

PIXI SUN SERUM SPF 30- avobenzone, octinoxate, octisalate, oxybenzone cream

PIXI, 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.

ACTIVE INGREDIENTS

OCTINOXATE (7.5%)

OXYBENZONE (6%)

OCTISALATE (5%)

AVOBENZONE (1%)

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 WITH WATER TO REMOVE.

▯STOP USE AND ASK A DOCTOR▯ IF SKIN 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. USE A WATER RESISTANT SUNSCREEN IF SWIMMING OR SWEATING. REAPPLY AT LEAST EVERY 2 HOURS.
- CHILDREN UNDER 6 MONTHS. ASK A DOCTOR. 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:
- LIMIT TIME IN THE SUN, ESPECIALLY FROM 10 AM - 2 PM
- WEAR LONG-SLEEVE SHIRTS, PANTS, HATS, AND SUNGLASSES

CHILDREN UNDER 6 MONTHS: ASK A DOCTOR.

AQUA (WATER), CAPRYLIC/CAPRIC TRIGLYCERIDE, CORN STARCH MODIFIED, CETEARYL OLIVATE, DIETHYLHEXYL 2,6-NAPHTHALATE, C12-15 ALKYL BENZOATE, SORBITAN OLIVATE, GLUCONOLACTONE, SQUALANE, GLYCERIN, CYCLOPENTASILOXANE, TOCOPHERYL ACETATE (D-ALPHA), GLYCINE SOJA (SOYBEAN) OIL, SODIUM HYALURONATE (L), XANTHAN GUM, CARBOMER, AMINOMETHYL PROPANOL, SODIUM BENZOATE, PHENETHYL ALCOHOL, CAPRYLYL CLYCOL, PHENOXYETHANOL, TRISODIUM ETHYLENEDIAMINE DISUCCINATE, POTASSIUM SORBATE. MADE IN USA.

PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN.

CALL TOLL FREE 1-800-792-5330



avobenzene, octinoxate, octisalate, oxybenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70686-102
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	1 g in 100 mL

OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
STARCH, CORN (UNII: O8232NY3SJ)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
SQUALANE (UNII: GW89575KF9)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SOYBEAN OIL (UNII: 241ATL177A)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
SODIUMBENZOATE (UNII: OJ245FE5EU)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TRISODIUMETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
POTASSIUMSORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70686-102-91	1 in 1 CARTON	08/03/2016	
1	NDC:70686-102-21	30 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/03/2016	

Labeler - PIXI, INC (830752593)

Registrant - PIXI, INC (830752593)

