BAIN DE SOLEIL MEGA TAN SPF 4- octinoxate and octocrylene lotion Bayer HealthCare 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.

Bain de Soleil®

Mega Tan ® SPF 4

Drug Facts

Active ingredient

Octinoxate 3.5%, Octocrylene 1%

Purpose

Sunscreen

Use

helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

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.

Directions

• use sparingly around hairline and eyebrows. Blend completely to avoid streaking. Wash and wipe hands immediately after each application

For Sunscreen Use

• apply liberally 15 minutes before sun exposure

- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: Ask a doctor

Other information

- protect this product from excessive heat and direct sun
- may stain or damage some fabrics or surfaces
- store at or below room temperature

Inactive ingredients

water, butylene glycol, cyclopentasiloxane, polyquaternium-37, mineral oil, PPG-1 trideceth-6, VP/eicosene copolymer, isohexadecane, tribehenin, cetyl palmitate, fragrance, distearyldimonium chloride, aloe barbadensis leaf extract, eucalyptus globulus leaf extract, prunus armeniaca (apricot) fruit extract, chamomilla recutita (matricaria) flower extract, theobroma cacao (cocoa) extract, elaeis guineensis (palm) kernel oil, lanolin, iodopropynyl butylcarbamate, DMDM hydantoin, cetyl alcohol, cetyl hydroxyethylcellulose, disodium EDTA, dihydroxyacetone

Questions?

866-288-3330

PRINCIPAL DISPLAY PANEL - 118 mL Tube Carton

BAIN de SOLEIL ®

MEGA TAN ®

4 spf

sunscreen with self tanner

faster, darker tan contains a self tanner moisturizers & botanicals

4 FL OZ (118mL)



BAIN & SOLEIL" MEGA TAN "

spf 4 | sunscreen with self tanner

Get your deepest most luxurious color

- Exclusive formula with self tanner to help you develop a deep, gorgeous, long-lasting tan
- Unique blend of moisturizers and botanical extracts to help keep skin soft and smooth
- · PABA-free, dermatologist tested

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Questions? 866-288-3330



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BAIN SOLEIL®

MEGA TAN®

spf 4

sunscreen with self tanner



BAIN SOLE II.



BAIN SOLEIL®

MEGA TAN®

spf 4

sunscreen with self tanner

MEGA TAN®



SUNSCIEEN with self tanner

faster, darker tan contains a self tanner moisturizers & botanicals

4 FL 0Z (118mL)

octinoxate and octocrylene lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11523-7094

Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	35 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
TRIBEHENIN (UNII: 80C9U7TQZ0)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
APRICOT (UNII: 269CJD5GZ9)	
CHAMOMILE (UNII: FGL3685T2X)	
COCOA (UNII: D9108TZ9KG)	
PALM KERNEL OIL (UNII: B0S90M0233)	
LANOLIN (UNII: 7EV65EAW6H)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIHYDROXYACETONE (UNII: O10DDW6JOO)	

Product Characteris	itics	
Color	white (off white)	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

Marketing In Marketing Category	nformation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Marketing I	nformation		
Marketing Information			
	118 mL in 1 TUBE; Type 0: Not a Combination Product		
7094-1	1 in 1 CARTON	05/21/1999	04/30/2021

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 9/2023 Bayer HealthCare LLC.