

NATURAL SUN AQ BODY AND FAMILY MILD SUN MILK - octinoxate, octisalate, titanium dioxide, avobenzone, enzacamene cream
THEFACESHOP CO., LTD

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

OCTINOXATE (7.50%)
OCTISALATE (3.00%)
TITANIUM DIOXIDE (2.34%)
AVOBENZONE (2.30%)
ENZACAMENE (2.00%)

WATER · CYCLOMETHICONE · GLYCERIN · DIPROPYLENE GLYCOL · DICAPRYLYL CARBONATE · OCTYLDODECYL NEOPENTANOATE · POTASSIUM CETYL PHOSPHATE · SORBITAN MONOSTEARATE · GLYCERYL MONOSTEARATE · POLYOXYL 100 STEARATE · DIMETHICONE · CETEARYL ALCOHOL · COPTIS · MINERAL OIL · XANTHAN GUM · STEARIC ACID · ALOE FEROX LEAF · SILICON DIOXIDE · EDETATE DISODIUM · IONONE · BENZYL BENZOATE · BUTYLPHENYL METHYLPROPIONAL · .ALPHA.-HEXYLCINNAMALDEHYDE

Face and Body Sun Block.

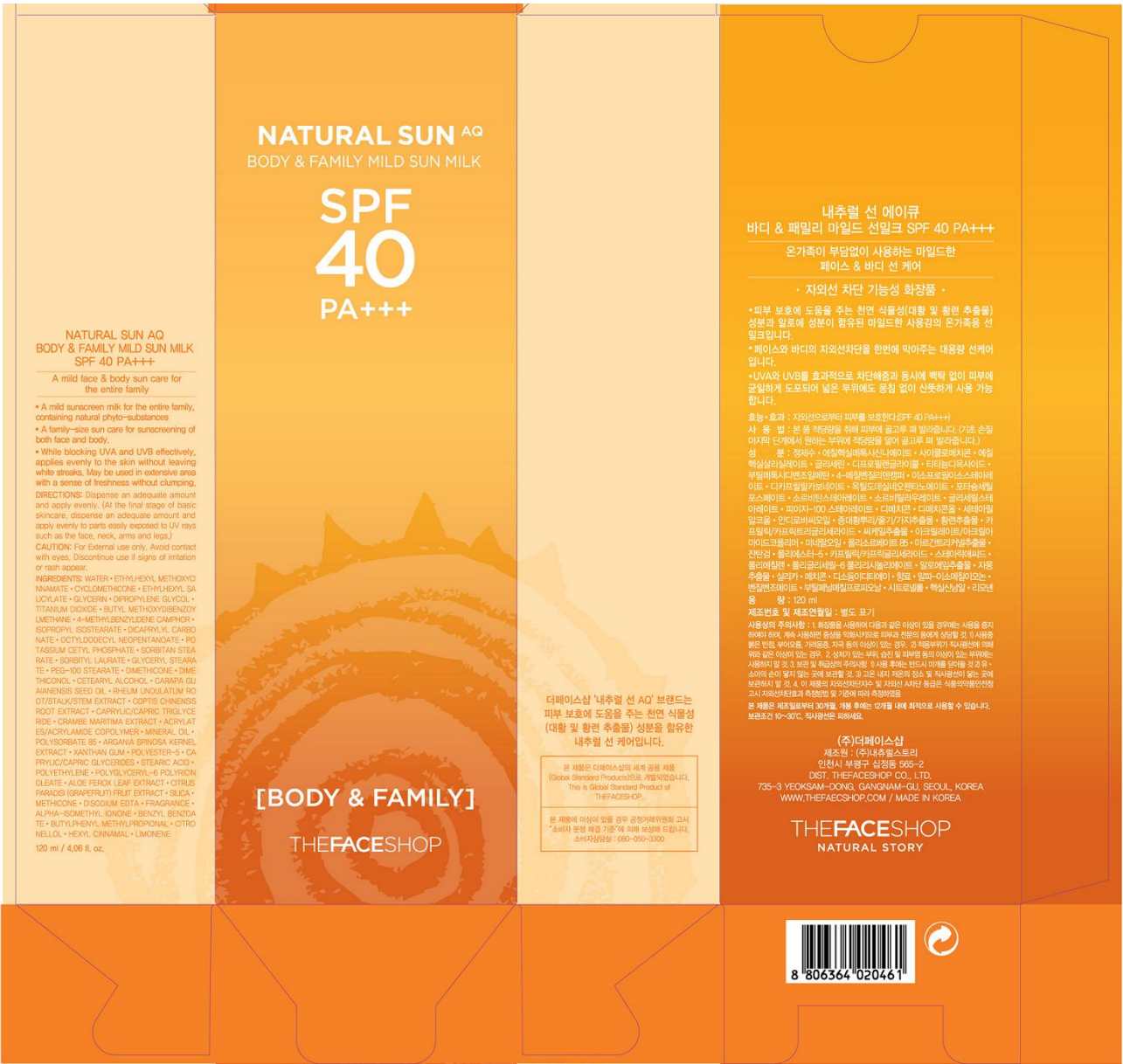
Avoid contact with eyes.

Discontinue use if sign of irritation or rash appear.

Dispense an adequate amount and apply evenly. (At the final stage of basic skincare, dispense an adequate amount and apply evenly to parts easily exposed to UV rays such as the face, neck, arms and legs)

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octinoxate, octisalate, titanium dioxide, avobenzone, enzacamene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51523-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	3 mL in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	2.34 mL in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.3 mL in 100 mL
ENZACAMENE (UNII: 8I3XWY40L9) (ENZACAMENE - UNII:8I3XWY40L9)	ENZACAMENE	2 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
MINERAL OIL (UNII: T5L8T28FGP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZYL BENZOATE (UNII: N863NB338G)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51523-10 1-02	1 in 1 BOX		
1	NDC:51523-10 1-01	120 mL in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/22/2010	

Labeler - THEFACESHOP CO., LTD (688329416)

Registrant - THEFACESHOP CO., LTD (688329416)

Establishment

Name	Address	ID/FEI	Business Operations
THEFACESHOP CO., LTD		688329416	manufacture