

ESIKA CORE SENSATIONS- octinoxate and oxybenzone lipstick
Ventura Corporation (San Juan, P.R)

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.

ēsika
Core Sensations
Lipstick

Active Ingredients

Octinoxate 6.5%, Oxybenzone 2%

Uses

Helps prevent sunburn.

Warnings

For external use only.

Stop use if skin rash occurs.

Keep out of reach of children.

Directions

Apply evenly before sun exposure and as needed. Apply lipstick following the curves of natural lip line.

Inactive Ingredients

Caprylic/capric triglyceride, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, octyldodecanol, vp/hexadecene copolymer, candelilla cera (euphorbia cerifera (candelilla) wax), castor isostearate beeswax succinate, cera alba (beeswax), ozokerite, polyethylene, copernicia cerifera cera (copernicia cerifera (carnauba) wax), tridecyl stearate, silica, glyceryl isostearate, isostearyl alcohol, myristyl myristate, neopentyl glycol dicaprylate/dicaprate, parfum (fragrance), butyrospermum parkii butter (butyrospermum parkii (shea) butter), glycerin, isopropyl myristate, mentha piperita oil (mentha piperita (peppermint) oil), beta-sitosterol, brassica campestris seed oil (brassica campestris (rapeseed) seed oil), sodium saccharin, phenoxyethanol, disteardimonium hectorite, silica silylate, ethyl menthane carboxamide, menthoxypropanediol, microcristallina cera (microcrystalline wax), tocopheryl acetate, methylparaben, petrolatum, phospholipids, bht, mica, schinus terebinthifolius seed extract, propylparaben, cholesterol, butylparaben, ethylparaben, cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, glycosphingolipids, dimethicone, trimethylsiloxysilicate. **May Contain:** diisopropyl dimer dilinoleate, ricinus communis seed oil (ricinus communis (castor) seed oil), hydrogenated polyisobutene, cetyl alcohol, menthyl lactate, propylene glycol, dipalmitoyl hydroxyproline, CI 15850 (red 7 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 45410 (red 27 lake), CI 77891 (titanium dioxide), CI 19140 (yellow 5 lake), CI 45380 (red 21 lake), CI 75470 (carmine), ppg-26-buteth-26, bertholletia excelsa seed oil, orbignya oleifera seed oil, peg-40 hydrogenated castor oil, silica dimethyl silylate, cetearyl ethylhexanoate, aqua (water), hydrogenated coconut oil, oleyl alcohol, cetyl ricinoleate, talc.

PRINCIPAL DISPLAY PANEL - 4 g Carton - MARRÓN DELICIA

ēsika

Core Sensations

Lipstick

4 g e (.14 oz.)

cerifera (carnauba) wax), tridecyl stearate, silica, glyceryl isostearate, isostearyl alcohol, myristyl myristate, neopenyl glycol dicaprylate/dicaprate, parium (fragrance), butyrospermum parkii butter (butyrospermum parkii (shea) butter), glycerin, isopropyl myristate, mentha piperita oil (mentha piperita (peppermint) oil), beta-sitosterol, brassica campestris seed oil (brassica campestris (rapeseed) seed oil), sodium saccharin, phenoxylethanol, disteardimonium hectorite, silica silylate, ethyl menthane carboxamide, menthoxypropylmethoxy, microcrystallina cera (microcrystalline wax), tocopheryl acetate, methylparaben, petrolatum, phospholipids, bht, mica, schinus terebinthifolius seed extract, propylparaben, cholesterol, butylparaben, ethylparaben, cetearyl alcohol, cetearyl glucoside, polyglyceryl-2 dipolyhydroxystearate, isobutylparaben, glycosphingolipids, dimethicone, ▼

trimethylsiloxysilicate. **May Contain:** diisopropyl dimer dilinoleate, ricinus communis seed oil (ricinus communis (castor) seed oil), hydrogenated polyisobutene, cetyl alcohol, menthyl lactate, propylene glycol, dipalmitoyl hydroxyproline, CI 15850 (red 7 lake), CI 77491 (iron oxides), CI 77492 (iron oxides), CI 77499 (iron oxides), CI 77019 (mica), CI 45410 (red 27 lake), CI 77891 (titanium dioxide), CI 19140 (yellow 5 lake), CI 45380 (red 21 lake), CI 75470 (carmine), ppg-26-buteth-26, bertholletia excelsa seed oil, orbignya oleifera seed oil, pag-40 hydrogenated castor oil, silica dimethyl silicate, cetearyl ethylhexanoate, aqua (water), hydrogenated coconut oil, oleyl alcohol, cetyl ricinoleate, talc.

