

SEPHORA ROUGE BALM SUNSCREEN SPF20 B04-SWEET FUCHSIA- octinoxate, octisalate, titanium dioxide lipstick

S+

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.

SEPHORA ROUGE BALM SUNSCREEN SPF20 B04-Sweet Fuchsia

Drug Facts

Active ingredients

Octinoxate 7.125%

Octisalate 3%

Titanium dioxide 1.83%

Purpose

Sunscreen

Use

- Helps protect against sunburn.

Warnings

Skincancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

Do not use

- on damaged or broken skin

Stop use and ask a doctor if

- rash occurs

Directions

- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating

Other information

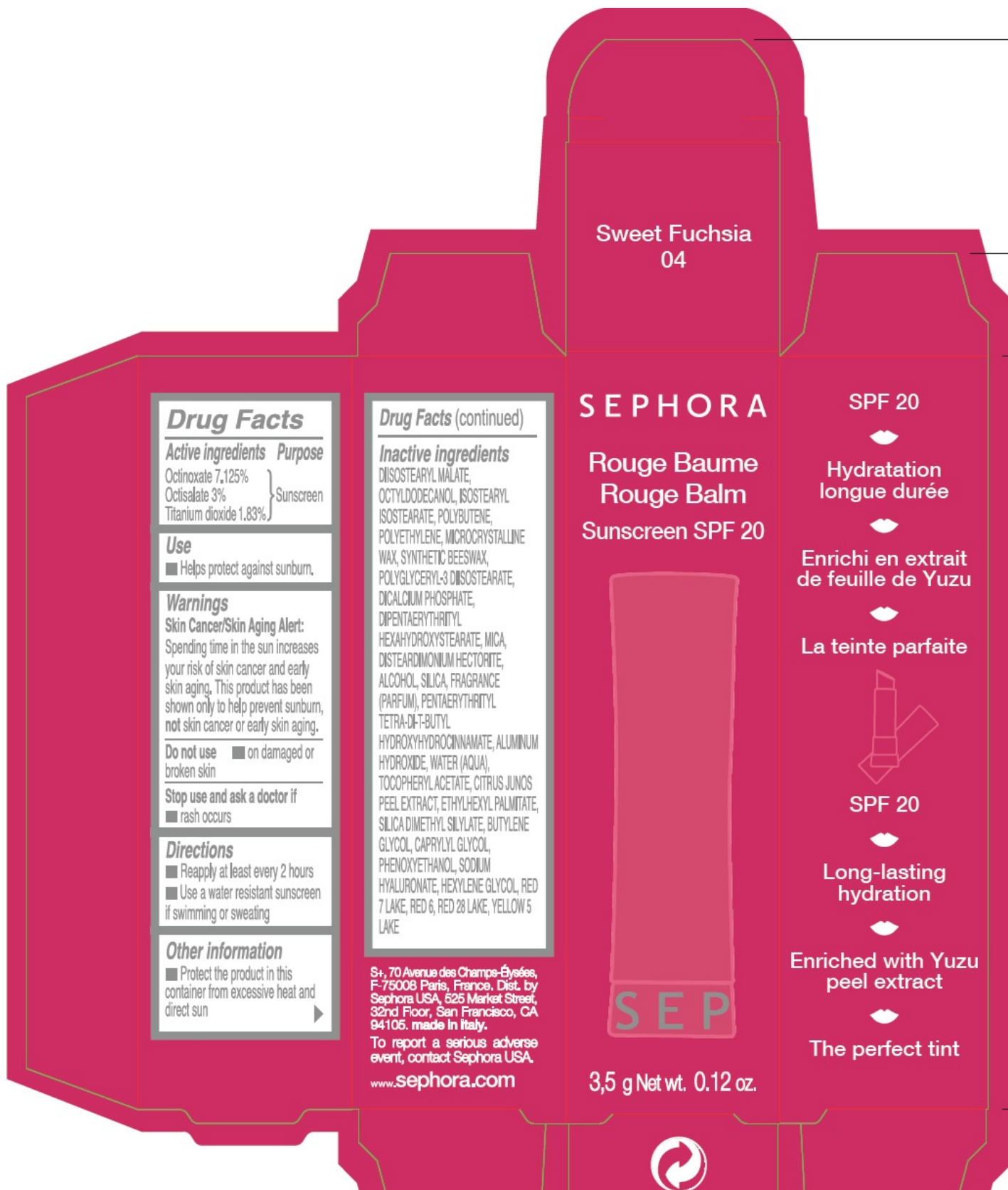
- Protect the product in this container from excessive heat and direct sun

