

**SUN BATHE SUNSCREEN SPF 20- avobenzene, octinoxate, octocrylene soap**  
**BABY BUBBA ENTERPRISES 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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**ACTIVE INGREDIENTS**

AVOBENZONE 1.6%  
OCTINOXATE 5.2%  
OCTOCRYLENE 4.2%

**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 AND RINSE WITH EXCESSIVE WATER TO REMOVE.

KEEP OUT OF REACH OF CHILDREN. IF PRODUCT IS SWALLOWED GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

STOP USE AND ASK A DOCTOR IF RASH OR IRRITATION OCCURS.

**DIRECTIONS**

- APPLY LIBERALLY 15 MINUTES BEFORE SUN EXPOSURE
- REAPPLY:
- 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 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.

**OTHER INFORMATION**

- PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUNLIGHT.

## INACTIVE INGREDIENTS

WATER, PROPYLENE GLYCOL, SODIUM STEARATE, GLYCERIN, SODIUM LAURETH SULFATE, SORBITOL, SODIUM LAURYL SULFATE, SODIUM MYRISTATE, SODIUM COCOYL ISETHIONATE, ACRYLATES COPOLYMER, FRAGRANCE (PARFUM), TRIETHANOLAMINE, TITANIUM DIOXIDE (CI 77891), POLYQUATERNIUM-16, SILICA, TETRASODIUM ETIDRONATE, PENTASODIUM PENTETATE, YELLOW 10 (CI 47005), POLYAMIDE-3, SORBITAN OLEATE, POLYSORBATE 20, CELLULOSE GUM, PEG-16, DMDM HYDANTOIN, IODOPROPYNYL BUTYL CARBAMATE, PG-HYDROXYETHYLCELLULOSE STEARYLDIMONIUM CHLORIDE, COCODIMONIUM HYDROXYPROPYL HYDROLYZED KERATIN.

## QUESTIONS OR COMMENTS?

PLEASE CALL TOLL FREE 1-844-799-SOAP

WWW.SUNBATHESOAP.COM



# SUN BATHE SUNSCREEN SPF 20

avobenzone, octinoxate, octocrylene soap

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70342-102
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.6 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5.2 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4.2 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM MYRISTATE (UNII: 06BLC4V0IV)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
TROLAMINE (UNII: 9O3K93S3TK)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYQUATERNIUM-16 (N-VINYLPYRROLIDINONE:3-METHYL-1-VINYLMIDAZOLIUM CHLORIDE (5:5)) (UNII: 1KX12A42IJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PENTASODIUM PENTETATE (UNII: 961TOZ5L7T)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
POLYAMIDE-3 (30000 MW) (UNII: 9AO559AXEB)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
POLYETHYLENE GLYCOL 800 (UNII: UH6KR4953D)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)	
PROPYLENE GLYCOL-HYDROXYETHYLCELLULOSE STEARYLDIMONIUM CHLORIDE (UNII: 3479326GXB)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70342-102-13	99 g in 1 PACKAGE; Type 0: Not a Combination Product	06/19/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/23/2016	

**Labeler** - BABY BUBBA ENTERPRISES INC (079865347)

## Establishment

Name	Address	ID/FEI	Business Operations
Bradford Soap Works, Inc.		001201045	manufacture(70342-102)

Revised: 6/2017

BABY BUBBA ENTERPRISES INC