

**LEADER MOISTURE SPF 15 LIP BALM- oxybenzone, octinoxate, petrolatum stick  
Cardinal Health (Leader)**

*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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**Drug Facts**

**Active ingredient**

Octinoxate (7.5%), Oxybenzone (3.5%)

Petrolatum (40.7%)

**Purpose**

Sunscreen, Sunscreen, Skin Protectant

**Keep Out of Reach of Children**

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

**Uses**

Helps prevent sunburn. Helps prevent and temporarily protects dry, chapped or windburned lips.

**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 prevent sunburn, not skin cancer or early aging.

For external use only: Stop use and ask a doctor: if rash or irritation develops and lasts.

**Directions**

Apply liberally before sun exposure and as needed. Children under 6 months of age: Ask a doctor before use.

**Inactive Ingredients**

Ozokerite, Mineral Oil, Isocetyl Stearate, Microcrystalline Wax, Isopropyl Lanolate, Lanolin, Copernicia Cerifera (Carnauba) Wax, Tocopheryl Acetate, Isopropyl Myristate, Aloe Barbadenis Leaf Extract, Paraffin, Cetyl Alcohol, Tocerpheryl Linoleate, Flavor, Methylparaben, Propylparaben.

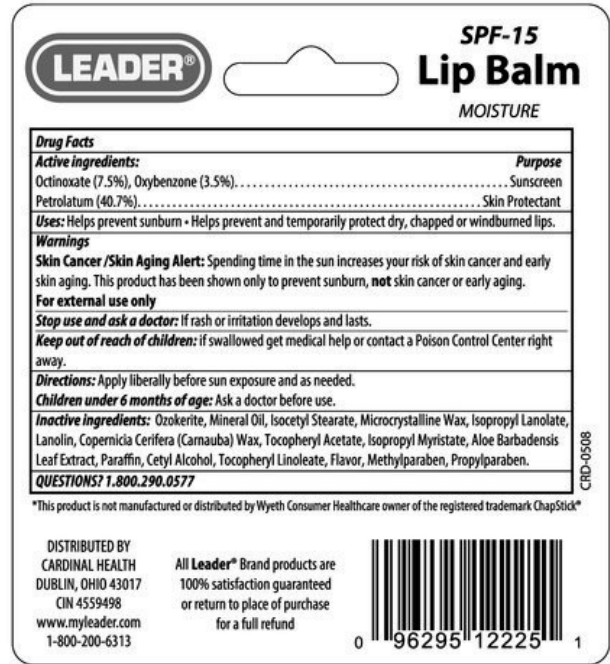
**Package/Label Principal Display Panel**

Front of Card

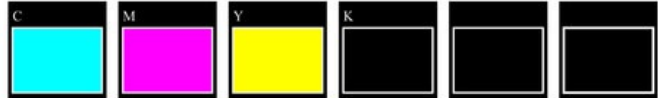
3.5in x 3.875in



Back of Card



## Imprint Color(s)



## Art Guidelines

### 1. Labels

- a. Positive imprint - 5 pt minimum ..... Sample Text
- b. Reverse imprint - 7 pt minimum ..... Sample Text
- c. Serif and italic types - 7 pt minimum ..... Sample Text
- d. Line weight, positive lines - .5 .....
- e. Line weight, reverse lines (gap) - .75 .....

- \* Ornate and display type faces will be printed on a case-by-case analysis.
- \* Registered marks and trademarks should be enlarged for clear printing.

## Color Variance Notification

- This PDF file is being viewed on an RGB monitor therefore there will be a variance between the color on your screen and the color of the actual finished product.
- This proof should be used to inspect the layout, spelling, color selection and approximate color appearance.
- Colors printed on different mediums (ie: leash and label) will not be an exact match.
- This proof is not an exact match of the finished product color or quality of the printed peice.

## LEADER MOISTURE SPF 15 LIP BALM

oxybenzone, octinoxate, petrolatum stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37205-693
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mg in 1 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3.5 mg in 1 g
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	40.7 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	17.13 mg in 1 g
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	16.75 mg in 1 g
<b>ISO CETYL STEARATE</b> (UNII: 3RJ7186O9W)	3.50 mg in 1 g
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	3.00 mg in 1 g
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	1 mg in 1 g
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	.60 mg in 1 g

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:37205-693-03	1 g in 1 CONTAINER		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352	03/15/2013	

**Labeler** - Cardinal Health (Leader) (097537435)**Registrant** - Cardinal Health (Leader) (097537435)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
OraLabs		801824756	MANUFACTURE(37205-693) , LABEL(37205-693)