PUERTO RICO: Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926. Made in Peru.

Core Sensations
Lipstick

4 g e (.14 oz.)

Active Ingredients: Octinoxate 6.5%, Oxybenzone 2%

Uses: Helps prevent sunburn.

Warnings: For external use only. Stop use if skin rash occurs. **Keep out of reach of children.**

Directions: Apply evenly before sun exposure and as needed. Apply lipstick following the curves of natural lip line.

Inactive Ingredients: Caprylic/capric triglyceride, dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, octyldodecanol, vp/hexadecene copolymer, candellilla cera (euphorbia cerifera (candelilla) wax), castor isostearate beeswax succinate, cera alba (beeswax), ozokerite, polyethylene, copernicia cerifera cera (copernicia ▼

ESIKA CORE SENSATIONS

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-364
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.065 g in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.020 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
CASTOR OIL (UNII: D5340Y2I9G)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MENTHYL LACTATE (UNII: 2BF9E65L7I)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BRASSICA RAPA VAR. RAPA OIL (UNII: N4G8379626)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
MICA (UNII: V8A1AW0880)
BRAZILIAN PEPPER (UNII: SUG822G7CD)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
CHOLESTEROL (UNII: 97C5T2UQ7J)
BUTYLPARABEN (UNII: 3QP1IU3FV8)
ETHYLPARABEN (UNII: 14255EXE39)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
DIMETHICONE (UNII: 92RU3N3Y1O)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
ALUMINUM OXIDE (UNII: LM26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
BRAZIL NUT OIL (UNII: 0G89T29HO6)
BABASSU OIL (UNII: 8QSB4M5477)
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)
WATER (UNII: 059QF0KO0R)
COCONUT OIL (UNII: Q9L0O73W7L)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TALC (UNII: 7SEV7J4R1U)

Product Characteristics			
Color	BROWN (MARRÓN DELICIA)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-364-02	1 in 1 CARTON		
1	NDC:13537-364-01	4 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/02/2011	

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-365
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.065 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.020 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
CASTOR OIL (UNII: D5340Y2I9G)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MENTHYL LACTATE (UNII: 2BF9E65L7I)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BRASSICA RAPA VAR. RAPA OIL (UNII: N4G8379626)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MICA (UNII: V8A1AW0880)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

CHOLESTEROL (UNII: 97C5T2UQ7J)
BUTYLPARABEN (UNII: 3QP1U3FV8)
ETHYLPARABEN (UNII: 14255EXE39)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
DIMETHICONE (UNII: 92RU3N3Y1O)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
ALUMINUM OXIDE (UNII: LM26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
BRAZIL NUT OIL (UNII: 0G89T29HO6)
BABASSU OIL (UNII: 8QSB4M5477)
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)
WATER (UNII: 059QF0KO0R)
COCONUT OIL (UNII: Q9L0O73W7L)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TALC (UNII: 7SEV7J4R1U)

Product Characteristics

Color	RED (ROJO AMOROSO)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-365-02	1 in 1 CARTON		
1	NDC:13537-365-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/02/2011	

ESIKA CORE SENSATIONS

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-366
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Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.065 g in 1 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.020 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
CASTOR OIL (UNII: D5340Y2I9G)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MENTHYL LACTATE (UNII: 2BF9E65L7I)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL ISO STEARATE (UNII: HYE7O27HAO)	
ISO STEARYL ALCOHOL (UNII: Q6130CQ44Y)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BRASSICA RAPA VAR. RAPA OIL (UNII: N4G8379626)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MICA (UNII: V8A1AW0880)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
BUTYL PARABEN (UNII: 3QPI1U3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	

