

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

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**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\aquaeau, dimethicone, butyloctyl salicylate, polydiethylsiloxane, c12-15 alkyl benzoate, isononyl isononanoate, diethylhexyl succinate, neopentyl glycol diheptanoate, methyl trimethicone, butylene glycol, ethylhexyl methoxycrylene, lauryl peg-9 polydimethylsiloxylethyl dimethicone, silica, laureth-4, cetyl peg/ppg-10/1 dimethicone, dipentaerythryl 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**

**ENVIRONMENTAL  
LIGHTWEIGHT SHIELD**

**BROAD SPECTRUM  
SPF 50**

30 ml e/1 FL.OZ.LIQ.



# 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
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	63 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	40 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)	
<b>DIETHYLHEXYL SUCCINATE</b> (UNII: 69W9UMG3P8)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKWBC543X)	
<b>METHYL TRIMETHICONE</b> (UNII: S73ZQI0GXM)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>ETHYLHEXYL METHOXYCRYLENE</b> (UNII: S3KFG6Q5X8)	
<b>LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: 25G622K2RA)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>LAURETH-4</b> (UNII: 6HQ855798J)	
<b>DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE</b> (UNII: D21K655H52)	
<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### 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 Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/15/2017	

**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)

**Establishment**

Name	Address	ID/FEI	Business Operations
The Estee Lauder Inc		802599436	manufacture(16555-008)

Revised: 11/2024

DARPHIN DIST.