# FACE IT 32800378- octinoxate, titanium oxide and zind oxide cream 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.

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#### **Active Ingredients**

OCTINOXATE •••• 7.3%
TITANIUM DIOXIDE ••• 15.0%
ZINC OXIDE •••• 5.9%

#### **Purpose**

Sunscreen

Sunscreen

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#### 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 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 generously and evenly 15 minutes before sun exposure.

Children under 6 months of age: Ask a doctor

**Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

Reapply at least every 2 hours.

Use a water-resistant sunscreen if swimming or sweating. Shake lightly 3-5 times before use. Dispense an adequate amount and apply evenly to the skin. Then,

pat lightly with fingers for full absorption. Re-apply a small amount to parts that require extra coverage and pat with fingers.

Double cleansing is recommended as this product adheres tightly to the skin. FACE IT One-ste p BB Cleanser may be used for simple and easy cleansing.

#### Other information

Protect the product in this container from excessive heat and direct sun. May stain or damage some fabrics or surfaces.

#### **Inactive Ingredients**

CYCLOPENTASILOXANE•WATER•BUTYLENE GLYCOL• DIMETHICONE•SD ALCOHOL 40-B•HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER•CAPRYLIC/CAPRIC GLYCERIDES•ISOHEXADECANE•SODIUM CHLORIDE• ALUMINUM HYDROXIDE•METHYL METHACRYLATE CROSSPOLYMER•STEARIC ACID•PEG-10 DIMETHICONE• 1,2-HEXANEDIOL•TRIETHOXYCAPRYLYLSILANE•SILICA• DISODIUM EDTA•ALOE BARBADENSIS LEAF EXTRACT• PORTULACA OLERACEA EXTRACT•ADANSONIA DIGITATA SEED EXTRACT•ALCOHOL•PHENOXYETHANOL• METHYLPARABEN•PROPYLPARABEN•ETHYLPARABEN• BUTYLPARABEN•ISOBUTYLPARABEN•FRAGRANCE• IRON OXIDES (CI 77491, CI 77492, CI 77499) Questions or comments? Call 1 (866) 638-8417

Distributed by:

THEFACESHOP NORTH AMERICA, INC.

Santa Fe Springs, CA 90670

BB

**SUNSCREEN** 

**CREAM** 

SPF50+

01 LIGHT

**BEIGE** 



#### **FACE IT 32800378**

octinoxate, titanium oxide and zind oxide cream cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51523-378	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	3.65 g in 50 mL	
Titanium Dioxide (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP)	Titanium Dioxide	7.5 g in 50 mL	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	2.95 g in 50 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				

Pac	ckaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>

1 NDC:51523-378-06	1 in 1 CARTON	11/20/2014		
1	50 mL in 1 TUBE; Type 0: Not a Combination Product			
Maybeting Information				
Marketing Information				
Marketing Categor	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not fin	nal part352	11/20/2014		

## Labeler - THEFACESHOP CO., LTD. (688329416)

### **Registrant** - The faceshop North America, Inc. (620459193)

Establishment				
Name	Address	ID/FEI	Business Operations	
THEFACESHOP Co., Ltd.		688329416	label(51523-378)	

Establishment				
Name	Address	ID/FEI	Business Operations	
COSMAX INC.		689019313	manufacture(51523-378)	

Revised: 11/2014 THEFACESHOP CO., LTD.