

LIP BALM- sunscreen lip balm stick
Private Label Select Ltd CO

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.

EMS Natural Lip Balm SPF15

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ALCOHOL, GLUTEN, CRUELTY, PESTICIDE, & PARABEN FREE

NATURAL LIP BALM
UVA/UVB PROTECTION
BROAD SPECTRUM SPF 15
UNSCENTED

NET WT 0.15 OZ (4.25G)

EASTERN MOUNTAIN SPORTS

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EASTERN MOUNTAIN SPORTS

DISTRIBUTED BY:
MOUNTAIN SPORTS LLC
MADE IN THE USA

Drug Facts	
Active Ingredients	Purpose
Octinoxate (7.5%)	Sunscreen
Oxybenzone (6%)	Sunscreen
Avobenzone (3%)	Sunscreen
Uses	
• Helps prevent sunburn	
Warnings	
For external use only.	
Do not use on damaged or broken skin.	
When using this product keep out of eyes. Rinse with water to remove.	
Stop use and ask a doctor if skin rash occurs.	
Keep out of reach of children.	
If swallowed, get medical help or contact a Poison Control Center right away.	
Sun Protection Measures	
Spending time in the sun increases your risk of skin cancer and early skin aging.	

EMS Natural Lip Balm SPF15 pt2

	<p>Drug Facts <i>(continued)</i></p> <hr/> <p>Directions</p> <ul style="list-style-type: none"> • Apply liberally 15 minutes before sun exposure. • Reapply at least every 2 hours. • Children under 6 months of age: Ask a doctor. <hr/> <p>Inactive Ingredients</p> <p>Sunflower seed oil*, Beeswax*, Coconut oil*, Shea Butter*, Natural Flavors, Grapeseed Oil, Tocopherol, Monoammonium Glycyrhizinate, Resveratrol</p> <p>*Certified Organic Ingredients</p> <hr/> <p>Other Information</p> <p>Protect this product from excessive heat and direct sun.</p> <hr/> <p>Questions?</p> <p>visit www.ems.com</p>
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LIP BALM

sunscreen lip balm stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-186
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TANGERINE PEEL (UNII: JU3D414057)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
RESVERATROL (UNII: Q369O8926L)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
TOCOPHEROL (UNII: R0ZB2556P8)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
ORANGE OIL (UNII: AKN3KSD11B)	

Product Characteristics

Color	white	Score	
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Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-186-25	4.25 g in 1 TUBE; Type 0: Not a Combination Product	11/30/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/30/2018	

Labeler - Private Label Select Ltd CO (005415463)

Registrant - Private Label Select Ltd CO (005415463)

Revised: 11/2018

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