

SHIELD AND HEAL MEDICATED LIP BALM- menthol stick
Shield and Heal 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.

Shield + Heal Medicated Lip Balm

Drug Facts

Active ingredient

Menthol 1%

Purpose

External analgesic

Use

for the temporary relief of pain and itching associated with fever blisters and cold sores.

Warnings

For external use only.

If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

When using this product

avoid contact with eyes.

Keep out of reach of children.

If 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: consult a doctor.

Other information

- Store at room temperature and avoid excessive heat.

Inactive ingredients

Helianthus Annuus (Sunflower) Seed Oil, Moringa Oil/Hydrogenated Moringa Oil Esters, Synthetic Beeswax, Euphorbia Cerifera (Candelilla) Wax, Copernicia Cerifera Cera, Ricinus Communis (Castor) Seed Oil, Lanolin, Butyrospermum Parkii (Shea) Butter, Tocopheryl Acetate, Butyrospermum Parkii (Shea) Butter Unsaponifiables, Camphor, Avena Sativa (Oat) Kernel Flour, Butyrospermum Parkii (Shea Butter), Citrus Aurantium Dulcis (Orange) Peel Oil, Cocos Nucifera (Coconut) Oil, Eucalyptus Globulus Leaf Oil, Garcinia Indica Seed Butter, