 mg in 1 g
---	------------	----------------

### Inactive Ingredients

Ingredient Name	Strength
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>MANGIFERA INDICA (MANGO) SEED BUTTER</b> (UNII: 4OXD9M35X2)	
<b>HYDROGENATED POLYISOBUTENE (450 MW)</b> (UNII: 7YR4ZFS62E)	
<b>BISABOLOL</b> (UNII: 24WE03BX2T)	
<b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	
<b>IRON OXIDES</b> (UNII: 1K09F3G675)	
<b>MENTHONE GLYCERIN ACETAL</b> (UNII: 7QQ1EE6RCP)	
<b>POLYBUTENE (1400 MW)</b> (UNII: 1NA5AO9GH7)	
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)	
<b>DIISOSTEARYL MALATE</b> (UNII: QBS8A3XZGQ)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>CAPRYLIC/CAPRIC TRIGLYCERIDE</b> (UNII: C9H2L21V7U)	
<b>BIS-DIGLYCERYL POLYACYLADIPATE-2</b> (UNII: 6L246LAM9T)	
<b>SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL</b> (UNII: 724GKU717M)	
<b>POLYGLYCERYL-3 PENTARICINOLEATE</b> (UNII: 7Q0OK5DOT4)	
<b>BUTYROSPERMUM PARKII (SHEA) BUTTER</b> (UNII: K49155WL9Y)	
<b>ROSA CANINA FRUIT OIL</b> (UNII: CR7307M3QZ)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>VP/HEXADECENE COPOLYMER</b> (UNII: KFR5QEN0N9)	
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68577-192-00	1 in 1 CARTON	10/01/2024	
1		17 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	10/01/2024	

**Labeler** - COSMAX USA, CORPORATION (010990210)

## Establishment

Name	Address	ID/FEI	Business Operations
COSMAX USA, CORPORATION		010990210	manufacture(68577-192)

Revised: 12/2024

COSMAX USA, CORPORATION