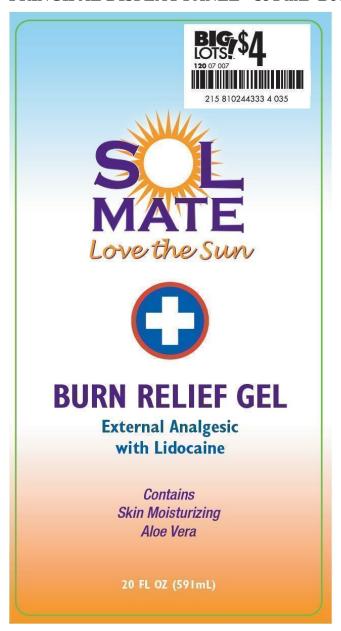
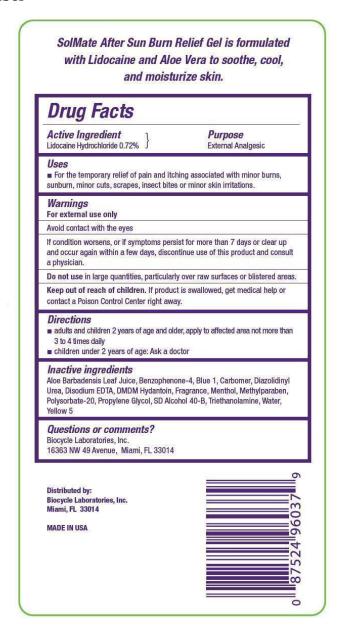
# SOLMATE BURN RELIEF GEL- lidocaine hydrochloride gel Prime Enterprises, Inc.

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.

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#### PRINCIPAL DISPLAY PANEL - 591 mL Bottle Label





SOL
MATE
LOVE THE SUN
BURN RELIEF GEL
External Analgesic
with Lidocaine
Contains

Skin Moisturizing

Aloe Vera

20 FL OZ (591 mL)

### **Active ingredients**

Lidocaine Hydrochloride 0.72 %

#### **Purpose**

External Analgesic

#### Uses

For the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin irritations.

#### Warnings

#### For external use only

- Avoid contact with the eyes.
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discountinue use of this product and consult a physician.

**Do not use** I in large quantities, particularly over raw surfaces or blistered areas.

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- Adults and children 2 years of age and older, apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: ask a doctor.

#### **Inactive ingredients**

Aloe Barbadensis Leaf Juice, Benzophenone-4, Blue 1, Carbomer, Diazolidinyl Urea, Disodium EDTA, DMDM Hydantoin, Fragrance, Menthol, Methylparaben, Polysorbate 20, Propylene Glycol, SD Alcohol 40-B, Triethanolamine, Water, Yellow 5

#### **Questions or Comments?**

Biocycle Laboratories, Inc.

16363 NW 49 Avenue, Miami, Fl 33014

#### SOLMATE BURN RELIEF GEL

lidocaine hydrochloride gel

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:58443-0145

TOPICAL

ı	Ingredient Name	Basis of Strength	Strength
ı	LIDO CAINE (UNII: 98 PI20 0 987) (LIDO CAINE - UNII: 98 PI20 0 987)	LIDOCAINE	0.057 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
BENZOPHENONE (UNII: 701M4TTV9O)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
DMDM HYDANTO IN (UNII: BYR0546TOW)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A218 C7H19 T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	
TROLAMINE (UNII: 903K93S3TK)	

## **Product Characteristics**

WATER (UNII: 059QF0KO0R)

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0145-7	591 mL in 1 BOTTLE		

## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	0 4/0 1/20 15	

## Labeler - Prime Enterprises, Inc. (101946028)

Establishment				
Name	Address	ID/FEI	Business Operations	
Prime Enterprises, Inc.		101946028	label(58443-0145), pack(58443-0145), manufacture(58443-0145), analysis(58443-0145)	

Revised: 1/2015 Prime Enterprises, Inc.