

**MISSHA GLAM SILKY BODY BALM SPF 27- titanium dioxide, octinoxate, zinc oxide cream
ABLE C&C 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 INGREDIENTS: Titanium Dioxide 7.54%, Ethylhexyl Methoxycinnamate 6.00%, Zinc Oxide 1.92%

INACTIVE INGREDIENT

INACTIVE INGREDIENTS:

Cetyl Ethylhexanoate, Octyldodecyl Myristate, Mica, Polyethylene, Zea Mays (Corn) Starch, Microcrystalline Wax, 4-Methylbenzylidene Camphor, Punica Granatum Seed Oil, Camellia Sinensis Seed Oil, Vitis Vinifera (Grape) Seed Oil, Prunus Armeniaca (Apricot) Kernel Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Talc, Methicone, Hydrogen Dimethicone, BHT, Tin Oxide, Carmine, Caprylyl Glycol, Ethylhexylglycerin, Fragrance

PURPOSE

PURPOSE: This combination of Cosmetic / OTC Drug can be used as a sun protection cream

WARNINGS

WARNING:

For external use only.

Do not swallow.

Keep out of reach of children.

Avoid contact with eyes.

Do not use on exposed wounds or if you are allergic to any ingredients of this product.

KEEP OUT OF REACH OF CHILDREN

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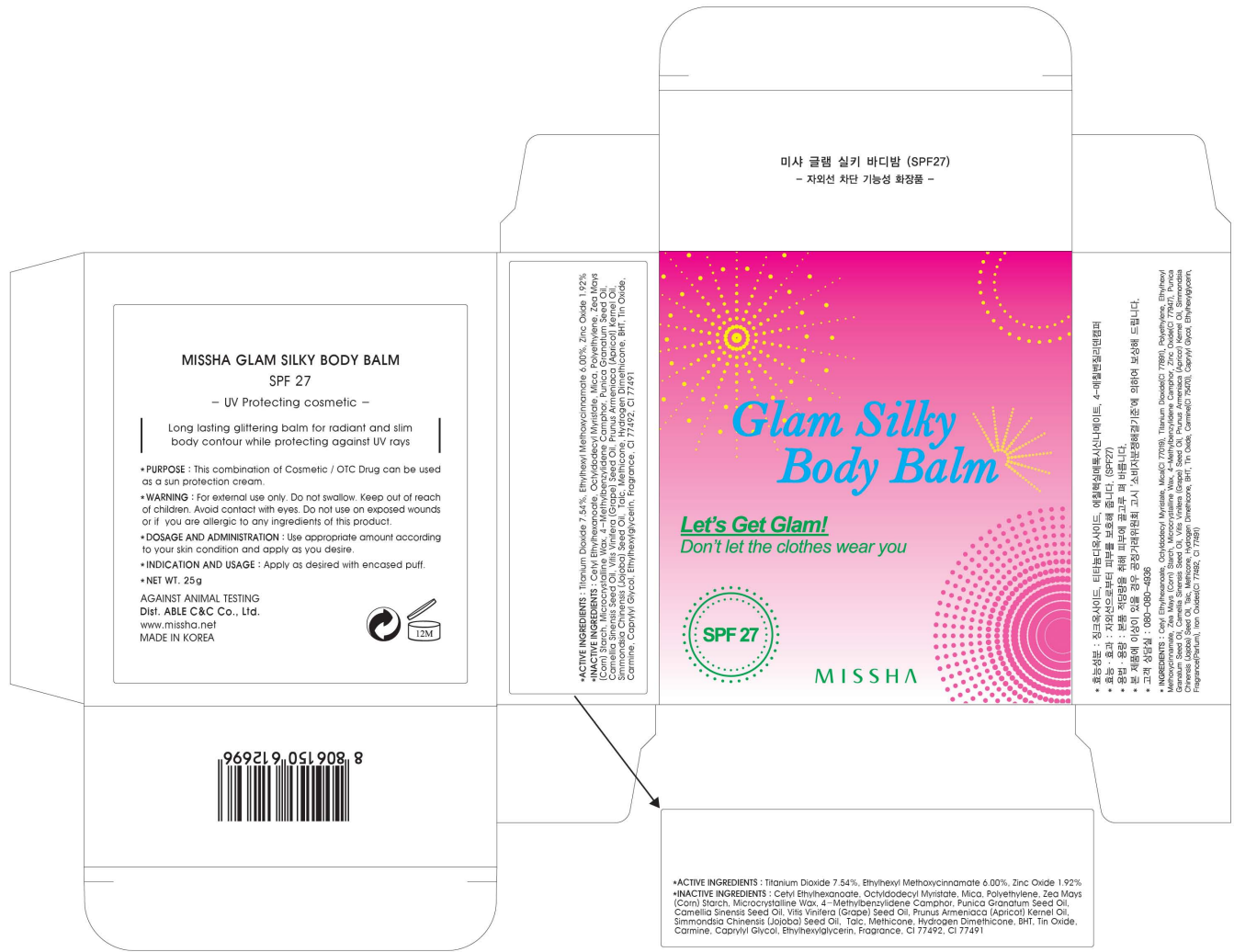
INDICATIONS AND USAGE

INDICATION AND USAGE: Apply as desired with encased puff.

DOSAGE AND ADMINISTRATION

DOSAGE AND ADMINISTRATION: Use appropriate amount according to your skin condition and apply as you desire.

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL



MISSHA GLAM SILKY BODY BALM SPF 27

titanium dioxide, octinoxate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13733-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.88 g in 25 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.5 g in 25 g
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.48 g in 25 g

Inactive Ingredients

Ingredient Name	Strength
Cetyl Ethylhexanoate (UNII: 134647WMX4)	
Octyldodecyl Myristate (UNII: S013N99GR8)	

Mica (UNII: V8A1AW0880)

Talc (UNII: 7SEV7J4R1U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13733-016-01	25 g in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2012	

Labeler - ABLE C&C CO., LTD. (689540284)

Registrant - ABLE C&C CO., LTD. (689540284)

Establishment

Name	Address	ID/FEI	Business Operations
ABLE C&C CO., LTD.		689540284	manufacture(13733-016)

Revised: 10/2012

ABLE C&C CO., LTD.