SUN TOTAL PROTECTOR 30 BROAD SPECTRUM SPF 30 DAILY PROTECTION-
octinoxate, octisalate, zinc oxide cream
MD Formulation.

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.

Acive ingredients:

Octinoxate 7.5%

Octisalate 4.0%

Zinc Oxide 7.8%

Warning:

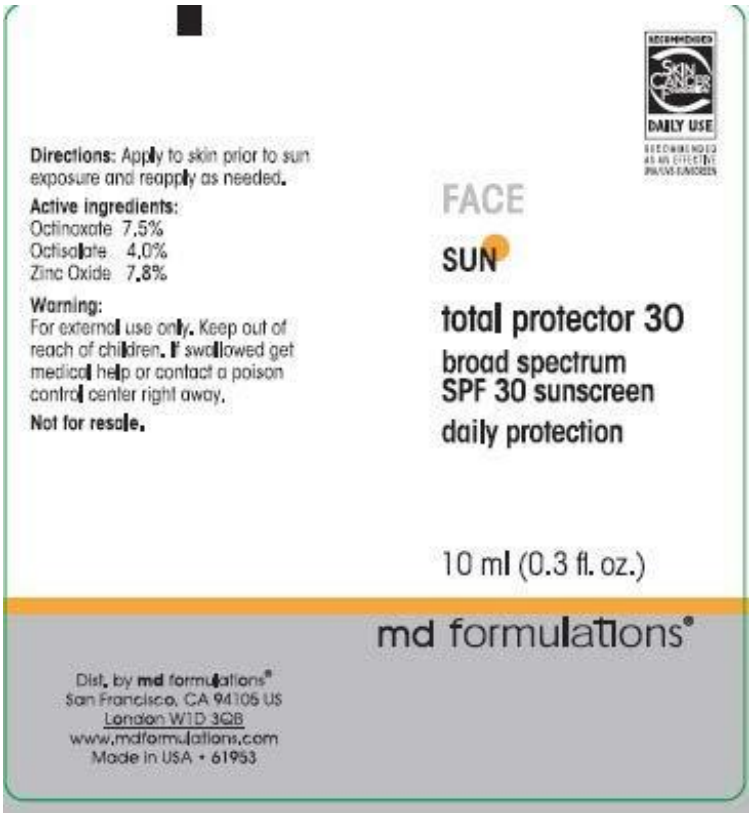
For external use only. Keep out of reach of children. If swallowed get medical help or contact a poison control center right away.

Not for resale.

Directions:

Apply to skin prior to sun exposure and reapply as needed.

Labeling



SUN TOTAL PROTECTOR 30 BROAD SPECTRUM SPF 30 DAILY PROTECTION

octinoxate, octisalate, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66078-440
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.0 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7.8 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALLANTOIN (UNII: 344S277G0Z)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
STEARETH-2 (UNII: V56DFE46J5)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
STEARETH-100 (UNII: 4OH5W9UM87)	
TRICONTANYL POVIDONE (4 TRICONTANYL BRANCHES/REPEAT) (UNII: N0SS3Q238D)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
TOCOPHERYL NICOTINATE, D-.ALPHA. (UNII: WI1J5UCY5C)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:66078-440-03	10.8 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/15/2012	

Labeler - MD Formulation. (087008363)

Registrant - Ei Inc. (105803274)

Establishment

Name	Address	ID/FEI	Business Operations
Ei Inc.		105803274	manufacture(66078-440) , label(66078-440)

Revised: 1/2013 MD Formulation.