

EVERY MAN JACK SPF 30 SUNSCREEN- octisalate, avobenzone, homosalate, octocrylene lotion
Prime Enterprises 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.

Every Man Jack SPF 30 Body Lotion

Active Ingredients

Avobenzone 3%

Octocrylene 5%

Homosalate 7.5%

Octisalate 5%

INACTIVE INGREDIENTS

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Butyrospermum Parkii (Shea) Butter, C12-15 Alkyl Benzoate, Carbomer, Ethylhexylglycerin, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Tetrasodium Glutamate Diacetate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

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 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.

Purpose

Sunscreen

Directions

- apply liberally 15 minutes before sun exposure
- 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 10am-2pm
 - wear long sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Other Information

- protect this product from excessive heat and direct sun

Questions or Comments?

877-875-5225, 9-5 PST weekdays.

Every Man Jack SPF 30 Fragrance Free Sun Protection Lotion

NEW

EVERY MAN JACK.

body defense | sun protection lotion

FRAGRANCE FREE SPF 30

defend.

Protect your body against the sun's harmful rays with this water and sweat resistant SPF 30 body lotion. Enriched with Vitamin E and aloe, this easy-to-rub-in lotion is great for everyday use. Ocean and reef safe.

free.

We strive to use as many clean ingredients as possible while still delivering exceptional performance. Free of oxybenzone, octinoxate, fragrance, parabens, phthalates, and dyes. Never tested on animals.

Drug Facts**Active Ingredients**

Avobenzone 3%, Homosalate, 7.5%, Octisalate 5%, Octocrylene 5%

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. • 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions • Apply liberally 15 minutes before sun exposure. • 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. to 2 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses. • Children under 6 months: ask a doctor.

Inactive Ingredients • Acrylates/C10-30 Alkyl Acrylate Copolymer, Aloe Barbadosis Leaf Juice, Butyrospermum Parkii (Shea) Butter, C12-15 Alkyl Benzoate, Carbomer, Ethylhexylglycerin, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Tetrasodium Glutamate Diacetate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

Other Information • Protect this product from excessive heat and direct sun.

Questions or Comments • 877-875-5225, 9-5 PST weekdays.

MADE IN THE USA FROM DOMESTIC AND IMPORTED INGREDIENTS AND COMPONENTS ©2020

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**EVERY MAN JACK.**body defense
sun protection lotion

30

FRAGRANCE FREE
SUNSCREEN
BROAD SPECTRUM SPF 30
WATER/SWEAT RESISTANT
(80 MINUTES)
OCEAN AND REEF SAFE



6.7 FL OZ e 200 mL

EVERY MAN JACK SPF 30 SUNSCREEN

octisalate, avobenzone, homosalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0360
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	75.75 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50.5 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.3 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
COCOA BUTTER (UNII: 512OYT1CRR)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
SHEA BUTTER (UNII: K49155WL9Y)	

Product Characteristics

Color	white (Off white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0360-4	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/04/2020	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	pack(58443-0360) , manufacture(58443-0360) , label(58443-0360) , analysis(58443-

