

**ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE
SPF 20 CLARO 2/BEIGE- octinoxate and zinc oxide cream**
**ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE
SPF 20 MEDIO1/BEIGE- octinoxate and zinc oxide cream**
**ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE
SPF 20 MEDIO2/BEIGE- octinoxate and zinc oxide cream**
**ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE
SPF 20 MEDIO3/BEIGE- octinoxate and zinc oxide cream**
**ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE
SPF 20 MEDIO4/BEIGE- octinoxate and zinc oxide cream**
**ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE
SPF 20 MEDIO5/BEIGE- octinoxate and zinc oxide cream**
**ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE
SPF 20 CLARO 1/BEIGE- octinoxate and zinc oxide cream**
Ventura International LTD

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.

**ÉSIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE
SPF 20**

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
OCTINOXATE 5 %	Sunscreen
ZINC OXIDE 4.2 %	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / 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.
- **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 liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.

- Children under 6 months of age: Ask a doctor

Other information

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

Inactive ingredients

WATER, DIMETHICONE, ISODODECANE, PEG-10 DIMETHICONE, GLYCERIN, PROPYLENE GLYCOL, POLYMETHYLSILSESQUIOXANE, POLYSILICONE-11, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, PEG/PPG-18/18 DIMETHICONE, HYDROXYACETOPHENONE, SILICA DIMETHYL SILYLATE, SODIUM CHLORIDE, PHENOXYETHANOL, SILICA, TOCOPHERYL ACETATE, METHYLPROPANEDIOL, CAPRYLYL GLYCOL, CHLORPHENESIN, DISTEARDIMONIUM HECTORITE, TRIETHOXYCAPRYLYLSILANE, SILANEDIOL SALICYLATE, BUTYLENE GLYCOL, TROMETHAMINE, FRAGRANCE, AESCULUS HIPPOCASTANUM (HORSE CHESTNUT) SEED EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, HYDROLYZED WHEAT PROTEIN, SILYBUM MARIANUM FRUIT EXTRACT, LINALOOL, d-LIMONENE, ALPHA-ISOMETHYL IONONE.

MAY CONTAIN : TITANIUM DIOXIDE, IRON OXIDES.

Dist. by Ventura Int. Ltd.

DBA Belcorp USA, Miami, FL 33126.

PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Claro 2/Beige

ésika
PRO

NATURAL MATTE

Mattifying foundation
adaptable to your skin
tone SPF 20

Net wt. 1 oz. e (30 g)

Drug Facts

Active Ingredients Purpose

Octinoxate 5%.....Sunscreen
Zinc Oxide 4.2%.....Sunscreen

Uses

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Warnings

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Other information

■ Protect the product in this container from excessive heat and direct sun. ▶

Drug Facts (continued)

Inactive ingredients

WATER, DIMETHICONE, ISODODECANE, PEG-10 DIMETHICONE, GLYCERIN, PROPYLENE GLYCOL, POLYMETHYLSILSESQUIOXANE, POLYSILICONE-11, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, PEG/PPG-18/18 DIMETHICONE, HYDROXYACETOPHENONE, SILICA DIMETHYL Silylate, SODIUM CHLORIDE, PHENOXYETHANOL, SILICA, TOCOPHERYL ACETATE, METHYLPROPANEDIOL, CAPRYLYL GLYCOL, CHLORPHENESIN, DISTEARDIMONIUM HECTORITE, TRIETHOXYCAPRYLYLSILANE, SILANEDIOL SALICYLATE, BUTYLENE GLYCOL, TROMETHAMINE, FRAGRANCE, AESCULUS HIPPOCASTANUM (HORSE CHESTNUT) SEED EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, HYDROLYZED WHEAT PROTEIN, SILYBUM MARIANUM FRUIT EXTRACT, LINALOOL, d-LIMONENE, ALPHA-ISOMETHYL IONONE, **MAY CONTAIN:** TITANIUM DIOXIDE, IRON OXIDES.

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Medio1/Beige

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PRO

NATURAL MATTE

Mattifying foundation
adaptable to your skin
tone SPF 20

Net wt. 1 oz. e (30 g)

Drug Facts

Active Ingredients Purpose

Octinoxate 5%.....Sunscreen
Zinc Oxide 4.2%.....Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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Drug Facts (continued)

Inactive ingredients

WATER, DIMETHICONE, ISODODECANE, PEG-10 DIMETHICONE, GLYCERIN, PROPYLENE GLYCOL, POLYMETHYLSILSESQUIOXANE, POLYSILICONE-11, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, PEG/PPG-18/18 DIMETHICONE, HYDROXYACETOPHENONE, SILICA DIMETHYL Silylate, SODIUM CHLORIDE, PHENOXYETHANOL, SILICA, TOCOPHERYL ACETATE, METHYLPROPANEDIOL, CAPRYLYL GLYCOL, CHLORPHENESIN, DISTEARDIMONIUM HECTORITE, TRIETHOXYCAPRYLYLSILANE, SILANEDIOL SALICYLATE, BUTYLENE GLYCOL, TROMETHAMINE, FRAGRANCE, AESCULUS HIPPOCASTANUM (HORSE CHESTNUT) SEED EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, HYDROLYZED WHEAT PROTEIN, SILYBUM MARIANUM FRUIT EXTRACT, LINALOOL, d-LIMONENE, ALPHA-ISOMETHYL IONONE, **MAY CONTAIN:** TITANIUM DIOXIDE, IRON OXIDES.

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Medio2/Beige

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PRO

NATURAL MATTE

Mattifying foundation
adaptable to your skin
tone SPF 20

Net wt. 1 oz. e (30 g)

Drug Facts

Active Ingredients Purpose

Octinoxate 5%.....Sunscreen
Zinc Oxide 4.2%.....Sunscreen

Uses

- Helps prevent sunburn.

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Other information

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Drug Facts (continued)

Inactive ingredients

WATER, DIMETHICONE, ISODODECANE, PEG-10 DIMETHICONE, GLYCERIN, PROPYLENE GLYCOL, POLYMETHYLSILSESQUIOXANE, POLYSILICONE-11, DIMETHICONE/VINYL DIMETHICONE COPOLYMER, HDI/TRIMETHYLOL HEXYLLACTONE COPOLYMER, PEG/PPG-18/18 DIMETHICONE, HYDROXYACETOPHENONE, SILICA DIMETHYL Silylate, SODIUM CHLORIDE, PHENOXYETHANOL, SILICA, TOCOPHERYL ACETATE, METHYLPROPANEDIOL, CAPRYLYL GLYCOL, CHLORPHENESIN, DISTEARDIMONIUM HECTORITE, TRIETHOXYCAPRYLYLSILANE, SILANEDIOL SALICYLATE, BUTYLENE GLYCOL, TROMETHAMINE, FRAGRANCE, AESCULUS HIPPOCASTANUM (HORSE CHESTNUT) SEED EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, HYDROLYZED WHEAT PROTEIN, SILYBUM MARIANUM FRUIT EXTRACT, LINALOOL, d-LIMONENE, ALPHA-ISOMETHYL IONONE, **MAY CONTAIN: TITANIUM DIOXIDE, IRON OXIDES.**

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Medio3/Beige

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PRO

NATURAL MATTE

Mattifying foundation
adaptable to your skin
tone SPF 20

Net wt. 1 oz. e (30 g)

Drug Facts

Active Ingredients Purpose

Octinoxate 5%.....Sunscreen
Zinc Oxide 4.2%.....Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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Drug Facts (continued)

Inactive ingredients

WATER, DIMETHICONE, ISODODECANE, PEG-10 DIMETHICONE, GLYCERIN, PROPYLENE GLYCOL, POLYMETHYLSILSESQUIOXANE, POLYSILICONE-11, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, PEG/PPG-18/18 DIMETHICONE, HYDROXYACETOPHENONE, SILICA DIMETHYL Silylate, SODIUM CHLORIDE, PHENOXYETHANOL, SILICA, TOCOPHERYL ACETATE, METHYLPROPANEDIOL, CAPRYLYL GLYCOL, CHLORPHENESIN, DISTEARDIMONIUM HECTORITE, TRIETHOXYCAPRYLYLSILANE, SILANEDIOL SALICYLATE, BUTYLENE GLYCOL, TROMETHAMINE, FRAGRANCE, AESCULUS HIPPOCASTANUM (HORSE CHESTNUT) SEED EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, HYDROLYZED WHEAT PROTEIN, SILYBUM MARIANUM FRUIT EXTRACT, LINALOOL, d-LIMONENE, ALPHA-ISOMETHYL IONONE, **MAY CONTAIN:** TITANIUM DIOXIDE, IRON OXIDES.

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Medio4/Beige

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PRO

NATURAL MATTE

Mattifying foundation
adaptable to your skin
tone SPF 20

Net wt. 1 oz. e (30 g)

Drug Facts

Active Ingredients Purpose

Octinoxate 5%.....Sunscreen
Zinc Oxide 4.2%.....Sunscreen

Uses

- Helps prevent sunburn.

Warnings

■ **Skin Cancer / 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.

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Other information

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Drug Facts (continued)

Inactive ingredients

WATER, DIMETHICONE, ISODODECANE, PEG-10 DIMETHICONE, GLYCERIN, PROPYLENE GLYCOL, POLYMETHYLSILSESQUIOXANE, POLYSILICONE-11, DIMETHICONE/VINYL DIMETHICONE COPOLYMER, HDI/TRIMETHYLOL HEXYLLACTONE COPOLYMER, PEG/PPG-18/18 DIMETHICONE, HYDROXYACETOPHENONE, SILICA DIMETHYL Silylate, SODIUM CHLORIDE, PHENOXYETHANOL, SILICA, TOCOPHERYL ACETATE, METHYLPROPANEDIOL, CAPRYLYL GLYCOL, CHLORPHENESIN, DISTEARDIMONIUM HECTORITE, TRIETHOXYCAPRYLYLSILANE, SILANEDIOL SALICYLATE, BUTYLENE GLYCOL, TROMETHAMINE, FRAGRANCE, AESCULUS HIPPOCASTANUM (HORSE CHESTNUT) SEED EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, HYDROLYZED WHEAT PROTEIN, SILYBUM MARIANUM FRUIT EXTRACT, LINALOOL, d-LIMONENE, ALPHA-ISOMETHYL IONONE, **MAY CONTAIN:** TITANIUM DIOXIDE, IRON OXIDES.

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Medio5/Beige

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PRO

NATURAL MATTE

Mattifying foundation
adaptable to your skin
tone SPF 20

Net wt. 1 oz. e (30 g)

Drug Facts

Active Ingredients Purpose

Octinoxate 5%.....Sunscreen
Zinc Oxide 4.2%.....Sunscreen

Uses

- Helps prevent sunburn.

Warnings

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Other information

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Drug Facts (continued)

Inactive ingredients

WATER, DIMETHICONE, ISODODECANE, PEG-10 DIMETHICONE, GLYCERIN, PROPYLENE GLYCOL, POLYMETHYLSILSESQUIOXANE, POLYSILICONE-11, DIMETHICONE/VINYL DIMETHICONE COPOLYMER, HDI/TRIMETHYLOL HEXYLLACTONE COPOLYMER, PEG/PPG-18/18 DIMETHICONE, HYDROXYACETOPHENONE, SILICA DIMETHYL SILYLATE, SODIUM CHLORIDE, PHENOXYETHANOL, SILICA, TOCOPHERYL ACETATE, METHYLPROPANEDIOL, CAPRYLYL GLYCOL, CHLORPHENESIN, DISTEARDIMONIUM HECTORITE, TRIETHOXYCAPRYLYLSILANE, SILANEDIOL SALICYLATE, BUTYLENE GLYCOL, TROMETHAMINE, FRAGRANCE, AESCULUS HIPPOCASTANUM (HORSE CHESTNUT) SEED EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, HYDROLYZED WHEAT PROTEIN, SILYBUM MARIANUM FRUIT EXTRACT, LINALOOL, d-LIMONENE, ALPHA-ISOMETHYL IONONE, **MAY CONTAIN: TITANIUM DIOXIDE, IRON OXIDES.**

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PRINCIPAL DISPLAY PANEL - 30 g Bottle Box - Claro 1/Beige

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PRO

NATURAL MATTE

Mattifying foundation
adaptable to your skin
tone SPF 20

Net wt. 1 oz. e (30 g)

Drug Facts

Active Ingredients Purpose

Octinoxate 5%.....Sunscreen
Zinc Oxide 4.2%.....Sunscreen

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Drug Facts (continued)

