

LIP SMACKER SPF 24 LEMON LIME RUSH - octinoxate, oxybenzone 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.

Lip Smacker SPF 24 Lemon Lime Rush

ACTIVE INGREDIENTS

OCTINOXATE 7.5% W/W, OXYBENZONE 6.0% W/W, PADIMATE O 8.0% W/W.

PURPOSE

SUNSCREEN

USE

HELPS PREVENT SUNBURN

WARNINGS

STOP USE AND ASK A DOCTOR IF RASH OR IRRITATION DEVELOPS AND LASTS.

DIRECTIONS

APPLY LIBERALLY BEFORE SUN EXPOSURE AND AS NEEDED.

ASK DOCTOR

CHILDREN UNDER 6 MONTHS OF AGE, ASK A DOCTOR.

PACKAGE LABEL DISPLAY

Lip SMACKER (R)

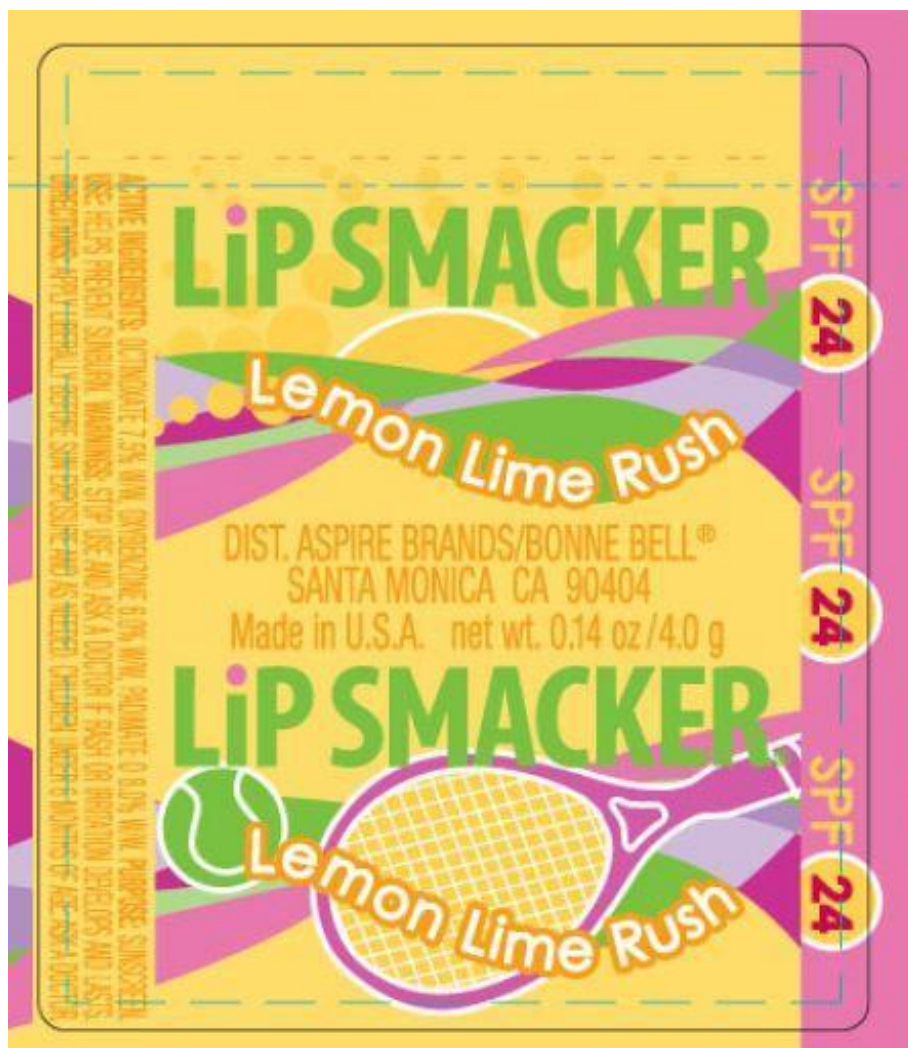
Lemon Lime Rush

DIST. ASPIRE BRANDS/BONNE BELL (R)

SANTA MONICA CA 90404

Made in U.S.A. net wt. 0.14 oz/4.0 g

SPF 24



LIP SMACKER SPF 24 LEMON LIME RUSH

octinoxate, oxybenzone lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50051-0019
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
RICINUS COMMUNIS SEED (UNII: 7EK4SFN1TX)	
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)	
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)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	LEMON (lemon) , LIME (lime)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50051-0019-4	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	10/11/2012	

Labeler - Bonne Bell LLC (004189809)

Establishment

Name	Address	ID/FEI	Business Operations
Apex International		015226132	manufacture(50051-0019)