

**GR SATIN SMOOTHING FLUID FOUNDATION SPF 15- octinoxate,  
oxybenzone liquid  
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.*

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**GR GOLDEN ROSE SATIN SMOOTHING Fluid Foundation**

***Drug Facts***

***Active ingredients***

Octinoxate 1% w/v  
Oxybenzone 0.1% 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***

**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***

• apply generously 15 minutes before the sun exposure • apply to cleansed skin • 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 sun Broad Spectrum SPF value of 15 or higher and other 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 of age: Ask a doctor

### **Other information**

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

### **Inactive ingredients**

Water(Aqua), Cyclopentasiloxane, Hydrogenated Polydecene, Glycerin, Propylene Glycol, Cetyl Peg/Ppg-10/1 Dimethicone, Talc, Polyglyceryl-3 Diisostearate, Distearidimonium Hectorite, Phenoxyethanol, Peg/Ppg-18/18 Dimethicone, Sodium Chloride, Dimethicone, Silica Dimethyl Silylate, Propylene Carbonate, Aluminum Hydroxide, Hydrogen Dimethicone, Trimethylsiloxysilicate, Allantoin, Sodium Benzoate, Xanthan gum, Titanium Dioxide, Tocopheryl Acetate, Fragrance, Disodium Edta, Bisabolol, Magnesium Stearate, Ethylhexylglycerin, Triethoxycaprylylsilane \*Iron Oxides. \*contains one or more of these ingredients.

GOLDEN ROSE

**SPF 15**

VITAMIN E

**DERMATOLOGICALLY TESTED**

#### **Manufactured By:**

ERKUL COSMETICS San. Tic. A.Ş.,  
Petrol Ofisi Cad. No:1  
Avcılar, ISTANBUL, TURKIYE,  
34310

Phone: +90 212 456 53 00

[www.goldenrose.com.tr](http://www.goldenrose.com.tr)  
[info@goldenrose.com.tr](mailto:info@goldenrose.com.tr)

**MADE IN TURKIYE**

#### **Distributed By:**

CELESTY LLC  
3970 NW 167<sup>TH</sup> ST.  
MIAMI GARDENS,  
FL 33054 - USA

[info@celesty.com](mailto:info@celesty.com)

**EU R.P.:** REACH Global Services SA,  
6 Rond point Schuman Brussels  
1040 BELGIUM

NO:21

# Packaging

## INNER PACKAGE



## OUTER PACKAGE

**Drug Facts**  
(continued)

**Inactive ingredients**

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**GOLDEN ROSE**

**SATIN SMOOTHING**  
Fluid Foundation  
**SPF 15**  
**1.2 fl.oz. (34 mL)**

**DERMATOLOGICALLY TESTED**

**Manufactured By:**  
ERKUL COSMETICS  
San. Tic. A.Ş.,  
Petrol Ofisi Cad. No:1  
Avclar, ISTANBUL, TÜRKİYE,  
34310

Phone: +90 212 456 53 00  
www.goldenrose.com.tr  
info@goldenrose.com.tr

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**Distributed By:**  
CELESTY LLC  
3970 NW 167<sup>TH</sup> ST.  
MIAMI GARDENS,  
FL 33054 - USA  
info@celesty.com

**Drug Facts**

Active ingredients	Purpose
Octinoxate 1% w/v	}...Sunscreen
Oxybenzone 0.1% w/v	

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**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 swallowed, get medical help or contact a Poison Control Center right away.

**Directions** ● apply generously 15 minutes before the sun exposure ● apply to cleansed skin ● 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 sun Broad Spectrum SPF value of 15 or higher and other 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 of age: Ask a doctor

**Other information** ● protect the product in this container from excessive heat and direct sun. ● store at room temperatures: 15°C- 30°C. ▶



## GR SATIN SMOOTHING FLUID FOUNDATION SPF 15

octinoxate, oxybenzone liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82715-104
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1 g in 100 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.1 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>HYDROGENATED POLYDECENE (3100 CST)</b> (UNII: 4U179ML4TJ)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4)</b> (UNII: 8INO2K35FA)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>PEG/PPG-18/18 DIMETHICONE</b> (UNII: 9H0AO7T794)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>HYDROGEN DIMETHICONE (13 CST)</b> (UNII: 4QGR4P2YOI)	
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82715-104-01	1 in 1 CARTON	07/22/2022	
1		34 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:82715-104-02	1 in 1 CARTON	07/22/2022	
2		34 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:82715-104-03	1 in 1 CARTON	07/22/2022	
3		34 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:82715-104-04	1 in 1 CARTON	07/22/2022	
4		34 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:82715-104-05	1 in 1 CARTON	07/22/2022	
5		34 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:82715-104-06	1 in 1 CARTON	07/22/2022	
6		34 mL in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:82715-104-07	1 in 1 CARTON	07/22/2022	
7		34 mL in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:82715-104-08	1 in 1 CARTON	07/22/2022	
8		34 mL in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:82715-104-09	1 in 1 CARTON	07/22/2022	
9		34 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 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(82715-104)

Revised: 7/2022

ERKUL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI