

LIP BALM SPF 15 - octinoxate oxybenzone ointment
Fercy Personal Care Products Co Limited

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.

Fercy Personal Care Products Lip Balm SPF 15 Drug Facts

Active Ingredient

Octinoxate 7.5%

Oxybenzone 3%

PURPOSE

sunscreen

USE

helps protect against sunburn and chapped lips

Warning

For external use only

keep out of eyes.

stop use if skin rash occurs.

keep out of reach of children.

Directions

Apply to lips prior to sun exposure.

apply to lips when dry or chapped.

Keep out of reach of children

Keep out of reach of children

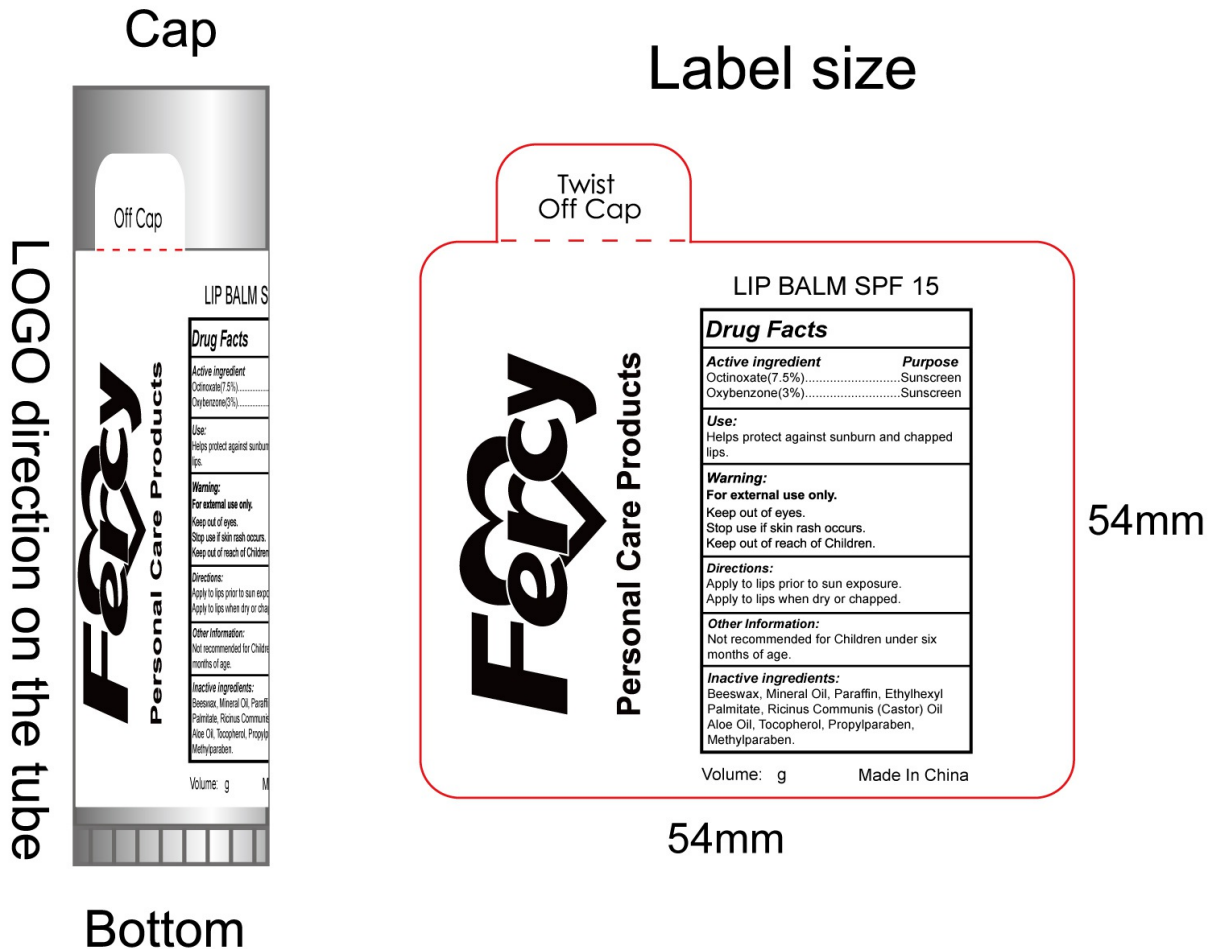
not recommended for children under six months of age

Inactive Ingredient

Mineral Oil,Paraffin,Beeswax,Ethylhexyl Palmitate,Ricinus

Communis,ALOE,Tocopherol,Propylparaben,Methylparaben

Lip Balm Label



LIP BALM SPF 15

octinoxate oxybenzone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50260-800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3 g in 100 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Mineral Oil (UNII: T5L8T28FGP)	27.5 g in 100 g
Paraffin (UNII: I9O0E3H2ZE)	26 g in 100 g
White Wax (UNII: 7G1J5DA97F)	23 g in 100 g
Ethylhexyl Palmitate (UNII: 2865993309)	6 g in 100 g
Ricinus Communis Seed (UNII: 7EK4SFN1TX)	4 g in 100 g
ALOE (UNII: V5VD430YW9)	1 g in 100 g
ALPHA-Tocopherol (UNII: H4N855PNZ1)	1 g in 100 g
Propylparaben (UNII: Z8IX2SC1OH)	0.5 g in 100 g
Methylparaben (UNII: A2I8C7HI9T)	0.5 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50260-800-01	2.8 g in 1 TUBE		
2	NDC:50260-800-02	3 g in 1 TUBE		
3	NDC:50260-800-03	4 g in 1 TUBE		
4	NDC:50260-800-04	4.2 g in 1 TUBE		
5	NDC:50260-800-05	4.8 g in 1 TUBE		
6	NDC:50260-800-06	5 g in 1 TUBE		
7	NDC:50260-800-07	6 g in 1 TUBE		
8	NDC:50260-800-08	8 g in 1 TUBE		
9	NDC:50260-800-09	9 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/09/2010	

Labeler - Fercy Personal Care Products Co Limited (529623870)

Establishment

Name	Address	ID/FEI	Business Operations
Fercy Personal Care Products Co Limited		529623870	manufacture

Revised: 1/2011

Fercy Personal Care Products Co Limited