

**PREBEL NUDE PROTECT SPF 70 SUNSCREEN- avobenzene, homosalate, octisalate, oxybenzone and octocrylene spray**  
**Prime Packaging Inc.**

*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.*

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**Nude Protect SPF 70 Sunscreen Spray**

***Active Ingredients***

Avobenzene 3%

Homosalate 12.5%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 6%

Sunscreen

Diethylhexyl 2,6-Naphthalate, Fragrance, Polyester-8, SD Alcohol 40-B, VA/Butyl Maleate/Isobornyl Acrylate Copolymer

***Uses***

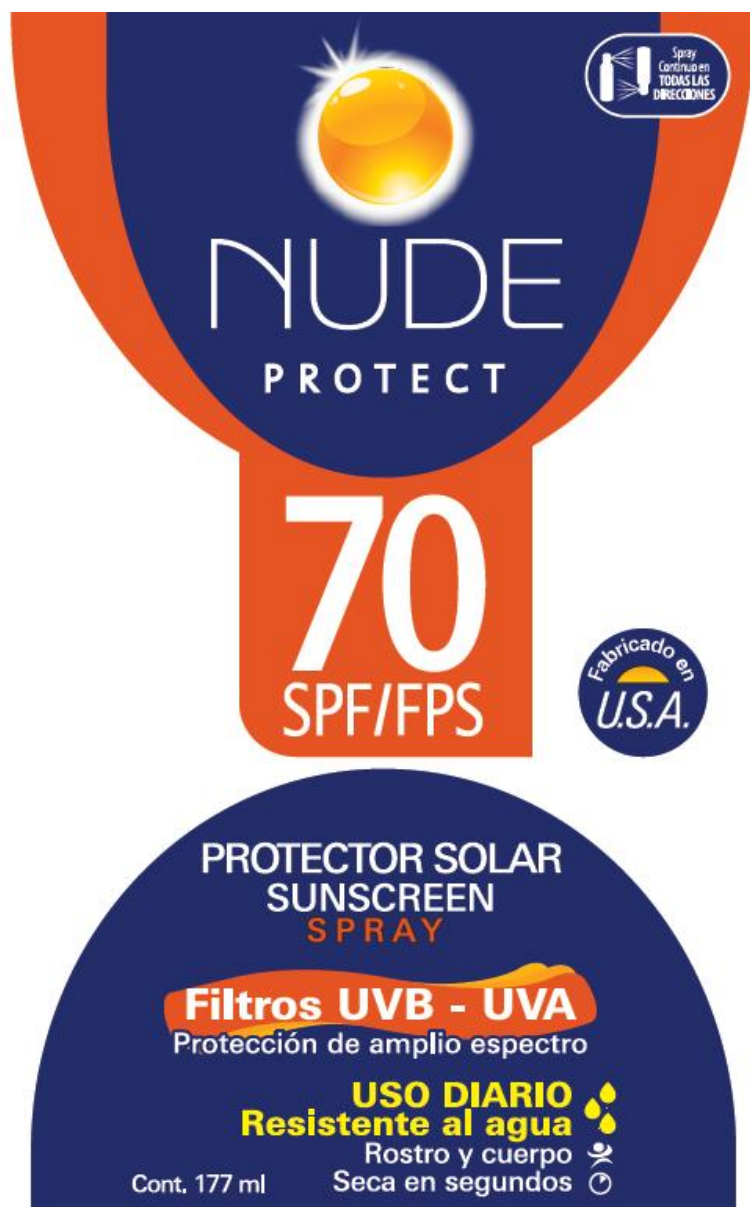
*\*Helps prevent sunburn*

*For external use only. When using this product avoid contact with eyes, if so, rinse with water to remove. Stop use and ask a doctor if irritation or rash occurs. Keep out of reach of children. Flammable, do not use near heat or flame. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 40°C (104°F).*

***Directions***

*Apply generously to all areas 15 minutes before sun exposure. Spray into hands to apply to face, do not spray directly. Reapply as needed or after towel drying. Ask a doctor before use on children under 6 months of age. Limit sun exposure, wear protective clothing. This product may stain some fabrics.*

**Nude Protect SPF 70 Sunscreen Spray**



**NUDE PROTECT**

**Nude Protect SPF/FPS 70** con factor de protección 70 en SPRAY es una fórmula de rápida absorción, con filtros solares UVA/UVB. Con **Nude Protect SPF/FPS 70** en SPRAY, podrás disfrutar todas las actividades de tu día a día!

**Nude Protect SPF/FPS 70 in SPRAY** is a fast absorption formula with UVA/UVB filters. With **Nude Protect SPF/FPS 70 in SPRAY** you will enjoy your activities all day long!

<b>Drug Facts:</b>	<b>Purpose</b>
<b>Active Ingredients:</b> Avobenzone 3%, Homosalate 12.5%, Octisalate 5%, Octocrylene 2.75%, Oxybenzone 6%.	Sunscreen
<b>Inactive Ingredients:</b> Diethylhexyl 2,6-Naphthalate, Fragrance, Polyester-8, SD Alcohol 40-8, VA/Butyl Maleate/Isobornyl Acrylate Copolymer	

**Usos:** \*Protege de quemaduras solares.  
**Uses:** \*Helps prevent sunburn.

**Precauciones:** Exclusivo para uso externo. Evita el contacto con los ojos, si esto ocurre lava con abundante agua. En caso de presentar signos de irritación o rasquiña suspende su uso y consulta con el dermatólogo. Mantén el producto fuera del alcance de los niños. Producto inflamable, no esparcir sobre llamas. No perforar o incinerar el envase. Contenido bajo presión. No lo almacenes a temperaturas superiores a los 40 °C (104 °F).  
**Warnings:** For external use only. When using this product avoid contact with the eyes, if so, rinse with water to remove. Stop use and ask a doctor if irritation or rash occurs. Keep out of reach of children. Flammable, do not use near heat or flame. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 40 °C (104 °F).

**Modos de uso:** Aplica generosamente en todas las partes del cuerpo 15 minutos antes de la exposición al sol. Rocía sobre las manos para aplicarlo en la cara, no lo apliques directamente. Reaplica el producto en intervalos frecuentes y después de nadar o secarse con toalla. Consulta al pediatra antes de aplicarlo en niños menores de 6 meses. Limita la exposición al sol. Usa ropa de protección. Este producto puede manchar algunas telas.  
**Directions:** Apply generously to all areas 15 minutes before sun exposure. Spray into hands to apply to the face, do not spray directly. Reapply as needed or after towel drying. Ask a doctor before use on children under 6 months of age. Limit sun exposure, wear protective clothing. This product may stain some fabrics.



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## PREBEL NUDE PROTECT SPF 70 SUNSCREEN

avobenzone, homosalate, octisalate, oxybenzone and octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13630-0096
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.6 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	106.5 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	42.6 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	23.43 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	51.12 mg in 1 mL

Inactive Ingredients				
Ingredient Name				Strength
ALCOHOL (UNII: 3K9958V90M)				
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)				
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)				
DIBUTYL MALEATE (UNII: 4X371TMK9K)				
Product Characteristics				
Color	yellow	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0096-4	177 mL in 1 CAN; Type 0: Not a Combination Product	03/07/2012	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	03/07/2012		

**Labeler** - Prime Packaging Inc. (805987059)

**Registrant** - Prime Packaging Inc. (805987059)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	manufacture(13630-0096) , analysis(13630-0096)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0096) , label(13630-0096)