ISOBUTYL PARABEN (UNII: 0QJ25X58G)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
BRAZIL NUT OIL (UNII: 0G89T29HO6)	
BABASSU OIL (UNII: 8QSB4M5477)	
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)	
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
WATER (UNII: 059QF0KO0R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	ORANGE (CIRUELA CONFIDENTE)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-366-02	1 in 1 CARTON		
1	NDC:13537-366-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/02/2011	

ESIKA CORE SENSATIONS

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-367
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.065 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.020 g in 1 g
Inactive Ingredients		
Ingredient Name	Strength	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)		
CASTOR OIL (UNII: D5340Y2I9G)		
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)		
OCTYLDODECANOL (UNII: 461N1O614Y)		
CANDELILLA WAX (UNII: WL0328HX19)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
TRIDECYL STEARATE (UNII: A8OE252M6L)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
MENTHYL LACTATE (UNII: 2BF9E65L7J)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)		
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)		
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)		
SHEA BUTTER (UNII: K49155WL9Y)		
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)		
GLYCERIN (UNII: PDC6A3C0OX)		
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)		
PEPPERMINT OIL (UNII: AV092KU4JH)		
BRASSICA RAPA VAR. RAPA OIL (UNII: N4G8379626)		
.BETA.-SITOSTEROL (UNII: S347WMO6M4)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)		
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PETROLATUM (UNII: 4T6H12BN9U)		
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
MICA (UNII: V8A1AW0880)		
BRAZILIAN PEPPER (UNII: SUG822G7CD)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
CHOLESTEROL (UNII: 97C5T2UQ7J)		
BUTYLPARABEN (UNII: 3QPIIU3FV8)		
ETHYLPARABEN (UNII: 14255EXE39)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)		
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)		
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
D&C RED NO. 7 (UNII: ECW0LZ41X8)		
ALUMINUM OXIDE (UNII: LM26O6933)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
BRAZIL NUT OIL (UNII: 0G89T29HO6)
BABASSU OIL (UNII: 8QSB4M5477)
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)
WATER (UNII: 059QF0KO0R)
COCONUT OIL (UNII: Q9L0O73W7L)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TALC (UNII: 7SEV7J4R1U)

Product Characteristics

Color	RED (FRESA COQUETA)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-367-02	1 in 1 CARTON		
1	NDC:13537-367-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/02/2011	

ESIKA CORE SENSATIONS

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-368
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.065 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.020 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
CASTOR OIL (UNII: D5340Y2I9G)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MENTHYL LACTATE (UNII: 2BF9E65L7I)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BRASSICA RAPA VAR. RAPA OIL (UNII: N4G8379626)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MICA (UNII: V8A1AW0880)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
BUTYL PARABEN (UNII: 3QP1IU3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	

BRAZIL NUT OIL (UNII: 0G89T29HO6)	
BABASSU OIL (UNII: 8QSB4M5477)	
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)	
CETEARYL ETHYLHEXANO ATE (UNII: 9M64UO4C25)	
WATER (UNII: 059QF0KO0R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	RED, PINK (MAGENTA ENAMORADA)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-368-02	1 in 1 CARTON		
1	NDC:13537-368-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/02/2011	

ESIKA CORE SENSATIONS

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-369
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.065 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.020 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
CASTOR OIL (UNII: D5340Y2I9G)	

TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MENTHYL LACTATE (UNII: 2BF9E65L7I)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BRASSICA RAPA VAR. RAPA OIL (UNII: N4G8379626)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MICA (UNII: V8A1AW0880)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
BUTYL PARABEN (UNII: 3QPII03FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
BRAZIL NUT OIL (UNII: 0G89T29HO6)	
BABASSU OIL (UNII: 8QSB4M5477)	
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)	
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
WATER (UNII: 059QF0K00R)	

COCONUT OIL (UNII: Q9L0O73W7L)

OLEYL ALCOHOL (UNII: 172F2WN8DV)

TALC (UNII: 7SEV7J4R1U)

