# DUANE READE BABY SUNSCREENSPF 50 SPF 50- avobenzone lotion DUANE READE 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.

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## **Drug Facts**

## **Active Ingredients**

Avobenzone 3.0 %

Homosalate 13.0%

Octisalate 5.0%

Octocrylene 7.0%

Oxybenzone 4.0%

## **Purpose**

Sunscreen

#### Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection
- retains SPF after 80 minutes of activity in the water

## Warnings

## For external use only

### 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 reach of children.

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

#### Other Information

• may stain some materials

#### Directions

- shake well
- apply generously before sun exposure and as needed
- Children under 6 months of age:ask a doctor
- reapplying frequently after towel drying, swimming or perspiring.

## **Inactive Ingredients**

Water, Stearic Acid, Sorbitol, Triethanolamine, VP/Eicosene Copolymer, Aluminium Starch Octenylsuccinate, Benzyl Alcohol, Sorbitan Isostearate, Dimethicone, Polyglyceryl-3 Diastearate, Fragrance, Methylparaben, Carbomer, Tocopherol, Propylparaben, Disodium EDTA

## **Principal Display Panel**

UNIQUELY NY  $DR_{TM}$  SINCE 1960

baby

SUNSCREEN

50

SPF

pediatrician tested

UVA/UVB Protection

Very Water Resistant

Moisturizing Lotion

8 FL OZ (237 mL)



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Directions • shake well • apply generously and evenly before sun exposure and as needed • children under 6 months of age: ask a doctor · reapply frequently and after towel drying, swimming or perspiring

Other Information • may stain some materials

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440 NINTH AVE. NY, NY 10001 (866) 375-6925 duanereade.com Made In U.S.A.

#### **DUANE READE BABY SUNSCREENSPF 50 SPF 50**

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67732-401
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 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 g in 100 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 g
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	4 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 903K93S3TK)	
ALUMINUM STARCH O CTENYLSUCCINATE (UNII: 19 PJ 0 O 6 2 9 4)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
<b>DIMETHICO NE</b> (UNII: 92RU3N3Y1O)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46 P231IQV8)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TOCOPHEROL (UNII: R0ZB2556P8)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67732-401-16	226 g in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/13/2012	

## Labeler - DUANE READE INC. (011988995)

Revised: 11/2012 DUANE READE INC.