

**FOR THE GARDENER LIP BALM SPF 30- octinoxate, octocrylene, octisalate, and oxybenzone stick
GANZ U.S.A., LLC**

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.

**time & again®
LIP BALM**

Active ingredients

Octinoxate 7.5%, Octocrylene 7.0%, Octisalate 5.0%, Oxybenzone 5.0%

Purposes

Sunscreens

Use

- helps prevent sunburn

Warnings

- Stop use if skin rash occurs

Inactive ingredients

petrolatum, isopropyl myristate, paraffin, candelilla wax, synthetic beeswax, polyethylene, cetyl alcohol, lanolin, isopropyl lanolate, oleyl alcohol, octyldodecanol, phenyl trimethicone, flavor, tocopheryl acetate, aloe barbadensis leaf extract, glycine soja (soybean) oil, titanium dioxide, methylparaben, propylparaben, silica, saccharin, DEA-oleth-3-phosphate

Other information

You may report serious adverse reaction to this product to: Ganz U.S.A., LLC #043, 60 Industrial Parkway, Cheektowaga, New York, 14227-9903

MANUFACTURED FOR:

GANZ, Cheektowaga, N.Y. 14227-9903

PRINCIPAL DISPLAY PANEL - 4 g Carton

time & again®

LIP BALM

SPF 30

ALOE & VITAMIN E

UVA/UVB SUNSCREEN PROTECTION



FOR THE GARDENER LIP BALM SPF 30

octinoxate, octocrylene, octisalate, and oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75862-018
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
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PARAFFIN (UNII: I9O0E3H2ZE)	
CANDELILLA WAX (UNII: WL0328HX19)	
LOW DENSITY POLYETHYLENE (UNII: J245LN42A1)	

CETYL ALCOHOL (UNII: 936JST6JCN)	
LANOLIN (UNII: 7EV65EAW6H)	
OLEYL ALCOHOL (UNII: 172F2WN8DV)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SOYBEAN OIL (UNII: 241ATL177A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN (UNII: FST467XS7D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75862-018-50	1 in 1 BOX		
1		4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	08/10/2011	

Labeler - GANZ U.S.A., LLC (798785242)