Inactive ingredients

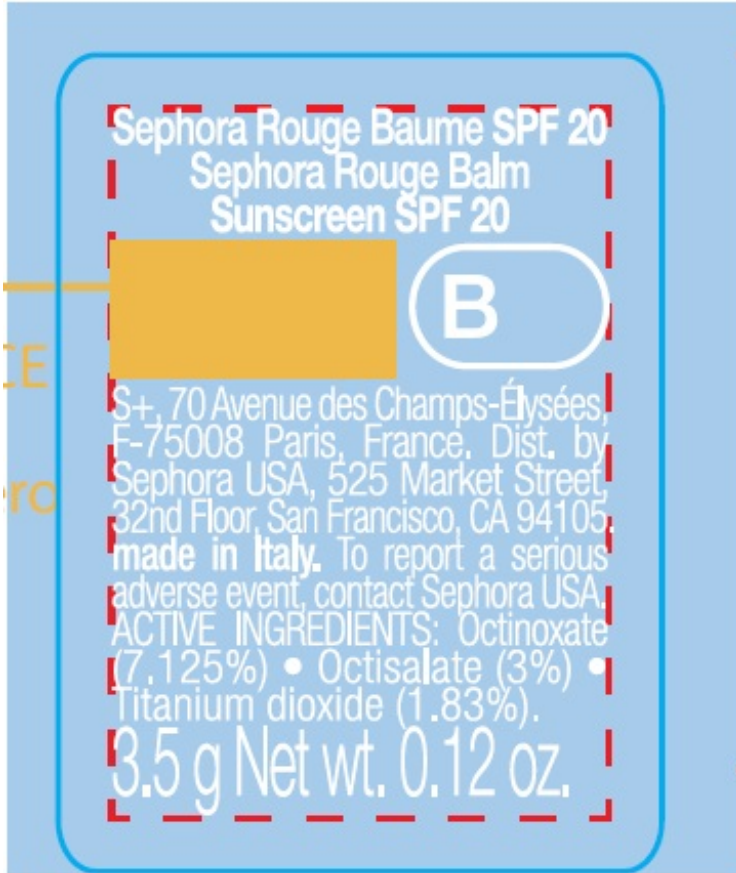
DIISOSTEARYL MALATE, OCTYLDODECANOL, ISOSTEARYL ISOSTEARATE, POLYBUTENE, POLYETHYLENE, MICROCRYSTALLINE WAX, SYNTHETIC BEESWAX, POLYGLYCERYL-3 DIISOSTEARATE, DICALCIUM PHOSPHATE, DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE, MICA, DISTEARDIMONIUM HECTORITE, ALCOHOL, SILICA,

FRAGRANCE (PARFUM), PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE, ALUMINUM HYDROXIDE, WATER (AQUA), TOCOPHEROL ACETATE, CITRUS JUNOS PEEL EXTRACT, ETHYLHEXYL PALMITATE, SILICA DIMETHYL SILYLATE, BUTYLENE GLYCOL, CAPRYLYL GLYCOL, PHENOXYETHANOL, SODIUM HYALURONATE, HEXYLENE GLYCOL, RED 7 LAKE, RED 28 LAKE, YELLOW 5 LAKE

Package Labeling:



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SEPHORA ROUGE BALM SUNSCREEN SPF20 B04-SWEET FUCHSIA

octinoxate, octisalate, titanium dioxide lipstick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:31720-503 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 7.125 mg in 1 g |
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 3 mg in 1 g |
| TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP) | TITANIUM DIOXIDE | 1.83 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| DIISO STEARYL MALATE (UNII: QBS8A3XZGQ) | |
| OCTYLDODECANOL (UNII: 461N1O614Y) | |
| ISO STEARYL ISO STEARATE (UNII: IV0Z586Z4Y) | |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) | |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY) | |
| POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8) | |
| ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J) | |
| DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42) | |
| MICA (UNII: V8A1AW0880) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| WATER (UNII: 059QF0K00R) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| CITRUS JUNOS FRUIT RIND (UNII: R13K440UHY) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| SILICA DIMETHYL SILYLATE (UNII: EU2PS0G0W) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:31720-503-16 | 1 in 1 CARTON | 12/18/2015 | |
| 1 | | 3.5 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 final | part352 | 12/18/2015 | |

Labeler - S+ (572406531)