GLYTONE DAILY BODY- avobenzone, octinoxate, octocrylene, oxybenzone lotion Pierre Fabre USA Inc.

Glytone Daily Body Lotion Broad Spectrum SPF 15

Drug Facts

Active Ingredients

Avobenzone 2%

Octinoxate 7.5%

Octocrylene 1.86%

Oxybenzone 3%

Purpose

Sunscreen

Use

Helps prevent sunburn

Warnings

- For external use only.
- **Sunburn alert:** This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for one week afterwards.

Do not use

- as a sunscreen for sunbathing.
- 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. Do not swallow.

If swallowed, get medical help or contact a Poison Control center right away.

Directions

- Apply Daily Body Lotion once daily or as directed by a doctor at least 15 minutes before sun exposure.
- At least every 2 hours apply a sunscreen with broad spectrum SPF 15 or higher for sun protection.
- 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 the risk, regulatory use a sunscreen with a broad spectrum SPF 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.

Other information

- Protect this product from excessive heat and direct sun.
- May stain fabrics.

Inactive ingredients

Water, Glycolic Acid, C12-15 Alkyl Benzoate, Cyclopentasiloxane, Sodium Hydroxide, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Cetearyl Alcohol, Cyclotetrasiloxane, PEG-40 Stearate, Butyrospermum Parkii (Shea) Butter, C13-14 Isoparaffin, Cetearyl Glucoside, Cetyl Alcohol, Cholesterol, Dimethiconol, Disodium EDTA, Laureth-7, Methylparaben, Phenoxyethanol, Polyacrylamide, Tocopheryl Acetate, Xanthan Gum.

Principal Display Panel 355 mL / 12 FL. OZ.

GLYTONE

Daily Body Lotion

Broad Spectrum SPF 15

Glycolic Acid Complex

355 mL / 12 FL. OZ



Drug Facts	Ш	Drug Facts (
Active ingredients Purpose Avobenzone 2 % Sunscreen Octinoxate 7,5 % Sunscreen Octorylene 1.86 % Sunscreen Oxybenzone 3 % Sunscreen		Directions Apply Daily Body at least 15 minut higher for sun prof swimming or sweatime in the sun in
Use ■ Helps prevent sunburn		skin aging. To decr a broad spectrum measures includin
Warnings For external use only, Sunburn alert: This product		 limit time in the wear long sleeve
contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for one week		Other inform = Protect this pro = May stain fabric
afterwards. = Do not use * as a sunscreen for sunbathing. • 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, Do not swallow, if swallowed, get medical help or contact a Poison Control center right away.		Inactive ingu WATER, GLYCOLIX BENZOATE, CYCLO HYDROXIDE, GLYCE PEG-100 STEARAT CYCLOTETRASILOX

Pierre Fabre Dermo-Cosmétique Distributed by: Pierre Fabre USA, Inc.
Parsippany, NJ 07054 800-GLYTONE (459-8663)
www.glytone.com

continued)

by Lotion once daily or as directed by a doctor ties before sun exposure, # At least every sunscreen with broad spectrum SPF 15 or ptection. # Use a water resistant sunscreen if tating # Sun Protection Measures, Spending noreases your risk of skin cancer and early rease the risk, regularly use a sunscreen with SPF 15 or higher and other sun protection no:

ng: ne sun, especially from 10 a.m. - 2 p.m. ve shirts, pants, hats, and sunglasses.

nation

duct from excessive heat and direct sun. ■ May stain fabrics.

Inactive ingredients
WATER, GLYCOLIC ACID, C12-15 ALKYL
BENZOATE, CYCLOPENTASLOXANE, SODLIM
HYDROXDE, GLYCENN, GLYCENY, STEARATE,
PES-100 STEARATE, CETEARYL ALCOHOL,
CYCLOTETRASLOXANE, PEG-40 STEARATE,
BUTYROSPERMUM, PARXII (SHEA), BUTTER,
C13-41 SUPPARAFTIN, CETEARYL, GLUCOSIDE,
CEYL ALCOHOL, CHOLESTEROL, DIMENBOONOL,
DISCOBLIM EDTA, LAURETH-7, METHYLPARASEN,
PHENDOXYETHANOL, POLYAGRYLAMIDE,
TOCOPHERYL ACETATE, XANTHAN GUM.



GLYTONE DAILY BODY

avobenzone, octinoxate, octocrylene, oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64760-713
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	3 g in 100 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.86 g in 100 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)		
CYCLOMETHICONE 4 (UNII: CZ227117JE)		
PEG-40 STEARATE (UNII: ECU18C66Q7)		
SHEA BUTTER (UNII: K49155WL9Y)		
LAURETH-7 (UNII: Z95S6G8201)		
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)		
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)		
CHOLESTEROL (UNII: 97C5T2UQ7J)		
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
DIMETHICONOL (100000 CST) (UNII: OSA9UP217S)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
WATER (UNII: 059QF0KO0R)		

CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 5 (UNII: 0THT5PCIOR)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:64760-713-01	355 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/03/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/03/2017	07/26/2025

Labeler - Pierre Fabre USA Inc. (117196928)

Registrant - Pierre Fabre USA Inc. (117196928)

Revised: 1/2024 Pierre Fabre USA Inc.