

**HYDRATING BODY SUNSCREEN- homosalate, octocrylene, octisalate, avobenzone lotion
frank body**

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.

Hydrating Body Sunscreen

Drug Facts

Active ingredients

Homosalate 10%

Octocrylene 8%

Octisalate 5%

Avobenzone 3%

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 generously and evenly 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 10a.m.-2p.m.
 - Wear long sleeve shirts, pants, hats and sunglasses
 - Children under 6 months of age: Ask a doctor

Inactive ingredients

Water, Beeswax, Isopropyl Palmitate, Cetearyl Alcohol, Cyclopentasiloxane, Cyclohexasiloxane, Cetareth-20, Hydroxyacetophenone, Carbomer, Benzyl Alcohol, Phenoxyethanol, Sodium Stearoyl Glutamate, Triethanolamine, Simmondsia Chinese Seed Oil, Rubus Idaeus Seed Oil, Tocopheryl Acetate, Sodium Hyaluronate, Parfum, Glycerin, Maltodextrin, Aloe Barbadensis Leaf Juice, Terminalia Ferdinandiana Fruit Extract, Citric acid

Other information

Protect the product in this container from excessive heat and direct sun

Questions or comments?

Contact us at **frankbody.com**

frank body

SPF 50+

HYDRATING BODY SUNSCREEN

UVA + UVB Broad Spectrum SPF 50+

With hyaluronic acid

Fast absorbing

Water resistant (80 minutes)

4.73 fl oz - 140 ml

Distributed by frank body: 33 Cremorne Street

Cremorne VIC 3121 Australia / frank body, LLC:

1145 Broadway, Floor 4 New York, NY 10001, USA

Made in Australia

frank body



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82975-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	80 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	

CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
KAKADU PLUM (UNII: 0ZQ1D2FDLI)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)
RUBUS IDAEUS SEED (UNII: M3CL7US2ZG)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
GLYCERIN (UNII: PDC6A3C0OX)
WATER (UNII: 059QF0K00R)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)
TROLAMINE (UNII: 9O3K93S3TK)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
JOJOBA OIL (UNII: 724GKU717M)
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)
BENZYL ALCOHOL (UNII: LKG8494WBH)
MALTODEXTRIN (UNII: 7CVR7L4A2D)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82975-101-01	140 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/31/2022	

Labeler - frank body (747810740)

Revised: 12/2022

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