Product Characteristics

Color	RED (ROSA TERNURA)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-369-02	1 in 1 CARTON		
1	NDC:13537-369-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/02/2011	

ESIKA CORE SENSATIONS

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-370
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.065 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.020 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
CASTOR OIL (UNII: D5340Y2I9G)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	

CETYL ALCOHOL (UNII: 936JST6JCN)	
MENTHYL LACTATE (UNII: 2BF9E65L7J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BRASSICA RAPA VAR. RAPA OIL (UNII: N4G8379626)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MICA (UNII: V8A1AW0880)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
BUTYLPARABEN (UNII: 3QPIU3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
BRAZIL NUT OIL (UNII: 0G89T29HO6)	
BABASSU OIL (UNII: 8QSB4M5477)	
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)	
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
WATER (UNII: 059QF0K00R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics				
Color	RED, PINK (MALVA ROMÁNTICA)		Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-370-02	1 in 1 CARTON		
1	NDC:13537-370-01	4 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part352	06/02/2011		

ESIKA CORE SENSATIONS				
octinoxate and oxybenzone lipstick				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-371	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	0.065 g in 1 g	
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)		OXYBENZONE	0.020 g in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)				
CASTOR OIL (UNII: D5340Y2I9G)				
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)				
OCTYLDODECANOL (UNII: 461N1O614Y)				
CANDELILLA WAX (UNII: WL0328HX19)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
TRIDECYL STEARATE (UNII: A8OE252M6L)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
MENTHYL LACTATE (UNII: 2BF9E65L7I)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)				
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)				

MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BRASSICA RAPA VAR. RAPA OIL (UNII: N4G8379626)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MICA (UNII: V8A1AW0880)	
BRAZILIAN PEPPER (UNII: SUG822G7CD)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
BUTYL PARABEN (UNII: 3QPIU3FV8)	
ETHYL PARABEN (UNII: 14255EXE39)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 21 (UNII: 08744Z6JNY)	
BRAZIL NUT OIL (UNII: 0G89T29HO6)	
BABASSU OIL (UNII: 8QSB4M5477)	
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)	
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
WATER (UNII: 059QF0KO0R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	RED (VINO SEDUCTOR)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-371-02	1 in 1 CARTON		
1	NDC:13537-371-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/02/2011	

ESIKA CORE SENSATIONS

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-372
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.065 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.020 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
CASTOR OIL (UNII: D5340Y2I9G)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MENTHYL LACTATE (UNII: 2BF9E65L7I)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	

GLYCERIN (UNII: PDC6A3C0OX)
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
PEPPERMINT OIL (UNII: AV092KU4JH)
BRASSICA RAPA VAR. RAPA OIL (UNII: N4G8379626)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
METHYL PARABEN (UNII: A2I8C7HI9T)
PETROLATUM (UNII: 4T6H12BN9U)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
MICA (UNII: V8A1AW0880)
BRAZILIAN PEPPER (UNII: SUG822G7CD)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
CHOLESTEROL (UNII: 97C5T2UQ7J)
BUTYL PARABEN (UNII: 3QPII03FV8)
ETHYL PARABEN (UNII: 14255EXE39)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)
DIMETHICONE (UNII: 92RU3N3Y1O)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
ALUMINUM OXIDE (UNII: LM26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
BRAZIL NUT OIL (UNII: 0G89T29HO6)
BABASSU OIL (UNII: 8QSB4M5477)
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)
WATER (UNII: 059QF0KO0R)
COCONUT OIL (UNII: Q9L0O73W7L)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TALC (UNII: 7SEV7J4R1U)

Product Characteristics

Color	BROWN (BRONCE CAUTIVANTE)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-372-02	1 in 1 CARTON		

1	NDC:13537-372-01	4 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part352	06/02/2011		

ESIKA CORE SENSATIONS

octinoxate and oxybenzone lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-373
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.065 g in 1 g
	OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.020 g in 1 g

