CLAPIEL DEFENSE SUNBLOCK- octinoxate, zinc oxide, octisalate, titanium dioxide cream
AUS KOREA 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.

ACTIVE INGREDIENT

Active Ingredient: ETHYLHEXYL METHOXYCINNAMATE 6.80%, ZINC OXIDE 5.00%, ETHYLHEXYL SALICYLATE 4.50%, TITANIUM DIOXIDE 4.00%

INACTIVE INGREDIENT

Inactive Ingredients: Water, Cyclopentasiloxane, Dipropylene Glycol, Peg-10 Dimethicone, Dicaprylyl Carbonate, Niacinamide, Disteardimonium Hectorite, Dimethicone, Magnesium Sulfate, Aluminum Hydroxide, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Phenoxyethanol, Viscum Album (Mistletoe) Leaf Extract, Centella Asiatica Extract, Portulaca Oleracea Extract, Stearic Acid, Fragrance, Polymethylsilsesquioxane, Methicone, Caprylyl Glycol, Dimethicone/Vinyl Dimethicone Crosspolymer, PEG-9 Plydimethylsiloxyethyl Dimethicone, Actinidia Chinensis (Kiwi) Fruit Extract, Camellia Sinensis Callus Culture Extract, Cucurbita Pepo (Pumpkin) Fruit Extract, Daucus Carota Sativa (Carrot) Root Extract, Glyceryl Caprylate, Mangifera Indica (Mango) Fruit Extract, Polyglyceryl-6 Plyricinoleate, Tocopheryl Acetate, Sodium Hyaluronate

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings: 1. In case of having following symptoms after using this, you’re advised to stop using it immediately. If you keep using it, the symptoms will get worse and need to consult a dermatologist. 1) In case of having problems such as red rash, swollenness, itching, stimulation during usage. 2) In case of having the same symptoms above on the part you put this product on by direct sunlight. 2. You are banned to use it on the part where you have a scar, eczema, or dermatitis. 3. In case of getting it into your eyes, you have to wash it immediately.

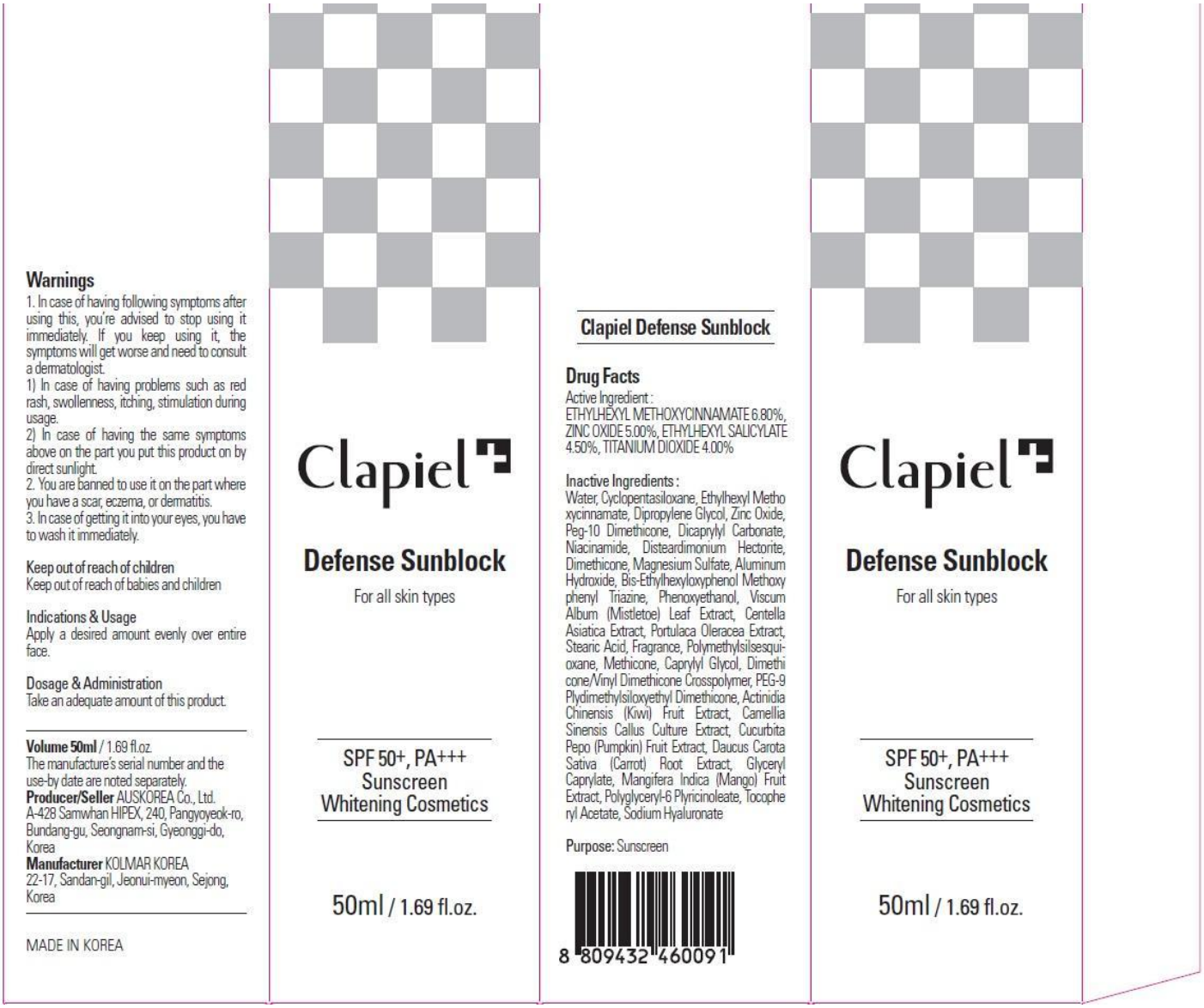
Keep out of reach of children: Keep out of reach of babies and children

DESCRIPTION

Indications & Usage: Apply a desired amount evenly over entire face.

Dosage & Administration: Take an adequate amount of this product.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



CLAPIEL DEFENSE SUNBLOCK

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69977-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.4 mg in 50 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	2.5 mg in 50 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.25 mg in 50 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.0 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Dipropylene Glycol (UNII: E107L85C40)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69977-050-01	50 mL in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/01/2015	

Labeler - AUS KOREA CO., LTD. (689515251)

Registrant - AUS KOREA CO., LTD. (689515251)

Establishment

Name	Address	ID/FEI	Business Operations
AUS KOREA CO., LTD.		689515251	manufacture(69977-050)

Revised: 7/2015 AUS KOREA CO., LTD.