

GLY-MIRACLE LIP BALM SPF 30- octinoxate, oxybenzone, octisalate lipstick
DSG INNOVATIONS INC

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 INGREDIENTS

OCTYL METHOXYCINNAMATE 7.3%, BENZOPHENONE-3 5.8%, OCTYL SALICYLATE 5.0%,
HOMOMETHYL SALICYLATE 5.4%

PURPOSE

SUNSCREEN



GLY-MIRACLE LIP BALM

SPF 30

BALSAMO DE LABIOS • STICK LEVRES

With BEES WAX, Aloe and Lanolin keeps Lips Moist And Protects Lips from Sun, Extreme Temperatures and Dryness .15 oz

INACTIVE INGREDIENTS:

Coconut Oil, Bees Wax, Candililla Wax, Shea Butter, Lanolin, Aloe Oil, Flavored

ACTIVE INGREDIENTS:

Octyl Methoxyinnamate 7.3%, Benzophenone-3 -5.8%, Octyl Salicylate 5.0%, Homomethyl Salicylate -5.4%

Manufactured in USA for:
DSG INNOVATIONS
CANADA T5M 1W7
www.glymiracle.com



GLY-MIRACLE LIP BALM SPF 30

octinoxate, oxybenzone, octisalate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73537-701
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.3 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5.8 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y)	5.4 g in 100 g
COCONUT OIL (UNII: Q9L0O73W7L)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CANDELILLA WAX (UNII: WL0328HX19)	
LANOLIN (UNII: 7EV65EAW6H)	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	
SHEA BUTTER (UNII: K49155WL9Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73537-701-12	4.25 g in 1 TUBE; Type 0: Not a Combination Product	12/11/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/11/2019	

Labeler - DSG INNOVATIONS INC (203900654)

Establishment

Name	Address	ID/FEI	Business Operations
DIVERSIFIED MANUFACTURING CORP		185073996	manufacture(73537-701)

Revised: 12/2019

DSG INNOVATIONS INC