PIXI SUN MIST SPF 30- amiloxate, octinoxate, octisalate, titanium dioxide spray 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

AMILOXATE (3%)

OCTINOXATE (7%)

OCTISALATE (3%)

TITANIUM DIOXIDE (1.9%)

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 AGIN 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 MEIDCAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- SHAKE WELL BEFORE USE.
- APPLY LIBERALLY 15 MINUTES BEFORE SUN EXPOSURE.
- REAPPLY:
- AFTER 40 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:
- 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.

INACTIVE INGREDIENTS

DISILOXANE, WATER/AQUA/EAU, ALCOHOL, CYCLOPENTASILOXANE, C12-15 ALKYL BENZOATE, DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE, CETYL PEG/PPG-10/1 DIMETHICONE, BUTYLENE GLYCOL, DICAPRYLYL CARBONATE, PHENOXYETHANOL, STEARIC ACID, SODIUM CHLORIDE, ALUMINUM HYDROXIDE, POLYHYDROXYSTEARIC ACID, ALUMINUM STEARATE, DIPROPYLENE GLYCOL, DISODIUM EDTA, JASMINUM OFFICINALE (JASMINE) OIL, ALOE BARBADENSIS LEAF EXTRACT, PORTULACA OLERACEA EXTRACT, ANTHEMIS NOBILIS FLOWER EXTRACT, BAMBUSA VULGARIS EXTRACT, TOCOPHEROL. MADE IN KOREA.

OTHER INFORMATION

PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN.

QUESTIONS OR COMMENTS?

CALL TOLL FREE 1-800-792-5330



PIXI SUN MIST SPF 30 amiloxate, octinoxate, octisalate, titanium dioxide spray Product Information Product Type HUMAN OTC DRUG Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AMILOXATE (UNII: 376KTP06K8) (AMILOXATE - UNII:376KTP06K8)	AMILOXATE	3 g in 100 mL		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL		
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	3 g in 100 mL		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	1.9 g in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
HEXAMETHYLDISILO XANE (UNII: D7M4659BPU)			
WATER (UNII: 059QF0KO0R)			
ALCOHOL (UNII: 3K9958V90M)			
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)			
CETYL PEG/PPG-10/1 DIMETHICO NE (HLB 1.5) (UNII: V2W71V8T0 X)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
DICAPRYLYL CARBONATE (UNII: 609 A3V1SUA)			
PHENO XYETHANOL (UNII: HIE492ZZ3T)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)			
POLYHYDRO XYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)			
ALUMINUM STEARATE (UNII: U6 XF9 NP8 HM)			
DIPROPYLENE GLYCOL (UNII: E107L85C40)			
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)			
JASMINUM OFFICINALE FLOWER (UNII: 0 Q8 K8 41432)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
PURSLANE (UNII: M6 S8 40 WXG5)			
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)			
BAMBUSA VULGARIS TOP (UNII: FIW80T6P6V)			
TOCOPHEROL (UNII: R0ZB2556P8)			

ı	P	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:70686-101- 13	80 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/03/2016	

Marketing Infor			
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)

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