

SUNSCREEN 30 SPF- octinoxate, oxybenzone lotion

Aztex Enterprises

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.

Drug Facts 30ml/1oz.

Active Ingredient Purpose

Octinoxate (7.3%) sunscreen

Oxybenzone (5.2%) sunscreen

Uses

Provides moderate protection against sunburn

For skin that burns easily

Warnings

For external use only.

When using this produce

Keep out of eyes, rinse with water to remove

Discontinue use of irritation and redness develop

Keep out of reach of children

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

If pregnant or breastfeeding, ask a health care professional before use

Directions

Apply generously and evenly before sun exposure

Reapply as needed or after swimming or perspiring

Inactive Ingredients

Acrylate/C10-30 Alkylacrylate Crosspolymer

BHT

C12-15 Alkyl Benzoate

Carbomer polymers

Diazolydinyl Urea

Disodium EDTA

Hexyl Laurate

Methylparaben, Propylparaben

PEG-8, Sorbitan Oleate, Tocopheryl Acetate

Propylene Glycol, Triethanolamine, VP/Eicosene copolymer



30 SPF
SUNSCREEN
 1 OZ. / 30 ML.

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Oxybenzone (5.2%).....	sunscreen
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<ul style="list-style-type: none"> • Provides moderate protection against sunburn. • For skin that burns easily. 	
Warnings	
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When using this product	
<ul style="list-style-type: none"> • Keep out of eyes. Rinse with water to remove. • Discontinue use if irritation and redness develop. 	
Keep out of reach of children.	
If swallowed, get medical help or contact a Poison Control Centre right away.	
If pregnant or breast-feeding, ask a health professional before use.	
Directions	
<ul style="list-style-type: none"> • Apply generously and evenly before sun exposure. • Reapply as needed or after swimming, or perspiring. 	
Inactive ingredients	
Acrylate/C10-30 Alkylacrylate Copolymer, BHT, C12-15 Alkyl Benzoate, Carbomer polymers, Diazolidinyl Urea, Disodium EDTA, Hexyl Laurate, Methylparaben, PEG-8, Propylene Glycol, Propylparaben, Sorbitan Oleate, Tocopheryl Acetate, Triethanolamine, and VP/Eicosene copolymer.	
Manufactured for: AZX SPORT 325 Century Drive Burlington, ON L7L 5J8 CANADA	
Made in Canada ▶ (L) 2395	

Not to Scale

AZX SPORT
 30 SPF
 Sunscreen
 1 oz. / 30 ml.
 Made in Canada

SUNSCREEN 30 SPF

octinoxate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75887-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	22 mL in 30 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	16 mL in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
CARBOMER 1342 (UNII: 809Y72KV36)
UREA (UNII: 8W8T17847W)
EDETATE DISODIUM (UNII: 7FLD91C86K)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
METHYL PARABEN (UNII: A2I8C7HI9T)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
TROLAMINE (UNII: 9O3K93S3TK)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75887-003-01	30 mL in 1 BOTTLE		
2	NDC:75887-003-02	60 mL in 1 BOTTLE		
3	NDC:75887-003-03	118 mL in 1 BOTTLE		
4	NDC:75887-003-04	236 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/18/2011	

Labeler - Aztex Enterprises (253232326)

Registrant - Aztex Enterprises (253232326)

Establishment			
Name	Address	ID/FEI	Business Operations
Aztex Enterprises		253232326	manufacture