

SUN-KISSED LIP BALM LEMON LIME SPF30- octinoxate, octocrylene, octisalate, and oxybenzone stick

KISS AND SHIELD LIP BALM LEMON LIME SPF 30- octinoxate, octocrylene, octisalate, and oxybenzone stick

INSPIRED BY COLOR LEMON LIME 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.

Lemon-Lime 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

PRINCIPAL DISPLAY PANEL - 4 g Box

time & again[®]

SPF30

UVA/UVB SUNSCREEN PROTECTION

LIP BALM

Net wt 4 g (0.14 Oz)



PRINCIPAL DISPLAY PANEL - 4 g Box

time & again[®]

SPF30

UVA/UVB SUNSCREEN PROTECTION

LIP BALM

Net wt 4 g (0.14 Oz)

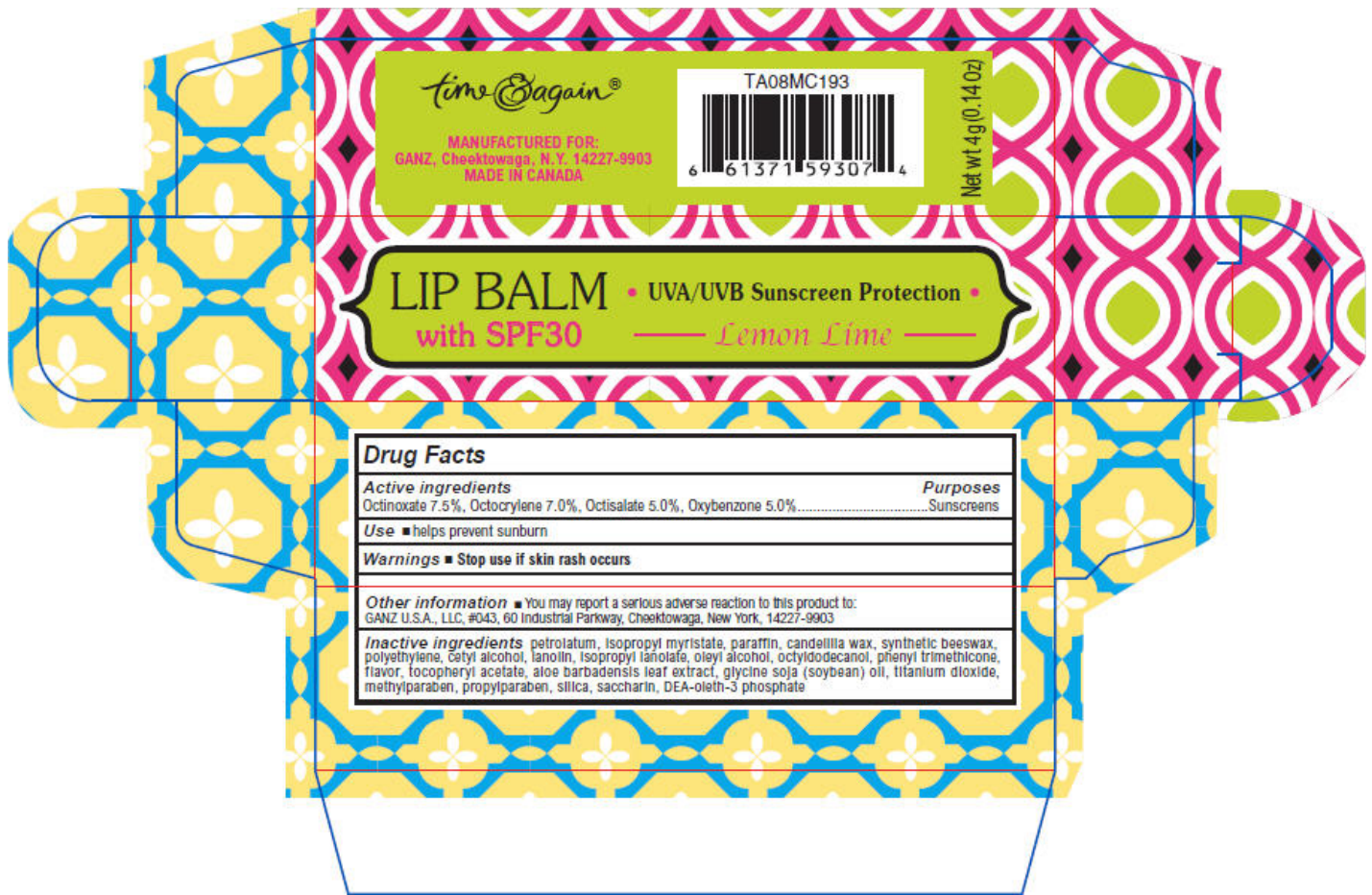


PRINCIPAL DISPLAY PANEL - 4 g Box

LIP BALM
 with SPF30

UVA/UVB Sunscreen Protection

Lemon Lime



SUN-KISSED LIP BALM LEMON LIME SPF30

octinoxate, octocrylene, octisalate, and oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75862-015
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: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	7 g in 100 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	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: J245LN42AI)	

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)
METHYLPARABEN (UNII: A2I8C7HI9T)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SACCHARIN (UNII: FST467XS7D)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75862-015-50	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	01/01/2011	

KISS AND SHIELD LIP BALM LEMON LIME SPF 30

octinoxate, octocrylene, octisalate, and oxybenzone stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75862-016
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: J245LN42AD)
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)
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Product Information

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