RUBBER DUCKY SPF 50 UNFRAGRANCED SUNSCREEN- avobenzone 3%, homosalate 10%, octocrylene 6% lotion Derma Care Research Labs, 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.

Rubber Ducky SPF 50 FF Sunscreen Lotion

Active Ingredients

Avobenzone 3%, Homosalate 10%, Octocrylene 6%

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 eyes 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 n the sun increases your risk of skin cancer and early skin aging. To decrease risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measure including:

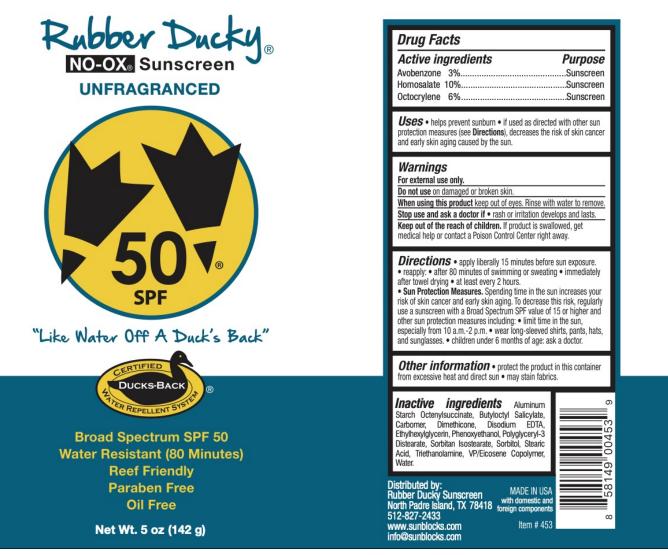
• limit time in the sun, especially from 10 am to 2 pm

- wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor.

Inactive Ingredients

Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Phenoxyethanol, Polyglyceryl-3 Distearate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water

Label



Rabber Ducky NO-OX Sunscreen	Drug Facts
UNFRAGRANCED	Active ingredients Purpose Avobenzone 3%Sunscreen Homosalate 10%Sunscreen Octocrylene 6%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.
501	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 or irritation develops and lasts. Keep out of the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away
SPF Like Water Off A Duck's Back"	 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.m2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses. • children under 6 months of age: ask a doctor.
DUCKS-BACK	Other information • protect the product in this container from excessive heat and direct sun • may stain fabrics.
Broad Spectrum SPF 50 Water Resistant (80 Minutes)	Inactive ingredients Auminum Starch Octenylsuccinate, Butyloctyl Salicylate, Carborner, Dimetricone, Disodium EDTA, Ethylhexylglycerin, Phenoxyettanol, Polyglycery-3 Distarate, Sorbitan Isostearate, Sorbitol, Stearic Acid, Triethanolamine, VP/Eicosene Copolymer, Water.
Reef Friendly Paraben Free Oil Free	Distributed by: Rubber Ducky Sunscreen MADE IN USA North Padre Island, TX 78418 With domestic and 512-827-2433 foreign components www.sunblocks.com

RUBBER DUCKY SPF 50 UNFRAGRANCED SUNSCREEN

avobenzone 3%, homosalate 10%, octocrylene 6% lotion

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:7	DC:72839-515	
Route of Administration	TOPICAL					
Active Ingredient/Active	Moiety					
Ingredient Name Basis of			Basis of Stre	ength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)			AVOBENZONE		3 g in 100 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)			HOMOSALATE		10 g in 100 g	
OCTOCRYLENE (UNII: 5A68WGF6W	M) (OCTOCRYLENE - UNII:54	A68WGF6WM)	OCTOCRYLENE		6 g in 100 g	
Inactive Ingredients						
	Ingredient Name				Strength	
CARBOMER 940 (UNII: 4Q93RCW2	7E)					
ALUMINUM STARCH OCTENYLSU	JCCINATE (UNII: I9PJ00629	4)				

DIMETHICONE 200 (UNII: RGS4T2AS00)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
TROLAMINE (UNII: 903K93S3TK)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	
SORBITOL (UNII: 506T60A25R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
1		142 g in 1 TUBE; Type 0: Not a Combination Product	05/10/2023			
2		(15/10/2023)				
Marketing Information						
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
01	rc monograph no	t part352	05/10/2023			

Labeler - Derma Care Research Labs, LLC (116817470)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment						
Name	Address	ID/FEI	Business Operations			
Derma Care Research Labs		116817470	manufacture(72839-515)			

Revised: 8/2023

Derma Care Research Labs, LLC