

PREP SPF 15 LIP GLOSS- zinc oxide sunscreen gel

PREP Cosmetics 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.

PREP SPF 15 Lip Gloss

Active Ingredient

Zinc Oxide 11%

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

For external use only

Do not use

Do not use on damaged or broken skin.

When Using

When using this product keep out of eyes. Rinse with water to remove.

Stop Use

Stop use and ask a doctor if rash occurs.

Keep out of reach of children

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

Directions

- Apply generously 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water-resistant sunscreen if swimming or sweating
- Children under 6 months: ask a doctor

Sun Protection Measures

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 am- 2 pm
- wear long-sleeved shirts, pants, hats. and sunglasses

Other Information

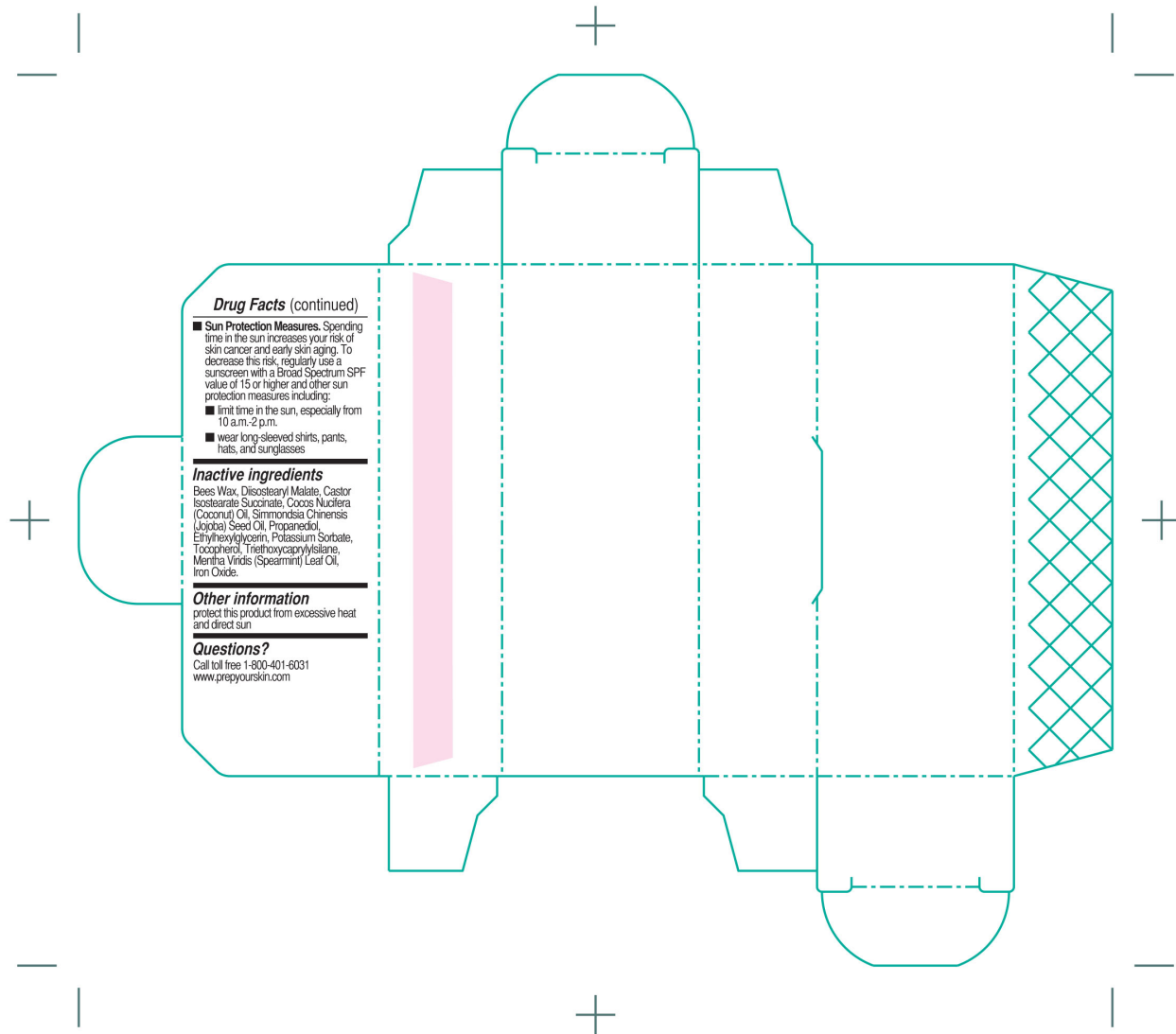
Protect this product from excessive heat and direct sun

Questions?

Call toll-free 1-800-401-6031

www.prepyourskin.com

Inactive Ingredients



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651 S ML King Jr Ave • Waukegan, IL 60085 • Phone 847.336.4200 • Fax 847.360.4924
1100 Venture Court • Suite 100 • Carrollton, Texas 75006 • Phone 972.478.6400 • Fax 972.478.6401

Proof C
12/31/2014

Product Information

P/N: PREP-LIP-GLOSS
J/N: 300759
Cust: PREP COSMETICS LLC
Size: 1.25x0.75x3.25
Die: 141821 Braille: NA
CR:

