

**DFNDR SUNSCREEN SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion
Block 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.

DFNDR SUNSCREEN SPF 50

ACTIVE INGREDIENTS

AVOBENZONE 3%

HOMOSALATE 10%

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, EARLY SKIN AGING BY THE SUN.

WARNING

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.
KEEP AWAY FROM FACE TO AVOID BREATHING IT.

STOP USE AND CONTACT A DOCTOR IS RASH OCCURS.

KEEP OUT OF REACH OF CHILDREN. IF PRODUCT IS 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 THE RISK, REGULARLY USE A SUNSCREEN WITH A BROAD SPECTRUM SPF OF 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

- CHILDREN UNDER 6 MONTHS: ASK A DOCTOR

INACTIVE INGREDIENTS

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









OTHER INFORMATION

- PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN.
- AVOID CONTACT WITH FABRICS - COULD CAUSE DISCOLORATION.

QUESTIONS AND COMMENTS

INFO@BLOCKGROUPLLC.COM

PO BOX 1799 MAMMOTH LAKES, CA 93546

<h3>Drug Facts</h3>	 <p>8 60002 12566 4</p>	<h1>DEFENDOR</h1> <h1>SUNSCREEN</h1>					
<p>Active Ingredients Purpose</p> <table border="0"> <tr> <td>Avobenzone 3%</td> <td rowspan="4">} Sunscreen</td> </tr> <tr> <td>Homosalate 10%</td> </tr> <tr> <td>Octisalate 5%</td> </tr> <tr> <td>Octocrylene 5%</td> </tr> </table>	Avobenzone 3%		} Sunscreen	Homosalate 10%	Octisalate 5%	Octocrylene 5%	<p>Uses</p> <ul style="list-style-type: none"> • 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.
Avobenzone 3%	} Sunscreen						
Homosalate 10%							
Octisalate 5%							
Octocrylene 5%							
<p>Warnings</p> <p>For external use only.</p> <p>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove. Keep away from face to avoid breathing it.</p> <p>Stop use and ask a doctor if rash occurs</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a poison control center right away.</p>	<p>mfd exclusively for Block LLC, Mammoth Lakes, CA</p>						
<p>Directions</p> <ul style="list-style-type: none"> • apply liberally 15 minutes before sun exposure • reapply: <ul style="list-style-type: none"> • 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 of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> • limit time in the sun, especially from 10 a.m. - 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses • children under 6 months: Ask a doctor 	<p>Inactive ingredients</p> <p>Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Ethylhexylglycerin, Fragrance, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water</p>						
<p>Other Information</p> <ul style="list-style-type: none"> • Protect this product from excessive heat and direct sun. • Avoid contact with fabrics - could cause discoloration. 	<p>Questions and comments info@blockgrouppllc.com PO Box 1799 Mammoth Lakes, CA 93546</p>	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> <p>50 <small>SPF</small></p> <p>SUNSCREEN BUILT TO</p> <p>LAST</p> </div> <div style="writing-mode: vertical-rl; transform: rotate(180deg);"> <p>BROAD SPECTRUM</p> </div> <div style="text-align: center;"> <p>80 <small>MINUTES</small></p> </div> <div style="text-align: center;"> <p>WATER RESISTANT</p>  </div> </div>					
<div style="display: flex; justify-content: space-around; align-items: center;">       </div>							

DFNDR SUNSCREEN SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76853-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
COCOA BUTTER (UNII: 512OYT1CRR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76853-106-11	90 mL in 1 TUBE; Type 0: Not a Combination Product	08/23/2020	
2	NDC:76853-106-12	180 mL in 1 TUBE; Type 0: Not a Combination Product	08/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/23/2020	

