SKINCEUTICALS PHYSICAL FUSION UV DEFENSE BROAD SPECTRUM SPF 50 SUNSCREEN- titanium dioxide and zinc oxide lotion
L'Oreal USA Products Inc

Drug Facts

Active ingredients

Titanium dioxide 6%

Zinc oxide 5%

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 liberally 15 minutes before sun exposure

- reapply:
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- 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
- children under 6 months of age: Ask a doctor

Other information

protect the product in this container from excessive heat and direct sun

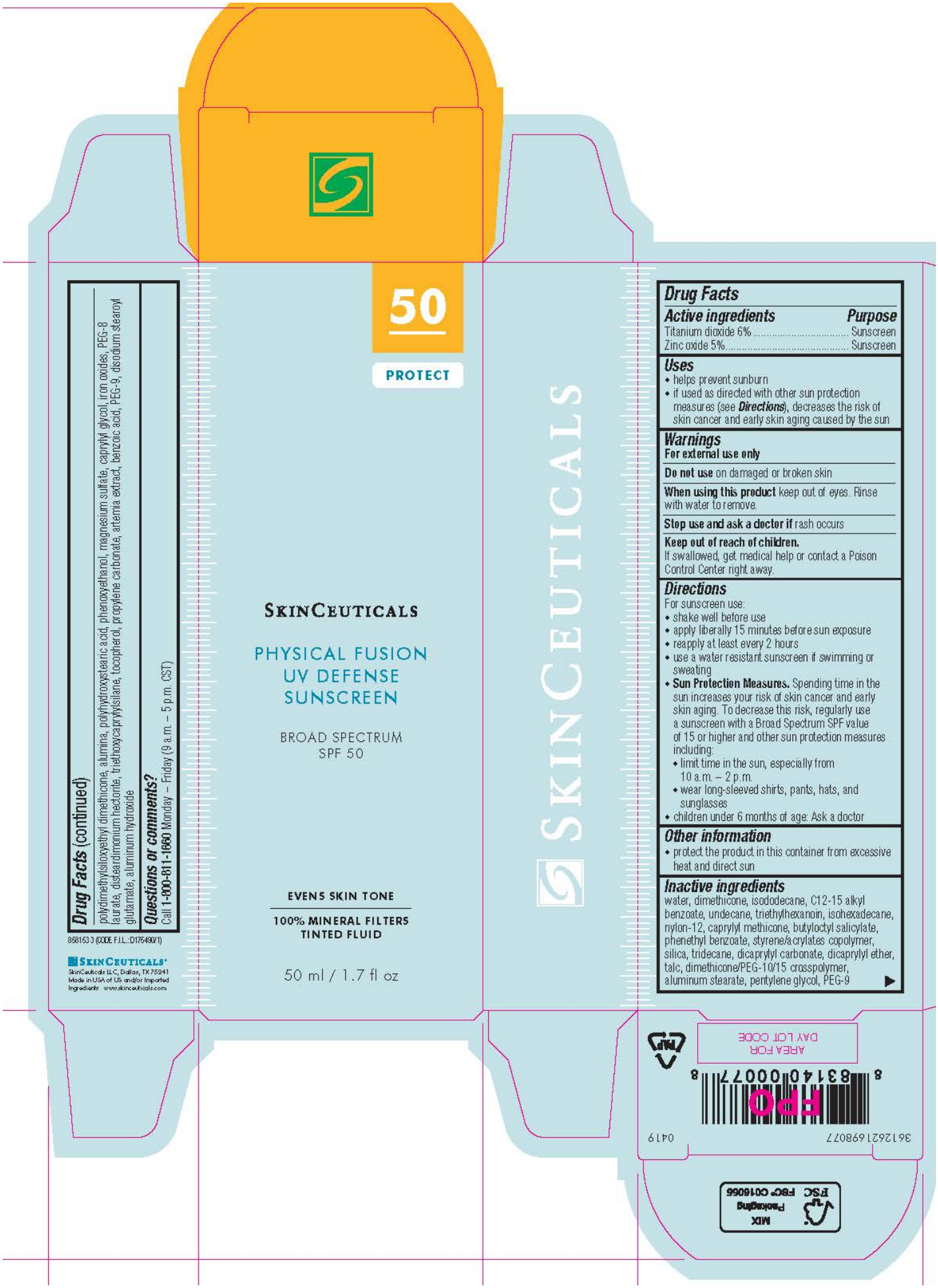
Inactive ingredients

water, dimethicone, isododecane, c12-15 alkyl benzoate, undecane, triethylhexanoin, isohexadecane, nylon-12, caprylyl methicone, butyloctyl salicylate, phenethyl benzoate, styrene/acrylates copolymer, silica, tridecane, dicaprylyl carbonate, dicaprylyl ether, talc, dimethicone/PEG-10/15 crosspolymer, aluminum stearate, pentylene glycol, PEG-9 polydimethylsiloxyethyl dimethicone, alumina, polyhydroxystearic acid, phenoxyethanol, magnesium sulfate, caprylyl glycol, iron oxides, PEG-8 laurate, disteardimonium hectorite, triethoxycaprylylsilane, tocopherol, propylene carbonate, artemia extract, benzoic acid, PEG-9, disodium stearoyl glutamate, aluminum hydroxide

Questions or comments?

