GOLDEN ROSE GLOW KISS TINTED LIP BALM VANILLA LATTE- avobenzone, octinoxate lipstick

ERKUL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI

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.

GOLDEN ROSE glow kiss TINTED LIP BALM VANILLA LATTE

Drug Facts

Active ingredient

Avobenzone 2.7% w/v Octinoxate 6% w/v

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- if used as directed with other sun protection measures (**see Directions**).
- Decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

Do not use • on damaged or broken skin

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

• apply to cleansed lips • can be applied two coats to increase coverage • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value 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.

Other information

- Protect the product in this container from excessive heat and direct sun.
- Store at room temperatures: 15°C- 30°C.

Drug Facts Inactive Ingredients

Hydrogenated Polyisobutene, Caprylic/Capric Triglyceride, Pentaerythrityl Tetraisostearate, Glyceryl Rosinate, Octyldodecanol, C30-50 Alcohols, Phenyl Trimethicone, Polyethylene, Titanium Dioxide, Shea (Butyrospermum parkii) Butter, Flavor, Meadowfoam (Limnanthes alba) Seed Oil, Phenoxyethanol, Polybutene, Tocopheryl Acetate, Glyceryl Behenate, Sodium Hyaluronate, Octadecyl Di-T-Butyl -4-Hydroxyhydrocinnamate, Iron Oxides*, D&C Red No. 7*.

*contains one or more of these ingredients.

SPF 15

DELICATE VANILLA AROMA VITAMIN E

Manufactured By:

ERKUL COSMETICS San. Tic. A.S., Petrol Ofisi Cad. No:1 Avcılar, Istanbul, Turkey, 34310

Phone: +90 212 456 53 00

www.goldenrose.com.tr info@goldenrose.com.tr

MADE IN TURKEY

Distributed By:

CELESTY LLC, 3970 NW 167 TH ST.MIAMI GARDENS, FL 33054 - USA info@celesty.com

EU R.P: Platin Beauty Consulting UG (haftungsbeschränkt) Bardowicker Str. 6, 21335 Lüneburg/GERMANY

Packaging

PRIMARY PACK

GOLDEN ROSE TINTED LIP BALM

SPF 15

01 VANILLA LATTE

DELICATE **VANILLA AROMA** VITAMIN E

ERKUL KOZMETİK San, Tic. A.S.





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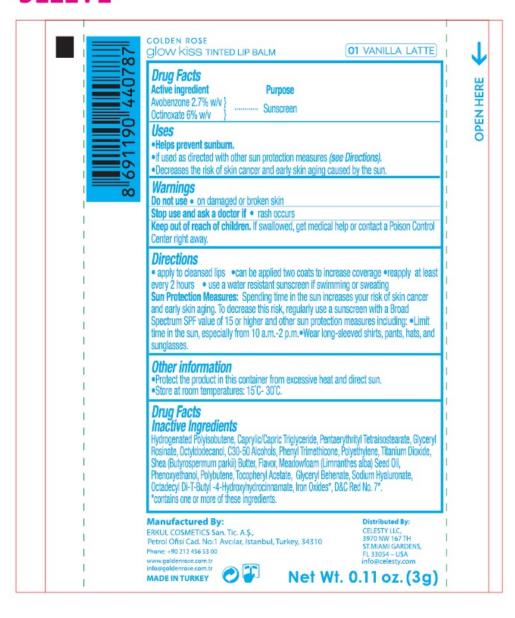
Rear



Front



SLEEVE



GOLDEN ROSE GLOW KISS TINTED LIP BALM VANILLA LATTE

avobenzone, octinoxate lipstick

Product	Inform	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82715-109

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.7 g in 100 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PENTAERYTHRITYL TETRAISOSTEARATE (UNII: 9D7IK5483F)	
GLYCERYL ROSINATE (UNII: SD112V492J)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
C30-50 ALCOHOLS (UNII: 4MCU204619)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SHEA BUTTER (UNII: K49155WL9Y)	
MEADOWFOAM SEED OIL (UNII: 412Z HA4T4Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
OCTADECYL DI-TERT-BUTYL-4-HYDROXYHYDROCINNAMATE (UNII: V88J661G2P)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 7 (UNII: ECW0LZ 41X8)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:82715-109- 01	3 g in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/22/2022	

Labeler - ERKUL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI (525225637)

Establishment					
Name	Address	ID/FEI	Business Operations		
ERKUL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI		525225637	manufacture(82715-109)		

Revised: 7/2022 ERKUL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI