ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 CLEAR 1 - BEIGE- octinoxate, titanium dioxide, and zinc oxide powder
ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 CLEAR 2 - BEIGE- octinoxate, titanium dioxide, and zinc oxide powder
ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 MEDIUM 1 - BEIGE- octinoxate, titanium dioxide, and zinc oxide powder
ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 MEDIUM 2 - BEIGE- octinoxate, titanium dioxide, and zinc oxide powder
ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 MEDIUM 3 - BEIGE- octinoxate, titanium dioxide, and zinc oxide powder
ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 MEDIUM 4 - BEIGE- octinoxate, titanium dioxide, and zinc oxide powder
ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 MEDIUM 5 - BEIGE- octinoxate, titanium dioxide, and zinc oxide powder
Ventura Corporation 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 Compact Powder High Definition and Double Finish SPF 15

Drug Facts

Active Ingredients	*Purpose*
OCTINOXATE 3%	Sunscreen
TITANIUM DIOXIDE 6.24%	Sunscreen
ZINC OXIDE 4.9%	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

MICA, POLYMETHYLSILSESQUIOXANE, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, DIMETHICONE, MAGNESIUM STEARATE, TRIMETHYLSILOXYSILICATE, ISOSTEARYL NEOPENTANOATE, HYDROGEN DIMETHICONE, TOCOPHERYL ACETATE, TRIETHOXYCAPRYLYLSILANE, PHENOXYETHANOL, ALUMINA, CAPRYLYL GLYCOL, CERAMIDE 3, CHLORPHENESIN. MAY CONTAIN : IRON OXIDES (CI 77492), IRON OXIDES (CI 77491), IRON OXIDES (CI 77499).

Dist. by Ventura Corp, Ltd., San Juan, Puerto Rico 00926.

PRINCIPAL DISPLAY PANEL - 6 g Bottle Box - CLEAR 1 - BEIGE

ésika
PRO

POLVOS HD
Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

ésika
PRO

POLVOS HD

Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

www.esika.biz

Drug Facts

Active Ingredients	Purpose
Octinoxate 3%	Sunscreen

PRINCIPAL DISPLAY PANEL - 6 g Bottle Box - CLEAR 2 - BEIGE

ésika
PRO

POLVOS HD
Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

ésika
PRO

POLVOS HD

Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

www.esika.biz

Drug Facts

Active Ingredients	Purpose
Octinoxate 3%	Sunscreen

PRINCIPAL DISPLAY PANEL - 6 g Bottle Box - MEDIUM 1 - BEIGE

ésika
PRO

POLVOS HD
Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

ésika
PRO

POLVOS HD

Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

www.esika.biz

Drug Facts

Active Ingredients	Purpose
Octinoxate 3%	Sunscreen

PRINCIPAL DISPLAY PANEL - 6 g Bottle Box - MEDIUM 2 - BEIGE

ésika
PRO

POLVOS HD
Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

ésika
PRO

POLVOS HD

Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

www.esika.biz

Drug Facts

Active Ingredients	Purpose
Octinoxate 3%	Sunscreen

PRINCIPAL DISPLAY PANEL - 6 g Bottle Box - MEDIUM 3 - BEIGE

ésika
PRO

POLVOS HD
Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

ésika
PRO

POLVOS HD

Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

www.esika.biz

Drug Facts

Active Ingredients	Purpose
Octinoxate 3%	Sunscreen

PRINCIPAL DISPLAY PANEL - 6 g Bottle Box - MEDIUM 4 - BEIGE

ésika
PRO

POLVOS HD
Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

ésika
PRO

POLVOS HD

Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

www.esika.biz

Drug Facts

Active Ingredients	Purpose
Octinoxate 3%	Sunscreen

PRINCIPAL DISPLAY PANEL - 6 g Bottle Box - MEDIUM 5 - BEIGE

ésika
PRO

POLVOS HD
Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

ésika
PRO

POLVOS HD

Compact powder high definition and double finish SPF 15

Net Wt. 0.21 oz. e (6 g)

www.esika.biz

Drug Facts

Active Ingredients	Purpose
Octinoxate 3%	Sunscreen

ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 CLEAR 1 - BEIGE

octinoxate, titanium dioxide, and zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43596-0054
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0624 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE NP (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0054-2	1 in 1 BOX	04/16/2017	
1	NDC:43596-0054-1	6 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	04/16/2017	

ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 CLEAR 2 - BEIGE

octinoxate, titanium dioxide, and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43596-0055
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0624 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE NP (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0055-2	1 in 1 BOX	04/16/2017	
1	NDC:43596-0055-1	6 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	04/16/2017	

ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 MEDIUM 1 - BEIGE

octinoxate, titanium dioxide, and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43596-0056
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0624 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE NP (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0056-2	1 in 1 BOX	04/16/2017	
1	NDC:43596-0056-1	6 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	04/16/2017	

ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 MEDIUM 2 - BEIGE

octinoxate, titanium dioxide, and zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43596-0057
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0624 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
MICA (UNII: V8A1AW0880)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE NP (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43596-0057-2	1 in 1 BOX	04/16/2017	
1	NDC:43596-0057-1	6 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	04/16/2017	

ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 MEDIUM 3 - BEIGE

octinoxate, titanium dioxide, and zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43596-0058
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0624 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
MICA (UNII: V8A1AW0880)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE NP (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:43596-0058-2	1 in 1 BOX	04/16/2017	
1	NDC:43596-0058-1	6 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	04/16/2017	

ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 MEDIUM 4 - BEIGE

octinoxate, titanium dioxide, and zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43596-0059
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0624 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE NP (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0059-2	1 in 1 BOX	04/16/2017	
1	NDC:43596-0059-1	6 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	04/16/2017	

ESIKA PRO COMPACT HIGH DEFININTION AND DOUBLE FINISH SPF 15 MEDIUM 5 - BEIGE

octinoxate, titanium dioxide, and zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43596-0060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.0624 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.049 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CERAMIDE NP (UNII: 4370DF050B)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0060-2	1 in 1 BOX	04/16/2017	
1	NDC:43596-0060-1	6 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	04/16/2017	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(43596-0054, 43596-0055, 43596-0056, 43596-0057, 43596-0058, 43596-0059, 43596-0060)

Revised: 4/2017 Ventura Corporation LTD