

MICKEY SUN SMACKER SPF 24 CLASSIC VANILLA - octinoxate, oxybenzone, padimate o lipstick

Bonne Bell 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.

Mickey Sun Smacker SPF 24 Classic Vanilla

Drug Facts

ACTIVE INGREDIENTS

Octinoxate 7.5 percent w per w

Oxybenzone 6.0 percent w per w

Padimate 0 8.0 percent w per w

PURPOSES

Sunscreen

USE

HELPS PREVENT SUNBURN.

WARNINGS

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

For external use only

Do not use

on damaged or broken skin

Stop use and ask a doctor

if rash occurs

When using this product

keep out of eyes. Rinse with water to remove

Keep out of the reach of children.

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

DIRECTIONS

- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating

- Reapply at least every 2 hours
- Children under 6 months of age: Ask a doctor.

Storage and Handling

Protect this product from excessive heat and direct sun

INACTIVE INGREDIENTS

RICINUS COMMUNIS (CASTOR) SEED OIL, CETYL ACETATE, BEESWAX (CERA ALBA), EUPHORBIA CERIFERA (CANDELILLA) WAX, FLAVOR/AROMA, POLYBUTENE, COPERNICIA CERIFERA (CARNAUBA) WAX, OZOKERITE, ACETYLATED LANOLIN ALCOHOL, SESAMUM INDICUM (SESAME) SEED OIL, ISOPROPYL MYRISTATE, BENZYL BENZOATE, PARAFFIN, POLYESTER-3, TRITICUM VULGARE (WHEAT) GERM OIL, MICA, PROPYLENE GLYCOL, STEARIC ACID, HYDROGENATED SOY GLYCERIDES, PROPYL GALLATE, CITRIC ACID, NEOTAME, CITRAL, LINALOOL, BENZYL ALCOHOL, GERANIOL, METHYL 2-OCTYNOATE, CINNAMAL, EUGENOL, FARNESOL, LIMONENE. **MAY CONTAIN (PLUS OR MINUS) TITANIUM DIOXIDE (CI 77891), BLUE 1 LAKE (CI 42090), RED 28 (CI 45410), RED 6 LAKE (CI 15850), RED 22 (CI 45380), YELLOW 5 LAKE (CI 19140), CARMINE (CI 75470).**

Questions or Comments

Call 1-866-984-1433

Package Label

SUNSCREEN LIP BALM SPF 24
SUN SMACKER
Classic Vanilla

(c) Disney

DIST. ASPIRE BRANDS/BONNE BELL (R)
SANTA MONICA CA 90404 N-1703 SARPSBORG NORWAY
Made in U.S.A. **net wt 0.14 oz 4.0 g**

Drug Facts

ACTIVE INGREDIENTS	PURPOSES
Octinoxate 7.5% w/w	Sunscreen
Oxybenzone 6.0% w/w	Sunscreen
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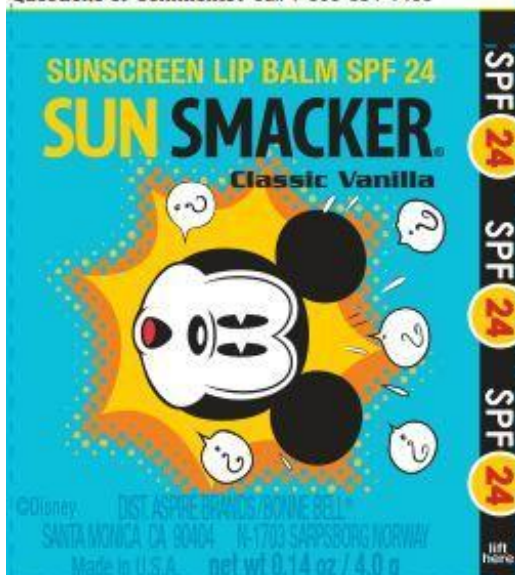
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octinoxate, oxybenzone, padimate o lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50051-0008
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
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 g
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
CETYL ACETATE (UNII: 4Q43814HXS)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
ACETYLATED LANOLIN ALCOHOLS (UNII: SNN716810P)	
SESAME OIL (UNII: QX10HYY4QV)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
BENZYL BENZOATE (UNII: N863NB338G)	
PARAFFIN (UNII: I9O0E3H2ZE)	
WHEAT GERM OIL (UNII: 14C97E680P)	
MICA (UNII: V8A1AW0880)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
NEOTAME (UNII: VJ597D52EX)	
CITRAL (UNII: T7EU0O9VPP)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GERANIOL (UNII: L837108USY)	
METHYL HEPTINE CARBONATE (UNII: 0TTP6YT2T3)	
CINNAMALDEHYDE (UNII: SR60A3XG0F)	
EUGENOL (UNII: 3T8H1794QW)	
FARNESOL (UNII: EB41QIU6JL)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C RED NO. 22 (UNII: 1678RXX8RT)	
D&C RED NO. 6 (UNII: 481744AI4O)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA (vanilla)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50051-0008-4	4 g in 1 CYLINDER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/06/2012	

Labeler - Bonne Bell LLC (004189809)

Revised: 9/2012

Bonne Bell LLC