INTRAL SENSITIVE SKIN ENVIRONMENTAL LIGHTWEIGHT SHIELD BROAD SPECTRUM SPF50- titanium dioxide and zinc oxide lotion DARPHIN DIST.

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.

INTRAL SENSITIVE SKIN ENVIRONMENTAL LIGHTWEIGHT SHIELD BROAD SPECTRUM SPF50

Drug Facts

Active ingredients

Titanium dioxide 6.3% Zinc oxide 4.0%

Purpose

Sunscreen

Uses

Helps prevent sunburn

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

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every two 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
- children under 6 months: ask a doctor

Inactive ingredients

water\aqua\eau, dimethicone, butyloctyl salicylate, polydiethylsiloxane, c12-15 alkyl benzoate, isononyl isononanoate, diethylhexyl succinate, neopentyl glycol diheptanoate, methyl trimethicone, butylene glycol, ethylhexyl methoxycrylene, lauryl peg-9 polydimethylsiloxyethyl dimethicone, silica, laureth-4, cetyl peg/ppg-10/1 dimethicone, dipentaerythrityl tri-polyhydroxystearate, dimethicone silylate, hydrolyzed wheat protein/pvp crosspolymer, isostearic acid, caprylyl glycol, dimethicone crosspolymer-3, polyhydroxystearic acid, triethoxycaprylylsilane, dimethicone/peg-10/15 crosspolymer, dipropylene glycol, phenoxyethanol, iron oxides (ci 77491), iron oxides (ci 77492) <iln41905>

Other information

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

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton

DARPHIN PARIS

INTRAL

SENSITIVE SKIN

ENVIRONMENTAL LIGHTWEIGHT SHIELD

BROAD SPECTRUM SPF 50

30 ml e/1 FL.OZ.LIQ.



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Drug Facts (cont.)

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DARPHIN

INTRAL

SENSITIVE SKIN

ENVIRONMENTAL LIGHTWEIGHT SHIELD

BROAD SPECTRUM SPF 50 30 ml e/1 FL.OZ.LIQ.

ENVIRONMENTAL LIGHTWEIGHT SHIELD BROAD SPECTRUM SPF 50 The strength of environmen protection in its most delicate form. Helps protect sensitive skin from pollution, including the eye area. With a gentle blend of 100% mineral UVA/UVB filters, this sheer, nude-toned fluid disappears on skin leaving it smooth, luminous and comfortably

Shake well. Apply in the morning after the appropriate cream. Also perfect as a makeup base.

Formulated without parabens. Dermatologist and ophthalmologist

Clinically-proven efficacy.



DARPHIN

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D7TK-01-1111

GR3509701

INTRAL SENSITIVE SKIN ENVIRONMENTAL LIGHTWEIGHT SHIELD **BROAD SPECTRUM SPF50**

titanium dioxide and zinc oxide lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16555-008	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	63 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	40 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
DIETHYLHEXYL SUCCINATE (UNII: 69W9UMG3P8)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LAURETH-4 (UNII: 6HQ855798J)	
DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE (UNII: D21K655H52)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
WATER (UNII: 059QF0KO0R)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:16555-008- 01	1 in 1 CARTON	07/15/2017		
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing In	nformation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date

Labeler - DARPHIN DIST. (105157494)

Registrant - Estee Lauder Companies Inc. (790802086)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Ltd.		202952982	manufacture(16555-008)

Establishment			
Name	Address	ID/FEI	Business Operations
Estee Lauder Cosmetics Ltd.		204132062	pack(16555-008) , label(16555-008)

Establishmen	t		
Name	Address	ID/FEI	Business Operations
The Estee Lauder Inc		802599436	manufacture(16555-008) , pack(16555-008) , label(16555-008)

Revised: 8/2023 DARPHIN DIST.