Specified Colors



Approved By

Name _____

Date _____

OK to Print New Proof Required

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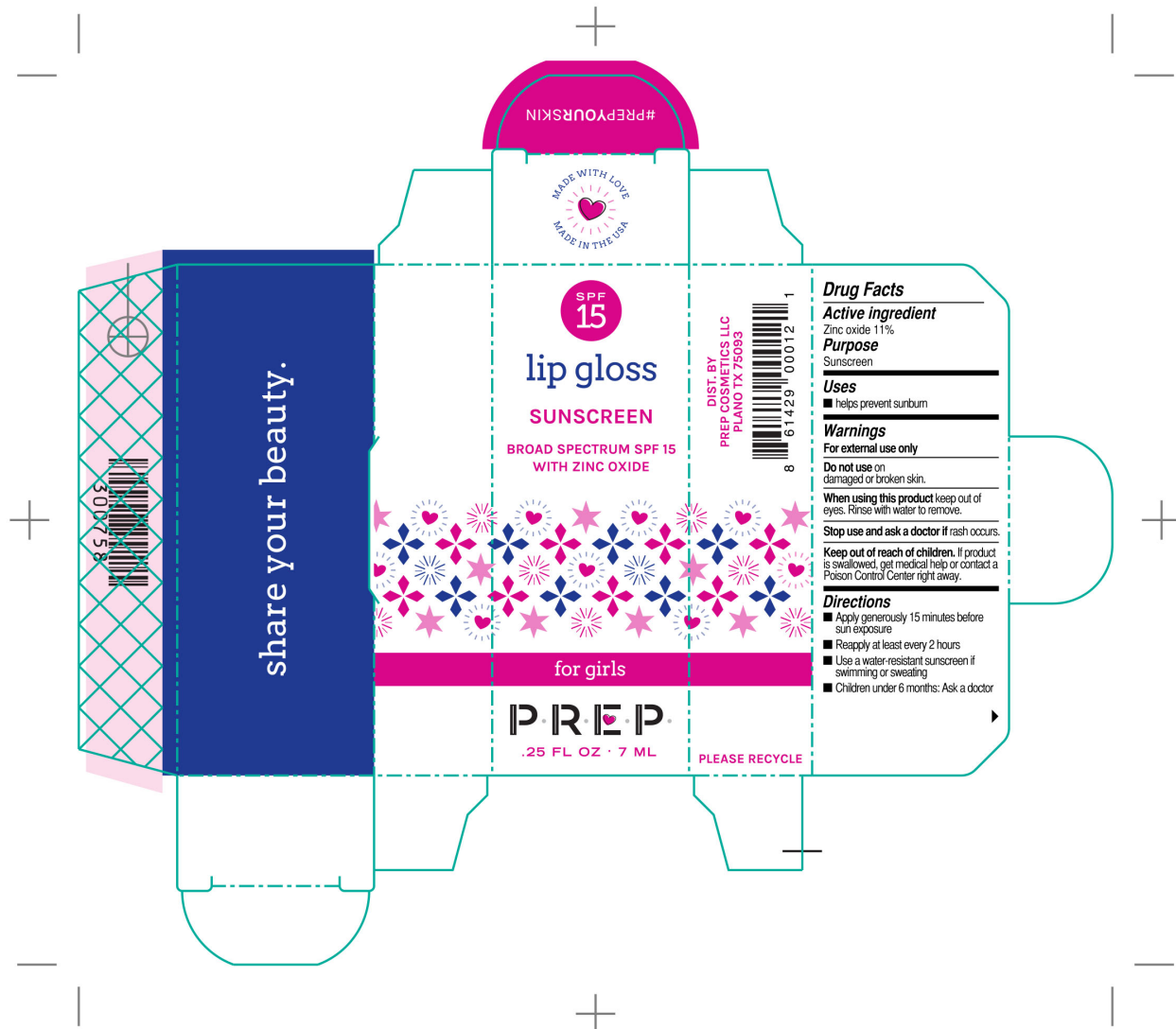
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PDF/X overprint When correctly rendered in compliance with PDF/X standards no 'x' should appear in any box. Please check overprint settings should you see an 'x'

Castor Oil, Coconut Oil, Diisostearyl Malate, Ethylhexylglycerin, Ferric Oxide Red, Isostearic Acid, Jojoba Oil, Potassium Sorbate, Propanediol, Spearmint Oil, Succinic Acid, Tocopherol, Triethoxycaprylsilane, Yellow Wax

Carton Label



Nosco complete packaging individual solutions™		651 S ML King Jr Ave • Waukegan, IL 60085 • Phone 847.336.4200 • Fax 847.360.4924 1100 Venture Court • Suite 100 • Carrollton, Texas 75006 • Phone 972.478.6400 • Fax 972.478.6401	Proof A 12/23/2014
Product Information P/N: PREP-LIP-GLOSS J/N: 300758 Cust: PREP COSMETICS LLC Size: 1.25 X .75 X 3.25 Dieline: NEW Braille: NA CR:	Specified Colors 	Approved By Name _____ Date _____ <input type="checkbox"/> OK to Print <input type="checkbox"/> New Proof Required We must have signed proof before we can begin production.	
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PREP SPF 15 LIP GLOSS

zinc oxide sunscreen gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70231-0012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	110 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CASTOR OIL (UNII: D5340Y2I9G)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
SUCCINIC ACID (UNII: AB6MNQ6J6L)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
COCONUT OIL (UNII: Q9L0O73W7L)	
JOJOBA OIL (UNII: 724GKU717M)	
PROPANEDIOL (UNII: 5965N8W85T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SPEARMINT OIL (UNII: C3M81465G5)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70231-0012-7	1 in 1 CARTON	01/11/2015	
1		7 mL 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 final	part352	01/11/2015	

Labeler - PREP Cosmetics LLC (053793815)

Registrant - Richard Hamer Associates LLC (067731889)

Establishment

Name	Address	ID/FEI	Business Operations
Taka USA Inc. dba Cosmetic Innovations		802860515	manufacture(70231-0012) , pack(70231-0012)

Revised: 7/2018

PREP Cosmetics LLC