HYDRATING BODY SUNSCREEN UVA AND UVB BROAD SPECTRUM SPF50-
homosalate, octocrylene, octisalate, avobenzone cream
Baxter Laboratories Pty. Ltd.

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 UVA and UVB Broad Spectrum SPF50

Active ingredients Purpose

Homosalate 10% .....Sunscreen

Octocrylene 8% .....Sunscreen

Octisalate 5% .....Sunscreen

Avobenzone 3% .....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

Keep our of reach of children.

Stop use and ask a doctor if rash occurs

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.
- 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, Isopropryl Palmitate, Cetearyl Alcohol, Cyclopentasiloxane, Cyclohexasiloxane, Ceteareth-20, Hydroxyacetophenone, Carbomer, Benzyl Alcohol, Phenoxyethanol, Sodium Stearoyl Glutamate, Triethanolamine, Simmondsia Chinensis

Seed Oil, Rubus Idaeus Seed Oil, Tocopheryl Acetate, Sodium Hyaluronate, Parfum, Glycerin, Maltodextrin, Aloe Barbadensis Leaf Juice, Terminalia Ferdinandiana Fruit Extract, Citric Acid

Other informaiton 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

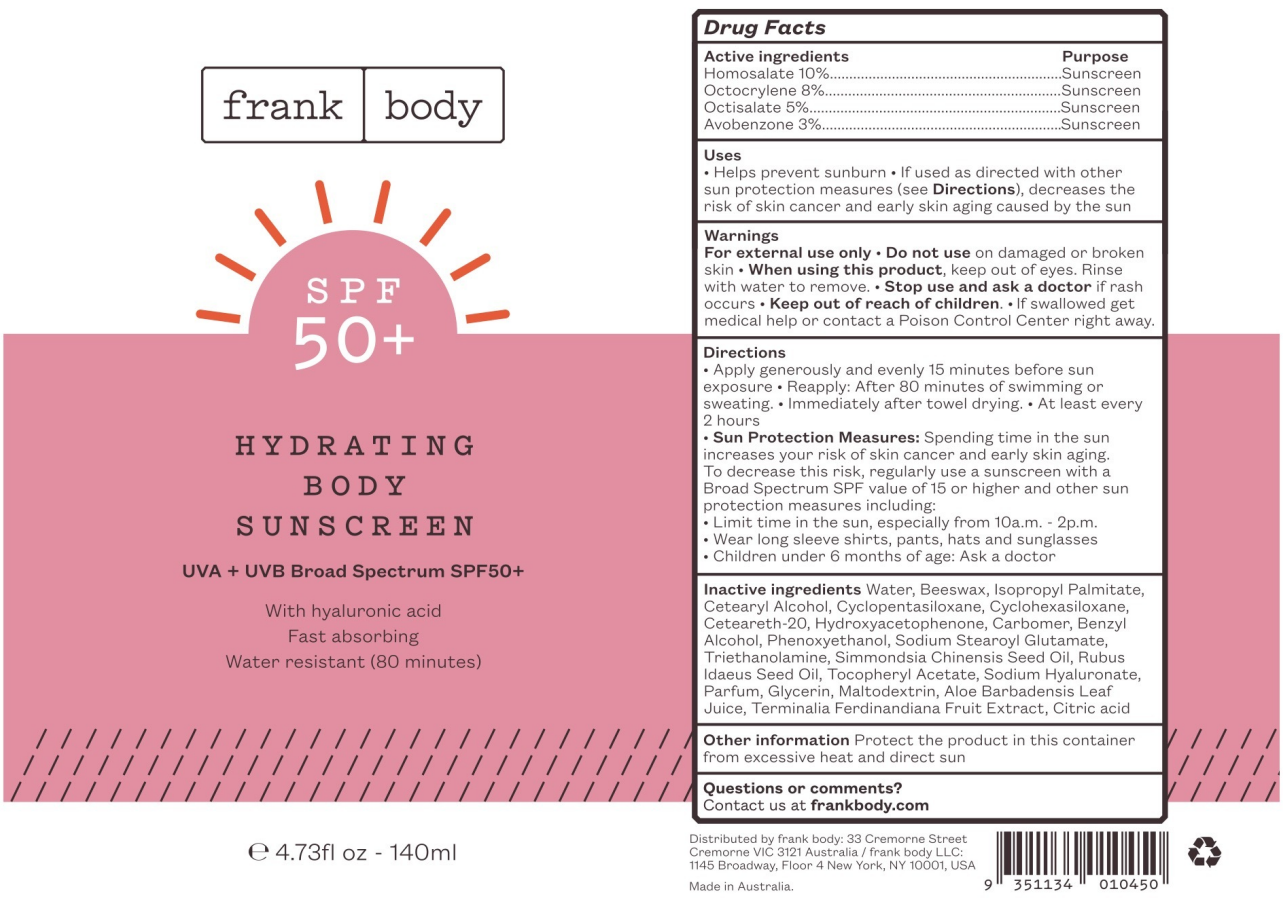
UVA + UVB Broad Spectrum SPF50+

With hyaluronic acid

Fast absorbing

Water resistant (80 minutes)

4.73fl oz - 140ml



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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70157-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
TROLAMINE (UNII: 9O3K93S3TK)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
JOJOBA OIL (UNII: 724GKU717M)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70157-009-01	140 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/01/2022	

Labeler - Baxter Laboratories Pty. Ltd. (740537709)

Revised: 11/2022 Baxter Laboratories Pty. Ltd.