Call 1-800-811-1660

Monday - Friday (9 a.m. - 5 p.m. CST)



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PROTECT

SKINCEUTICALS

PHYSICAL FUSION
UV DEFENSE
SUNSCREEN

BROAD SPECTRUM
SPF 50

EVENS SKIN TONE

100% MINERAL FILTERS
TINTED FLUID

50 ml / 1.7 fl oz

SKINCEUTICALS

Drug Facts (continued)

polydimethylsiloxyethyl dimethicone, alumina, polyhydroxystearic acid, phenoxyethanol, magnesium sulfate, caprylyl glycol, iron oxides, PEG-8 laurate, disteardimonium hectorite, triethoxycaprylylsilane, tocopherol, propylene carbonate, artemia extract, benzoic acid, PEG-9, disodium stearoyl glutamate, aluminum hydroxide

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868163 3 (CODE F.I.L.: D175490/1)

SKINCEUTICALS®
SkinCeuticals LLC, Dallas, TX 75241
Made in USA of US and/or Imported Ingredients www.skinceuticals.com

Drug Facts

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Titanium dioxide 6%	Sunscreen
Zinc oxide 5%	Sunscreen

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Warnings
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Stop use and ask a doctor if rash occurs

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

Directions
For sunscreen use:
- shake well before use
- apply liberally 15 minutes before sun exposure
- 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
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Other information
- protect the product in this container from excessive heat and direct sun

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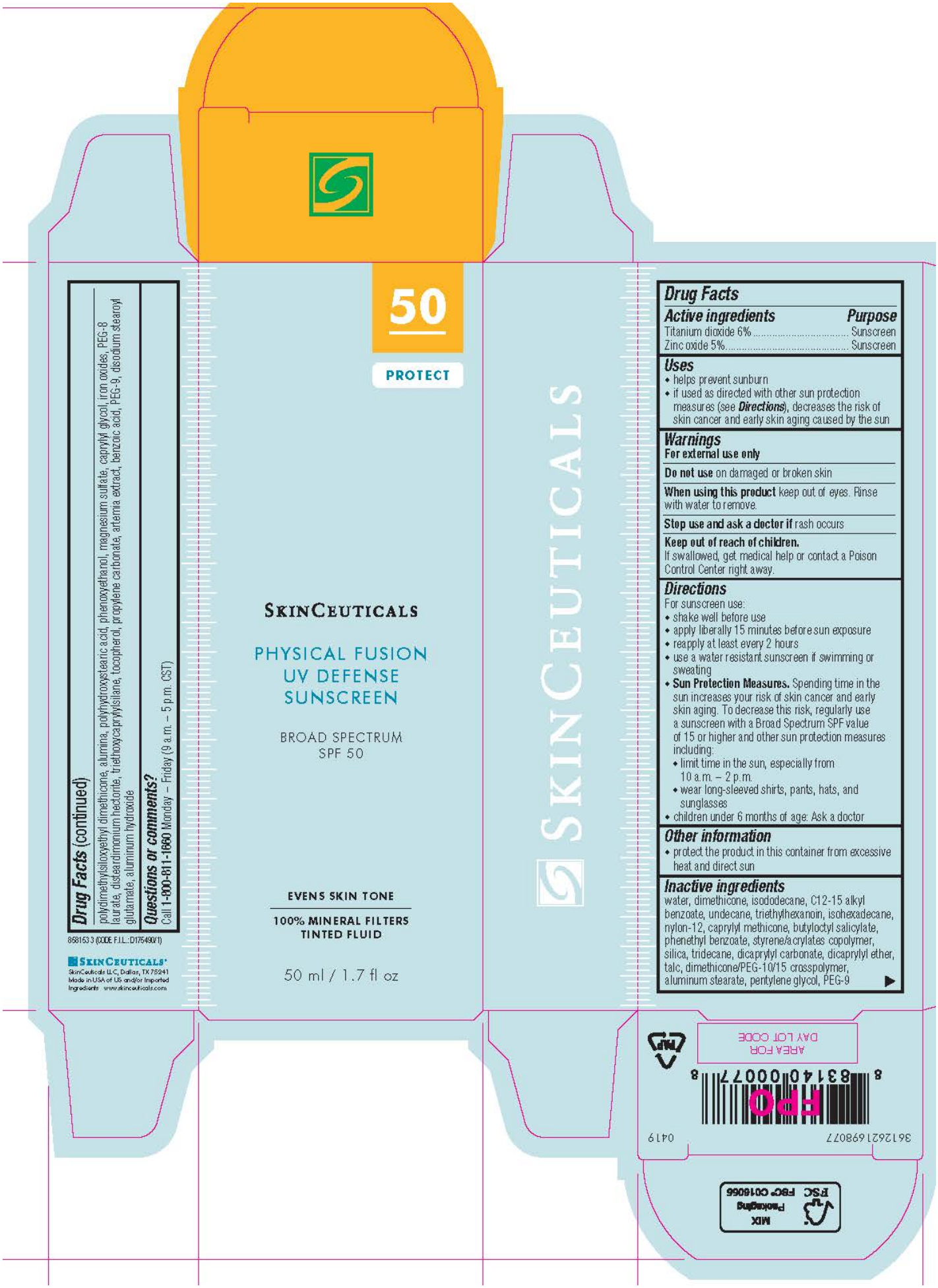
AREA FOR DAY LOT CODE

FPO

8 83140 00077 8

361262169807 7 0419

MIX
Packaging
FSC FSC® C016056



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SKINCEUTICALS PHYSICAL FUSION UV DEFENSE BROAD SPECTRUM SPF 50 SUNSCREEN

titanium dioxide and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49967-077
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	60 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	50 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
UNDECANE (UNII: JV0QT00NUE)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
NYLON-12 (UNII: 446U8J075B)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIDECANE (UNII: A3LZF0L939)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	

TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POLYETHYLENE GLYCOL 450 (UNII: 5IRA46LB71)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-077-01	1 in 1 CARTON	01/01/2011	
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-077-02	4 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2011	
3	NDC:49967-077-03	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2011	
4	NDC:49967-077-04	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/01/2011	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
Goodier Cosmetics LP		007317209	manufacture(49967-077)

Revised: 12/2023 L'Oreal USA Products Inc