SKINCEUTICALS CLEAR DAILY SOOTHING UV DEFENSE DAILY SUNSCREEN BROAD SPECTRUM SPF 50- homosalate, octisalate, octocrylene and zinc oxide lotion L'Oreal USA Products Inc

Drug Facts

Active ingredients

Homosalate 8%

Octisalate 5%

Octocrylene 5%

Zinc oxide 7%

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 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
- children under 6 months of age: Ask a doctor

Other information

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

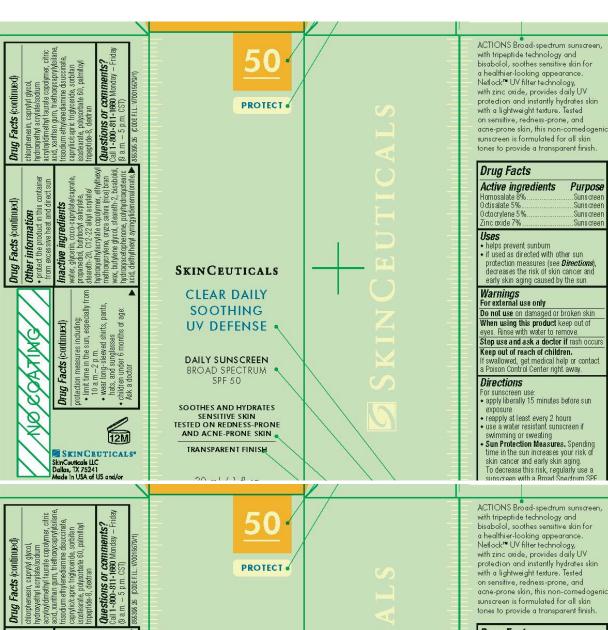
Inactive ingredients

water, glycerin, coco-caprylate/caprate, propanediol, butyloctyl salicylate, steareth-20, c12-22 alkyl acrylate/hydroxyethylacrylate copolymer, ethylhexyl methoxycrylene, oryza sativa (rice) bran wax, butylene glycol, steareth-2, bisabolol, hydroxyacetophenone, polyhydroxystearic acid, diethylhexyl syringylidenemalonate, chlorphenesin, caprylyl glycol, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, citric acid, xanthan gum, triethoxycaprylylsilane, trisodium ethylenediamine disuccinate, caprylic/capric triglyceride, sorbitan isostearate, polysorbate 60, palmitoyl tripeptide-8, dextran

Questions or comments?

Call 1-800-811-1660

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



PROTECT &

CLEAR DAILY SOOTHING UV DEFENSE

DAILY SUNSCREEN BROAD SPECTRUM SPF 50

SOOTHES AND HYDRATES SENSITIVE SKIN TESTED ON REDNESS-PRONE AND ACNE-PRONE SKIN

TRANSPARENT FINISH

with tripeptide technology and bisabolol, soothes sensitive skin for a healthier-looking appearance. Netlock™ UV filter technology, with zinc oxide, provides daily UV protection and instantly hydrates skin with a lightweight texture. Tested on sensitive, redness-prone, and acne-prone skin, this non-comedogenic sunscreen is formulated for all skin tones to provide a transparent finish

3

A STATE

É

20

3

ST.

Ť

Ø

Drug Facts Purpose Active ingredients Homosalate 8% Octisalate 5%... Sunscreer Octocrylene 5% Zinc oxide 7%... Sunscreer Sunscreer

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. Pinse 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 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 SPE

SKINCEUTICALS

00 1710

protection measures including:

• limit time in the sun, especially fro
10 a.m.—2 p.m.

• wear long-sleeved shirts, parts,
hats, and sunglasses
• hats, and sunglasses
Ask a dodor Drug Facts (continued)

thylenediamine di: pric triglyceride, si polysorbate 60, p

(C00E F.I.L.: V700

hydroxyethyl methoxycryle wax, butylen hydroxyaceto acid, diethyll

Drug Facts (continued)

container

Other information

• protect the product in this contain excessive heat and direct s

Drug Facts (continued)

12M SKINCEUTICALS SkinCeuticals LLC Dallas, TX 75241 Made in USA of US



SKINCEUTICALS CLEAR DAILY SOOTHING UV DEFENSE DAILY SUNSCREEN BROAD SPECTRUM SPF 50

homosalate, octisalate, octocrylene and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-992
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	70 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	

PROPANEDIOL (UNII: 5965N8W85T) **BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)** STEARETH-20 (UNII: L0Q8IK9E08) ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8) RICE BRAN (UNII: R60QEP13IC) **BUTYLENE GLYCOL** (UNII: 3XUS85K0RA) STEARETH-2 (UNII: V56DFE46J5) LEVOMENOL (UNII: 24WE03BX2T) HYDROXYACETOPHENONE (UNII: G1L3HT4CMH) POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) **DIETHYLHEXYL SYRINGYLIDENEMALONATE** (UNII: 3V5U97P248) CHLORPHENESIN (UNII: 1670DAL4SZ) CAPRYLYL GLYCOL (UNII: 00YIU5438U) HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S **AT 1.5%)** (UNII: 86FQE96TZ4) CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) XANTHAN GUM (UNII: TTV12P4NEE) TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q) MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) **SORBITAN ISOSTEARATE** (UNII: 01S2G2C1E4) POLYSORBATE 60 (UNII: CAL22UVI4M) PALMITOYL TRIPEPTIDE-8 (UNII: 55HZC7YQA7) **DEXTRAN 40** (UNII: K3R6Z DH4DU)

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-992- 01	1 in 1 CARTON	05/01/2024	
1		30 mL in 1 JAR; Type 0: Not a Combination Product		
2	NDC:49967-992- 02	4 mL in 1 TUBE; Type 0: Not a Combination Product	05/01/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/01/2024	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment				
Name	Address	ID/FEI	Business Operations	
Beauty Manufacturing Solutions Corp.		783200723	manufacture(49967-992)	

Revised: 7/2024 L'Oreal USA Products Inc