

LIP BALM SPF- octinoxate, zinc oxide stick
Harry's, 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.

Lip Balm SPF 15

Drug Facts

Active ingredients

Octinoxate 7.5%

Zinc Oxide 6.0%

Purpose

Sunscreen

Use

helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early aging.

For external use only

Do not use

on damaged or broken skin

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

if rash or irritation occurs

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

• apply liberally 15 minutes before sun exposure • re-apply at least every 2 hours • use a water-resistant sunscreen if swimming or sweating • children under 6 months: ask a doctor

Inactive ingredients

Hydrogenated Coconut Oil, Butyrospermum Parkii (Shea) Butter, Microcrystalline Wax, Beeswax, C12-15 Alkyl Benzoate, C18-C70 Isoparaffin, Myristyl Myristate, Polyethylene, Flavor, Paraffin, Menthyl

Lactate, Tocopheryl Acetate, Polyhydroxystearic Acid, Helianthus Annuus (Sunflower) Seed Oil, Sodium Saccharin, Triethoxycaprylylsilane, Limonene, BHT, Linalool, Cucumis Sativus (Cucumber) Seed Extract, Citric Acid

Other information

Protect the product in this container from excessive heat and direct sun

Questions or comments?

Call 1-888-212-6855

Package Labeling:

PREVENTS DRYNESS. FEELS COOL. NO SHINE. PEPPERMINT-Y.

HARRY'S

LIP BALM SPF 15

MOISTURIZES & PROTECTS

Drug Facts (continued)

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Drug Facts (continued)

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NET WT 0.2 OZ / 5.7 g EACH

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Made in the USA
 Harry's, Inc.
 New York, NY 10013
 Harry's, H, Give a Shave and Mammoth Design are trademarks of Harry's, Inc.

Drug Facts

Active ingredients Octinoxate 7.5%, Zinc Oxide 6.0%	Purpose Sunscreen
Use helps prevent sunburn	

LIP BALMS 3X

LIP BALMS 3X

OUTSIDE

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Uses: Helps prevent sunburn.

**Warnings: When using this product,
keep out of eyes. Stop use if rash occurs.**

ACTIVE INGREDIENTS: OCTINOXATE (7.5%) ZINC OXIDE (6.0%) **INACTIVE INGREDIENTS:** HYDROGENATED COCONUT OIL, BUTYROSPERMUM PARKII BUTTER, MICROCRYSTALLINE WAX, BEESWAX, C12-15 ALKYL BENZOATE, C18-C70 ISOPARAFFIN, MYRISTYL MYRISTATE, POLYETHYLENE, FLAVOR, PARAFFIN, MENTHYL LACTATE, TOCOPHERYL ACETATE, POLY-HYDROXYSTEARIC ACID, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, SODIUM SACCHARIN, TRIETHOXYCAPRYLYLSILANE, LIMONENE, BHT, LINALOOL, CUCUMIS SATIVUS (CUCUMBER) SEED EXTRACT, CITRIC ACID.

HARRYS.COM

Distributed by ADKM, Inc. NY, NY 10003

H'

**LIP BALM
SPF 15**

NET WT 5.7 g / 0.2 oz

LIP BALM SPF

octinoxate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70533-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	60 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED COCONUT OIL (UNII: JY81OXM1OM)	
SHEA BUTTER (UNII: K49155WL9Y)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
PARAFFIN (UNII: I9O0E3H2ZE)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
CUCUMBER SEED (UNII: BT3S9L53JK)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70533-002-57	1 in 1 CARTON	04/03/2016	
1		5.7 g in 1 TUBE; 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	04/01/2016	

Labeler - Harry's, Inc. (079239206)

Revised: 4/2016

Harry's, Inc.