Inactive ingredients

WATER, DIMETHICONE, ISODODECANE, PEG-10 DIMETHICONE, GLYCERIN, PROPYLENE GLYCOL, POLYMETHYLSILSESQUIOXANE, POLYSILICONE-11, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, PEG/PPG-18/18 DIMETHICONE, HYDROXYACETOPHENONE, SILICA DIMETHYL Silylate, SODIUM CHLORIDE, PHENOXYETHANOL, SILICA, TOCOPHERYL ACETATE, METHYLPROPANEDIOL, CAPRYLYL GLYCOL, CHLORPHENESIN, DISTEARDIMONIUM HECTORITE, TRIETHOXYCAPRYLYLSILANE, SILANEDIOL SALICYLATE, BUTYLENE GLYCOL, TROMETHAMINE, FRAGRANCE, AESCULUS HIPPOCASTANUM (HORSE CHESTNUT) SEED EXTRACT, CAMELLIA SINENSIS LEAF EXTRACT, HYDROLYZED WHEAT PROTEIN, SILYBUM MARIANUM FRUIT EXTRACT, LINALOOL, d-LIMONENE, ALPHA-ISOMETHYL IONONE, **MAY CONTAIN:** TITANIUM DIOXIDE, IRON OXIDES.

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ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE SPF 20 CLARO 2/BEIGE

octinoxate and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-177
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.05 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.042 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TROMETHAMINE (UNII: 023C2WHX2V)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW) (UNII: J2S07SB0YL)	
MILK THISTLE (UNII: U946SH95EE)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-177-02	1 in 1 BOX	10/19/2018	
1	NDC:14783-177-01	30 g 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	10/19/2018	

ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE SPF 20 MEDIO1/BEIGE

octinoxate and zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-171
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.05 g in 1 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.042 g in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TROMETHAMINE (UNII: 023C2WHX2V)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW) (UNII: J2S07SB0YL)	
MILK THISTLE (UNII: U946SH95EE)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-171-02	1 in 1 BOX	10/19/2018	
1	NDC:14783-171-01	30 g 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	10/19/2018	

ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE SPF 20 MEDIO2/BEIGE

octinoxate and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-172
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.05 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.042 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
TROMETHAMINE (UNII: 023C2WHX2V)
HORSE CHESTNUT (UNII: 3C18L6RJAZ)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW) (UNII: J2S07SB0YL)
MILK THISTLE (UNII: U946SH95EE)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
ISOMETHYL--ALPHA--IONONE (UNII: 9XP4LC555B)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-172-02	1 in 1 BOX	10/19/2018	
1	NDC:14783-172-01	30 g 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	10/19/2018	

ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE SPF 20 MEDIO3/BEIGE

octinoxate and zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-173
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.05 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.042 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TROMETHAMINE (UNII: 023C2WHX2V)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW) (UNII: J2S07SB0YL)	
MILK THISTLE (UNII: U946SH95EE)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-173-02	1 in 1 BOX	10/19/2018	
1	NDC:14783-173-01	30 g 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	10/19/2018	

ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE SPF 20 MEDIO4/BEIGE

octinoxate and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-174
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.05 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.042 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSPOG0W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TROMETHAMINE (UNII: 023C2WHX2V)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW) (UNII: J2S07SB0YL)	
MILK THISTLE (UNII: U946SH95EE)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	

LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-174-02	1 in 1 BOX	10/19/2018	
1	NDC:14783-174-01	30 g 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	10/19/2018	

ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE SPF 20 MEDIO5/BEIGE

octinoxate and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-175
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.05 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.042 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CHLORPHENESIN (UNII: I670DAL4SZ)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
TROMETHAMINE (UNII: 023C2WHX2V)
HORSE CHESTNUT (UNII: 3C18L6RJAZ)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW) (UNII: J2S07SB0YL)
MILK THISTLE (UNII: U946SH95EE)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-175-02	1 in 1 BOX	10/19/2018	
1	NDC:14783-175-01	30 g 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	10/19/2018	

ESIKA PRO NATURAL MATTIFYING FOUNDATION ADAPTABLE TO YOUR SKIN TONE SPF 20 CLARO 1/BEIGE

octinoxate and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-176
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.05 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.042 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TROMETHAMINE (UNII: 023C2WHX2V)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW) (UNII: J2S07SB0YL)	
MILK THISTLE (UNII: U946SH95EE)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-176-02	1 in 1 BOX	10/19/2018	
1	NDC:14783-176-01	30 g 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	10/19/2018	

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	manufacture(14783-171, 14783-172, 14783-173, 14783-174, 14783-175, 14783-176, 14783-177)

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Ventura International LTD