

**SOL-OR KIDS BROAD SPECTRUM SPF- avobenzone, homosalate, octisalate, octocrylene spray
Prime Packaging, Inc.**

Sol-or Broad Spectrum SPF 50 Continuous Spray Sunscreen

Active Ingredients

Avobenzone 3%

Homosalate 15%

Octisalate 5%

Octocrylene 2.75%

Purpose

Sunscreen

Uses

- Continued use of sunscreen can reduce the risk of cancer and premature skin aging caused by the sun. (see ***Directions***)

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. Keep away from face to avoid breathing it. Contents under pressure- do not puncture or incinerate.

Do not store at temperatures above 120°F.

Stop use and ask 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.

Flammable

Do not use near heat, flame or while smoking.

Directions

- Spray liberally and spread evenly by hand 15 minutes before sun exposure, hold container 4 to 6 inches from the skin to apply, do not spray directly into face. Spray on hands then apply to face, do not apply in windy conditions, use in a well-ventilated area
- **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 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-sleeve shirts, pants, hats, and sunglasses
 - Children under 6 months: Ask a doctor

Inactive Ingredients

Aloe Barbadensis Extract, Cocos Nucifera (Coconut) Oil, Diethylhexyl 2,6-Naphthalate, Fragrance (Parfum), Isopropyl Alcohol, Mineral Oil (Paraffinum Liquidum), Polyester-8, SD Alcohol 40-B (Alcohol Denat.), VA/Butyl Maleate/Isobornyl Acrylate Copolymer

Other Information

- Protect this product from excessive heat and direct sun.
- Avoid spraying on fabrics-could cause discoloration.

Question or comments?

Medellin: 266 9131 Colombia: 01 8000 9 76567 SOLOR sol-or.com

Mercadeo@quifarma.com

NO-AD Sunscreen Broad Spectrum SPF 30 Continuous Spray

UVA
UVB
PROTECTION

**Continuous
Spray
Sunscreen**

sol-or®

ESP Equatorial Sun Protection **Kids**

BROAD SPECTRUM SPF 50+
AMPLIO ESPECTRO FPS 50+

Water Resistant (80 Minutes)
Resistente al Agua (80 Minutos)

Infantil

with Aloe Vera and Coconut Oil
con Sábila y Aceite de Coco
177mL 6 Fl. Oz.

Drug Facts / Información

Active Ingredients / Ingredientes Activos
 Avobenzone 3%, Homosalate 15% }
 Octisalate 5%, Octocrylene 2,75% } **Purpose / Propósito**
 Sunscreen / Protector Solar

Uses / Uso

- Continued use of sunscreen can reduce the risk of cancer and premature skin aging caused by the sun. (see **Directions**)
- El uso continuo del bloqueador solar puede disminuir el riesgo de cáncer y el envejecimiento prematuro de la piel causados por el sol. (ver **Indicaciones**)

Warnings / Precauciones

- For external use only.** / Solo para uso externo.
- Do not use** on damaged or broken skin.
- No utilizar** sobre piel lastimada o herida.
- When using this product** keep out of eyes. Rinse with water to remove. Keep away from face to avoid breathing it. Contents under pressure – do not puncture or incinerate. Do not store at temperatures above 120°F.
- Cuando use este producto** manténgalo alejado de los ojos. Lavar con agua para remover. Mantener lejos de la cara para evitar inhalarlo. No almacene a temperaturas por encima de 48°C. Contenido bajo presión – no perforar o incinerar.
- Stop use** and ask a doctor if rash occurs
- Descontinuar el uso** y consultar a un doctor en caso de irritación
- Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.
- Mantenga fuera del alcance de los niños. En caso de ingestión, buscar ayuda médica o contactar inmediatamente un Centro de Control por Envenenamiento
- Flammable.** Do not use near heat, flame or while smoking.
- Inflamable.** No utilice cerca de calor, llama o al fumar.

Directions / Indicaciones de Uso

- Spray liberally and spread evenly by hand 15 minutes before sun exposure, hold container 4 to 6 inches from the skin to apply, do not spray directly into face. Spray on hands then apply to face, do not apply in windy conditions, use in a well-ventilated area
- Reapply:**
 - After 80 minutes of swimming or sweating,
 - Immediately after towel drying
 - At least every 2 hours
- Rocie abundantemente y distribuya uniformemente con las manos 15 minutos antes de exponerse al sol. Aplique a 4-6 pulgadas de la piel. No utilizar el spray directamente en la cara. Rocie en las manos y luego aplíquelo en el rostro. No lo aplique en lugares donde haya mucho viento. Utilícelo en zona con buena ventilación.
- Reaplique después de 80 minutos de nadar o sudar. Inmediatamente después de secarse.
- Y por lo menos cada dos horas mientras este expuesto al sol.

Sun Protection Measures / Medidas de protección solar.

- 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 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-sleeve shirts, pants, hats and sunglasses.
 - Children under 6 months: Ask a doctor / La exposición al sol aumenta el riesgo de cáncer y el envejecimiento precoz de la piel. Para disminuir este riesgo use regularmente un protector solar de amplio espectro SPF15 o más alto y otras medidas de protección contra el sol incluyendo: Limitar el tiempo en el sol, especialmente de 10 a.m. – 2 p.m. Usar gafas de sol, pantalones, sombreros y camisetas de manga larga.
- Niños menores de 6 meses: Consultar a un doctor

Inactive ingredients / Ingredientes inactivos
 Aloe Barbadensis Extract, Cocos Nucifera (Coconut) Oil, Diethylhexyl 2,6-Naphthalate, Fragrance (Parfum), Isopropyl Alcohol, Mineral Oil (Paraffinum Liquidum), Polyester-8, SD Alcohol 40-B (Alcohol Denat.), VA/Butyl Maleate/Isobornyl Acrylate Copolymer

Other information / Información adicional

- Protect this product from excessive heat and direct sun.
- Avoid spraying on fabrics—could cause discoloration.
- Proteger este producto del calor excesivo y el sol directo.
- Evite usar el spray sobre la ropa ya que puede manchar algunos tejidos.

Question or comments? / ¿ Preguntas o comentarios?
 Medellín: 266 9131 Colombia: 01 8000 9 76567
 mercadeo@quifarma.com sol-or.com
 Elaborado por: Prime Enterprises, Inc. 16363, NW 49 Ave. Miami, Florida 33014 USA
 NSOC51394-12CO

Importado por:
Quifarma
Calle 61 No. 51D 53
Medellín - Colombia

sol-or®

SOL-OR KIDS BROAD SPECTRUM SPF
 avobenzone, homosalate, octisalate, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0283
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	126.75 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	23.24 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	42.25 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.35 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color	yellow (Light Yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0283-4	149 g in 1 CAN; Type 0: Not a Combination Product	09/20/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	09/20/2022	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0283) , label(13630-0283) , analysis(13630-0283) , pack(13630-0283)

Establishment

Name	Address	ID/FEI	Business Operations
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Prime Packaging, Inc.

805987059

label(13630-0283) , pack(13630-0283)

Revised: 12/2023

Prime Packaging, Inc.