

OCEAN POTION 50 INSTANT DRY KID SPOTSTICK - avobenzone, homosalate, octisalate, octocrylene liquid

Sun & Skin Care Research, LLC

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.

Drug Facts

Active Ingredients

Homosalate: 15%

Octisalate: 5%

Octocrylene: 7%

Avobenzone: 3%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- If used as directed with other skin 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. **Stop use and ask a doctor if** rash occurs. **When using this product** keep out of eyes. Rinse with water to remove. **Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. **Flammable** Do not use near heat or open flames. Keep treated skin away from fire, sparks or flames until dry.

Directions

- Apply liberally 15 minutes before sun exposure, depress sponge top to initiate product application
- reapply after 80 minutes of swimming or sweating and 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 limiting time in the sun, especially from 10a.m.-2p.m., wear long-sleeved shirts, pants hats and sunglasses.
- children under 6 months: Ask a doctor

Other Information

- For use on skin only
- Avoid contact with fabric
- Protect this product from excessive heat and direct sun

Ocean Potion® Broad Spectrum SPF 50+ KidSpot™ Dab-On Stick is an easy to use, portable sunscreen solution. The dab-on applicator is convenient, with a long lasting, highly water resistant formula that stays where you put it. Designed for older, active children, its freshly scented pineapple mango fragrance makes application fun and easy to repeat.

Fruity Fragrance

- **Easy to Apply**
- **Dab-On Application**
- **Dries Instantly**
- **Matte Finish - No Greasy Look or Feel**

Face • Nose • Ears • Scalp

Drug Facts

Active ingredients	Purpose
Avobenzone: 3.0%, Homosalate 15.0%, Octisalate: 5.0%, Octocrylene: 7.0%	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 product is swallowed, get medical help or contact a Poison Control Center right away

Do not use near heat or open flames. Keep treated skin away from fire, sparks or flames until dry

Directions

- Apply liberally 15 minutes before sun exposure, depress sponge top to initiate product application

Drug Facts (continued)

• reapply:

- after 80 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: Ask a doctor

Inactive Ingredients

Acrylates / Octylacrylamide Copolymer, Cholecalciferol, Denatured Alcohol, Dimethyl Capramide, Fragrance, Glycerin, Polyester-8

Other Information

- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-800-715-3485



Manufactured and Distributed By:
Sun and Skin Care Research, Inc.
 851 Greensboro Rd. | Cocoa, FL 32926
www.oceanpotion.com Made in U.S.A.



0 00774 00581 2



Broad Spectrum
SPF 50+

50+
INSTANT DRY
KID SPOTTM

Non-Greasy
Sunscreen for:

Face • Nose
Ears • Scalp

now:

- ✓ Hypo-Allergenic
- ✓ Oxybenzone Free
- ✓ Paraben Free
- ✓ Vitamin D₃ Fortified

.65 FL OZ (19mL)

Dab-On

Fruity
Fragrance

- Pediatrician Recommended
- Water Resistant (80 minutes)



DAB-ON STICK
KID SPOT

Broad Spectrum SPF 50+

50+

Drug Facts

Active Ingredients

Avobenzone 3.0%, Homosalate 15.0%,
 Octisalate 5.0%, Octocrylene 7.0%

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 ■ **Stop use and ask a doctor if** rash occurs ■ **When using this product** keep out of eyes. Rinse with water to remove. ■ **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

■ **Do not use near heat or open flames.** Keep treated skin away from fire, sparks or flames until dry

Directions ■ Apply liberally 15 minutes before sun exposure, depress sponge top to initiate product application ■ reapply • after 80 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: Ask a doctor

Inactive Ingredients Acrylates / Octylacrylamide Copolymer,

Cholecalciferol, Denatured Alcohol, Dimethyl Capramide, Fragrance, Glycerin, Polyester-8

Other Information For use on skin only. Avoid contact with fabric • protect this product from excessive heat and direct sun

Mfd. & Dist. by: **Sun and Skin Care Research, Inc.**

851 Greensboro Rd. | Cocoa, FL 32926 | 1-800-715-3485

www.oceanpotion.com Made in U.S.A.

OCEAN POTION 50 INSTANT DRY KID SPOTSTICK

avobenzone, homosalate, octisalate, octocrylene liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62802-581
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 mL in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mL in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 mL in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62802-581-01	19 mL in 1 BOTTLE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2012	

Labeler - Sun & Skin Care Research, LLC (849772207)

Establishment

Name	Address	ID/FEI	Business Operations
Sun & Skin Care Research, LLC		849772207	manufacture

Revised: 5/2012

Sun & Skin Care Research, LLC