

SEPHORA ROUGE BALM SUNSCREEN SPF20 B05-GENTLE CORAL- 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 B05-Gentle Coral

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

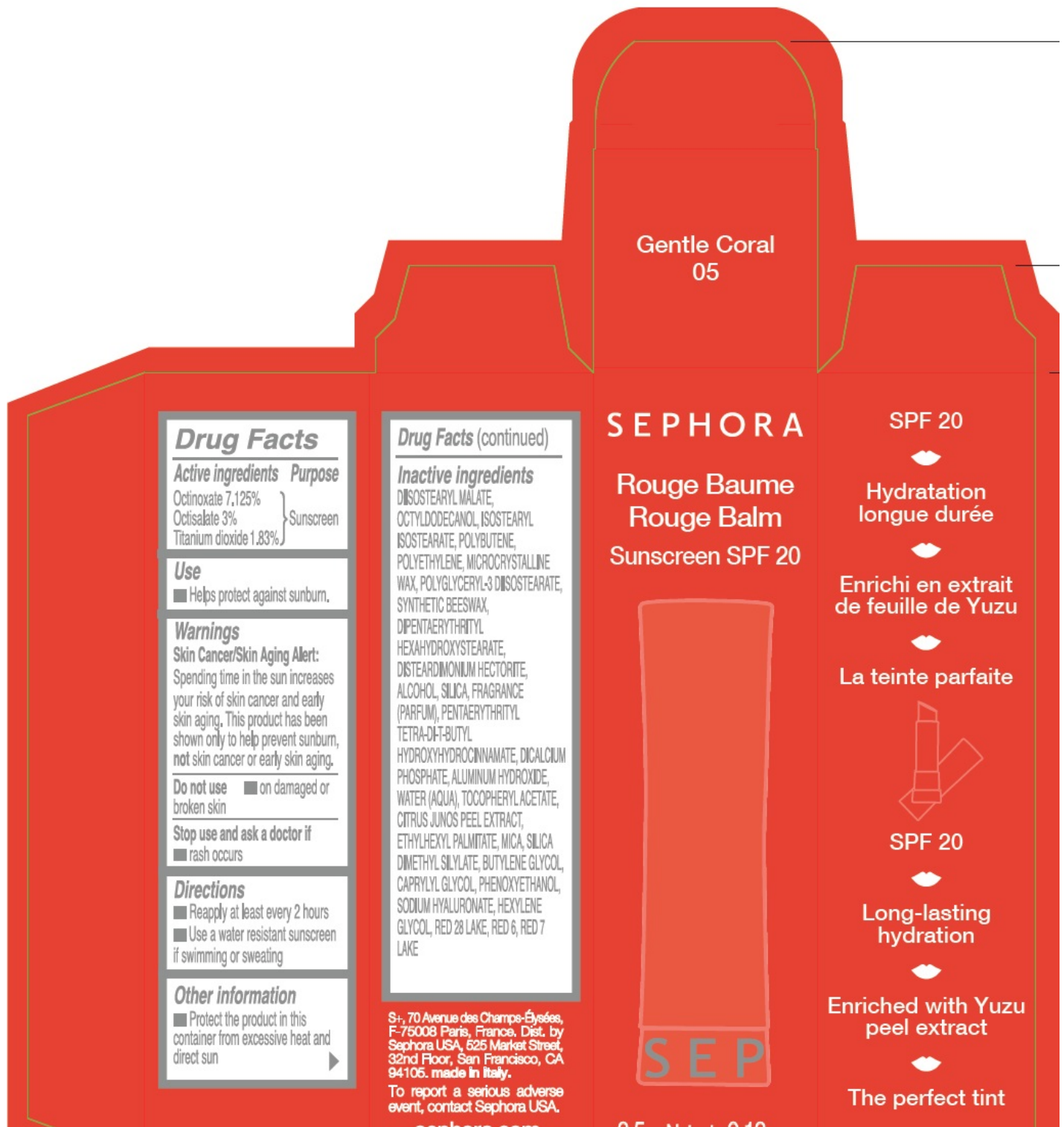
- Protect the product in this container from excessive heat and direct sun

Inactive ingredients

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

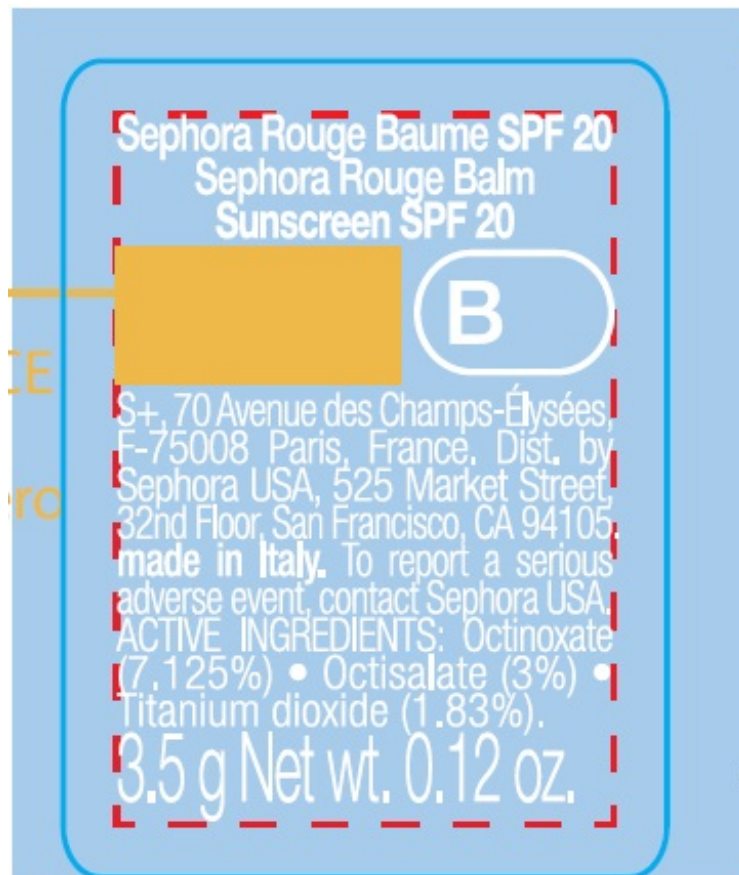
FRAGRANCE (PARFUM), PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE, DICALCIUM PHOSPHATE, ALUMINUM HYDROXIDE, WATER (AQUA), TOCOPHEROL ACETATE, CITRUS JUNOS PEEL EXTRACT, ETHYLHEXYL PALMITATE, MICA, SILICA DIMETHYL SILYLATE, BUTYLENE GLYCOL, CAPRYLYL GLYCOL, PHENOXYETHANOL, SODIUM HYALURONATE, HEXYLENE GLYCOL, RED 28 LAKE, RED 6, RED 7 LAKE

Package Labeling:





4C



SEPHORA ROUGE BALM SUNSCREEN SPF20 B05-GENTLE CORAL

octinoxate, octisalate, titanium dioxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:31720-504
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
WATER (UNII: 059QF0K00R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CITRUS JUNOS FRUIT RIND (UNII: R13K440UHY)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
MICA (UNII: V8A1AW0880)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSPOG0W)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
ISO STEARYL ISO STEARATE (UNII: IV0Z586Z4Y)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:31720-504-16	1 in 1 CARTON	12/19/2015	
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	12/19/2015	

Labeler - S+ (572406531)