

**CERAVINE LIP BALM - oatmeal stick****Biostandard 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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**Drug Facts****Active ingredient**

Colloidal Oatmeal (0.1%)

**Purpose**

Skin Protectant

**Uses**

- Temporarily relieves pain and itching commonly associated with dryness
- Helps prevent and heal dry; chapped and cracked lips

**Warnings**

- If irritation or rash persists, consult a physician

**Do not use on**

cuts, scrapes, or broken skins

**Stop use and ask a doctor**

if irritation or rash persists.

**Keep out of reach of children.**

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

**Directions**

Apply generously as needed.

**Other information**

Store between 0 C to 28 C (62 F to 82.4 F)

**Inactive ingredients**

Ricinus Communis (Castor) Seed Oil, Cera Alba (Beeswax), Olea Europaea (Olive) Fruit Oil,

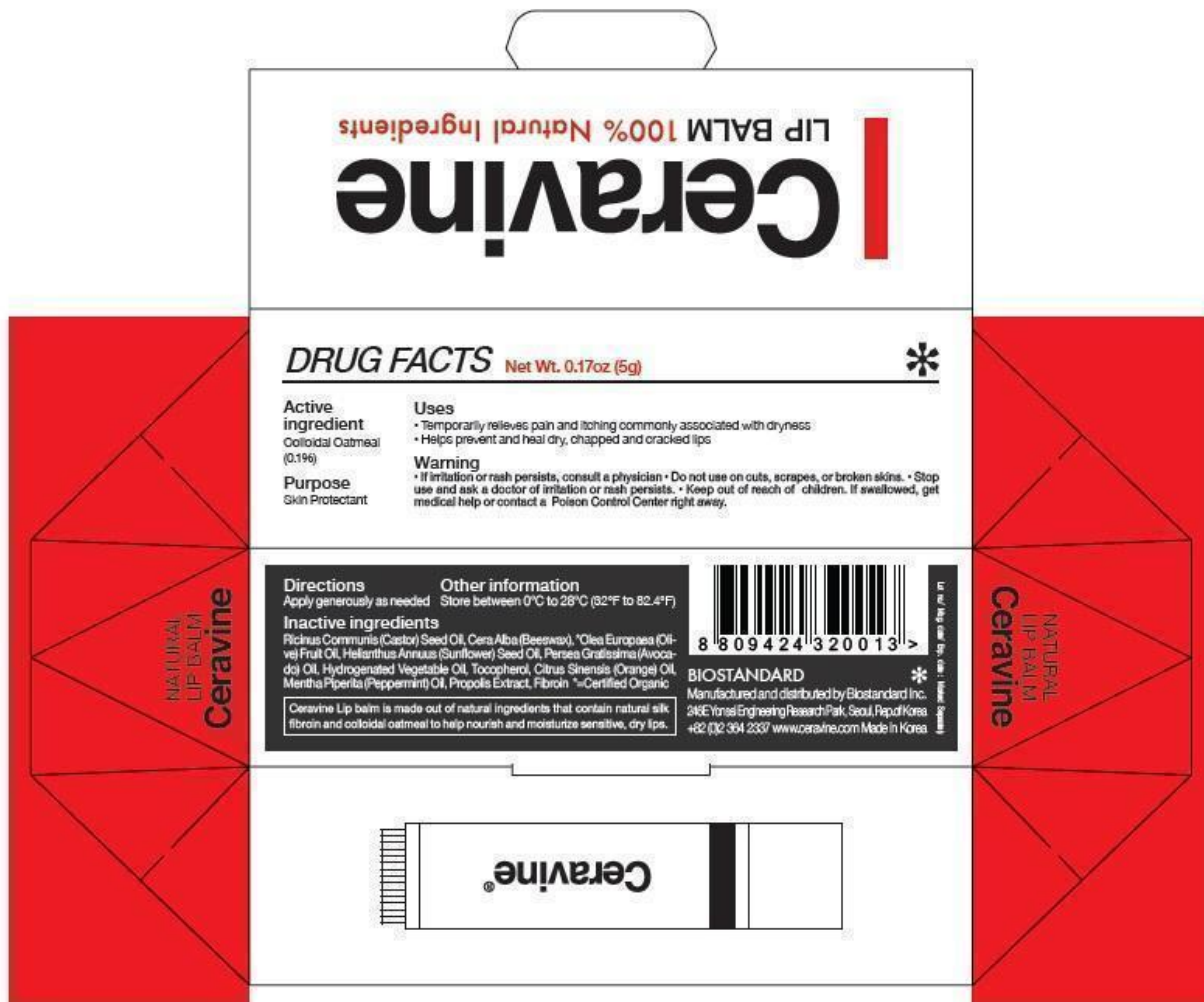
Helianthus Annus (Sunflower) Seed Oil, Persea Gratissima (Avocado) Oil, Hydrogenated Vegetable Oil, Tocopherol, Citrus Sinensis (Orange) Oil, Mentha Piperita (Peppermint) Oil, Propolis Extract, Fibroin

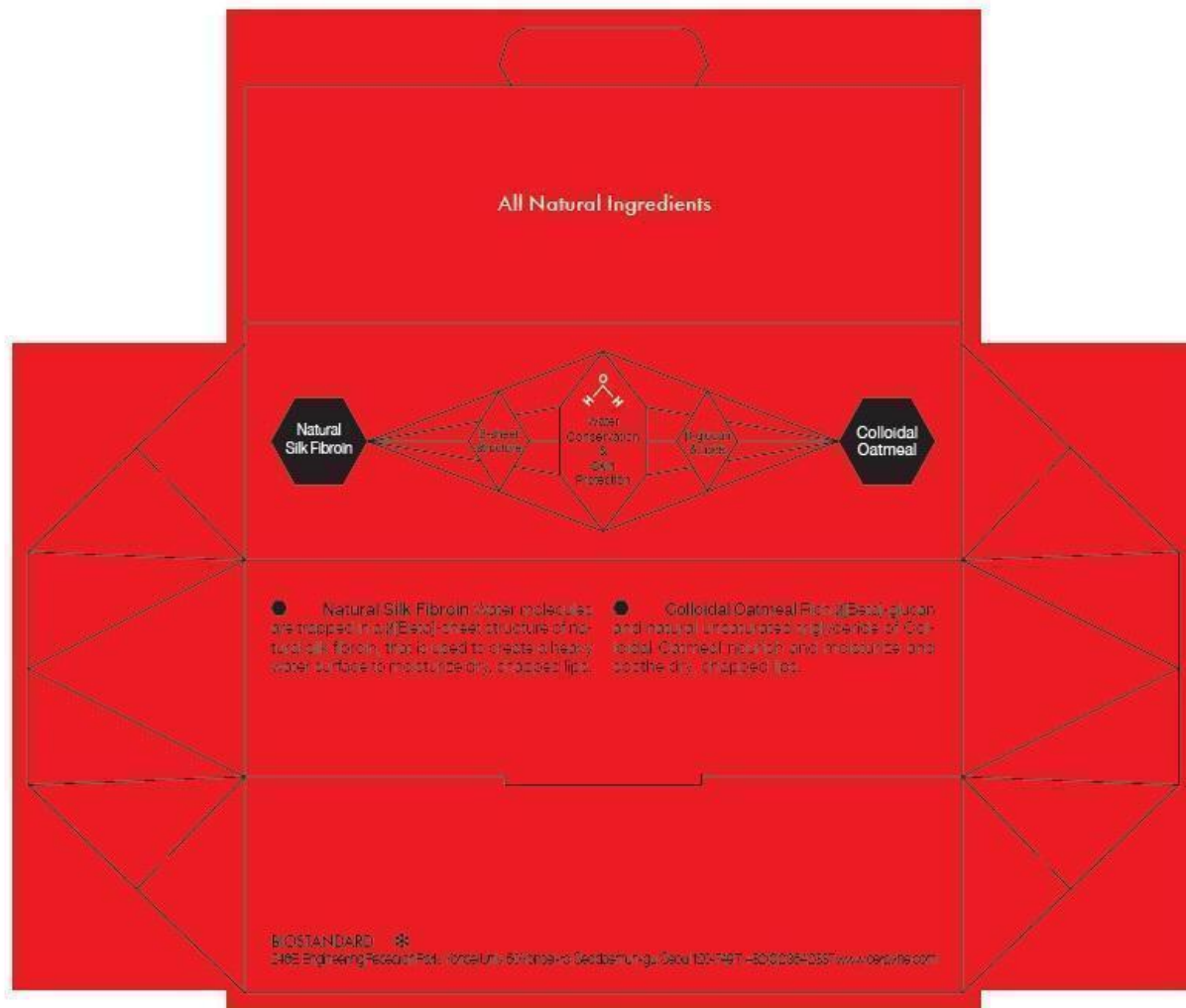
## Principal Display Panel

Ceravine LIP BALM

100% Natural Ingredients

Net Wt. 0.17 oz (5g)





## CERAVINE LIP BALM

oatmeal stick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61403-030
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	0.0003 g in 5 g

### Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
OLIVE OIL (UNII: 6UYK2W1W1E)	

SUNFLOWER OIL (UNII: 3W1JG795YI)				
AVOCADO OIL (UNII: 6VNO72PFC1)				
TOCOPHEROL (UNII: R0ZB2556P8)				
ORANGE OIL (UNII: AKN3KSD11B)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
PROPOLIS WAX (UNII: 6Y8XYV2NOF)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61403-030-01	1 in 1 CARTON		
1		5 g in 1 APPLICATOR; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part347	08/04/2015	

**Labeler** - Biostandard Inc. (688735402)

**Registrant** - Biostandard Inc. (688735402)

Establishment			
Name	Address	ID/FEI	Business Operations
Biostandard Inc.		688735402	manufacture(61403-030)