

DERMATOUCH HYDRATING CLEAR MOISUTRIZER SPF 25- avobenzone, homosalate, octisalate lotion
Spa de Soleil

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.

Dermatouch Hydrating Clear Moisutrizer SPF 25

Active Ingredients

Avobenzone 3.0%

Homosalate 15.0%

Octisalate 5.0%

Purpose

Sunscreen

Warnings

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 or irritation occurs or lasts.
- . If swallowed, seek medical help or contact a poison control center right away.
- . Keep out of reach of children.
- . Jar is glass and may shatter if dropped.

Directions

Directions: Apply generously and evenly thirty minutes before sun exposure. Reapply at least every two hours. Use a water-resistant sunscreen if swimming or sweating.
Children under six months of age: Consult a doctor.

Inactive Ingredients

Inactive Ingredients: Aqua, SD Alcohol 40-B, Glycerin, Cetearyl Ethylhexanoate, Ammonium Polyacryloyldimethyl Taurate, *CO Glycerin, *CO Humulus Lupulus (Hops) Extract, *CO Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, *CO Calendula Officinalis Flower Extract, *CO Chamomilla Recutita (Matricaria) Flower Extract, *CO Citrus Limon (Lemon) Peel Extract, *CO Cucumis Sativus (Cucumber) Seed Extract, *CO

Camellia Sinensis Leaf Extract, *CO Pyrus Malus (Apple) Fruit Extract, *CO Spirulina Platensis Extract, Phenoxyethanol, Ethylhexylglycerin *Certified Organic

Uses: . Helps prevent sunburn. . Higher SPF gives more sunburn protection. . 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.

KEEP OUT OF REACH OF CHILDREN

Principal Display Panel

Dermatouch[®]
**HYDRATING
 CLEAR
 MOISTURIZER**
 BROAD SPECTRUM SPF 25

Drug Facts

Active Ingredients:	Purpose:
Azobenzene 3.0%	Sunscreen
Homosalate 15.0%	Sunscreen
Octisalate 5.0%	Sunscreen

Uses: • Helps prevent sunburn. • Higher SPF gives more sunburn protection. • 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 or irritation occurs or lasts. • If swallowed, seek medical help or contact a poison control center right away. • Keep out of reach of children. • Jar is glass and may shatter if dropped.

Directions: Apply generously and evenly thirty minutes before sun exposure. Reapply at least every two hours. Use a water-resistant sunscreen if swimming or sweating.
 Children under six months of age: Consult a doctor.
 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.

Other Information: Protect the product in this container from excessive heat.

Inactive Ingredients: Aqua, SD Alcohol-40-B, Glycerin, Cetearyl Ethylhexanoate, Ammonium Polyacryloyldimethyl Taurate, *CO Glycerin, *CO Humulus Lupulus (Hops) Extract, *CO Lavandula Angustifolia (Lavender) Flower/Leaf/STEM Extract, *CO Calendula Officinalis Flower Extract, *CO Chamomilla Recutita (Matricaria) Flower Extract, *CO Citrus Lemon (Lemon) Peel Extract, *CO Cucumis Sativus (Cucumber) Seed Extract, *CO Camellia Sinensis Leaf Extract, *CO Pyrus Malus (Apple) Fruit Extract, *CO Spinulisa Platensis Extract, Phenoxethanol, Ethylhexylglycerin
 *Certified Organic

Made in USA DCMSPF2522-B
 Manufactured by Spa de Soleil, Inc.
www.homespacollection.com



**THIS LIGHTWEIGHT
 SPF MOISTURIZER
 PROVIDES DAILY
 HYDRATION**

**MINERAL OIL-FREE • FRAGRANCE-FREE
 PHTHALATE-FREE • PARABEN-FREE
 CRUELTY-FREE • DYE-FREE**



Dermatouch[®]
**HYDRATING
 CLEAR
 MOISTURIZER**



**AIRLESS, FINGERLESS,
 HYGIENIC APPLICATION
 CLEAN, SAFE, & EASY TO USE**

BROAD SPECTRUM SPF 25

2 fl. oz. | 59 mL



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avobenzone, homosalate, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-8309
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.5 mg in 50 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 mg in 50 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7.5 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)	
MATRICARIA CHAMOMILLA LEAF (UNII: 6I9LN466F0)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-8309-1	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/18/2022	

Labeler - Spa de Soleil (874682867)

Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-8309)

Revised: 1/2022

Spa de Soleil