Inactive Ingredients		
	Ingredient Name	Strength
	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
	DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
	CASTOR OIL (UNII: D5340Y2I9G)	
	TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
	OCTYLDODECANOL (UNII: 461N1O614Y)	
	CANDELILLA WAX (UNII: WL0328HX19)	
	CARNAUBA WAX (UNII: R12CBM0EIZ)	
	TRIDECYL STEARATE (UNII: A8OE252M6L)	
	CETYL ALCOHOL (UNII: 936JST6JCN)	
	MENTHYL LACTATE (UNII: 2BF9E65L7I)	
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
	GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
	ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
	MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
	NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
	SHEA BUTTER (UNII: K49155WL9Y)	
	DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
	GLYCERIN (UNII: PDC6A3C0OX)	
	ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
	PEPPERMINT OIL (UNII: AV092KU4JH)	
	BRASSICA RAPA VAR. RAPA OIL (UNII: N4G8379626)	
	.BETA.-SITOSTEROL (UNII: S347WMO6M4)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
METHYL PARABEN (UNII: A2I8C7HI9T)
PETROLATUM (UNII: 4T6H12BN9U)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
MICA (UNII: V8A1AW0880)
BRAZILIAN PEPPER (UNII: SUG822G7CD)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
CHOLESTEROL (UNII: 97C5T2UQ7J)
BUTYL PARABEN (UNII: 3QPIIU3FV8)
ETHYL PARABEN (UNII: 14255EXE39)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)
DIMETHICONE (UNII: 92RU3N3Y1O)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
ALUMINUM OXIDE (UNII: LM26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
BRAZIL NUT OIL (UNII: 0G89T29HO6)
BABASSU OIL (UNII: 8QSB4M5477)
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)
WATER (UNII: 059QF0KO0R)
COCONUT OIL (UNII: Q9L0O73W7L)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TALC (UNII: 7SEV7J4R1U)

Product Characteristics			
Color	RED (FUCSIA FESTIVA)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-373-02	1 in 1 CARTON		
1	NDC:13537-373-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/02/2011	

ESIKA CORE SENSATIONS

octinoxate and oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-374
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.065 g in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.020 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIPENTAERYTHRITYL HEXACAPRYLATE/HEXACAPRATE (UNII: 554N82UWVW)	
CASTOR OIL (UNII: D5340Y2I9G)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TRIDECYL STEARATE (UNII: A8OE252M6L)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MENTHYL LACTATE (UNII: 2BF9E65L7I)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
NEOPENTYL GLYCOL DICAPRATE (UNII: 77T908SE82)	
SHEA BUTTER (UNII: K49155WL9Y)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
BRASSICA RAPA VAR. RAPA OIL (UNII: N4G8379626)	
.BETA.-SITOSTEROL (UNII: S347WMO6M4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
METHYL PARABEN (UNII: A2I8C7HI9T)	

PETROLATUM (UNII: 4T6H12BN9U)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
MICA (UNII: V8A1AW0880)
BRAZILIAN PEPPER (UNII: SUG822G7CD)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
CHOLESTEROL (UNII: 97C5T2UQ7J)
BUTYLPARABEN (UNII: 3QP1IU3FV8)
ETHYLPARABEN (UNII: 14255EXE39)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
DIMETHICONE (UNII: 92RU3N3Y10)
D&C RED NO. 7 (UNII: ECW0LZ41X8)
ALUMINUM OXIDE (UNII: LM26O6933)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
D&C RED NO. 27 (UNII: 2LRS185U6K)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
D&C RED NO. 21 (UNII: 08744Z6JNY)
BRAZIL NUT OIL (UNII: 0G89T29HO6)
BABASSU OIL (UNII: 8QSB4M5477)
POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT)
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)
WATER (UNII: 059QF0KO0R)
COCONUT OIL (UNII: Q9L0O73W7L)
OLEYL ALCOHOL (UNII: 172F2WN8DV)
TALC (UNII: 7SEV7J4R1U)

Product Characteristics

Color	ORANGE (CORAL ENCANTADOR)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-374-02	1 in 1 CARTON		
1	NDC:13537-374-01	4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/02/2011	

Labeler - Ventura Corporation (San Juan, P.R) (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Yobel Supply Chain Management, S. A.		934116930	MANUFACTURE

Revised: 7/2011

Ventura Corporation (San Juan, P.R)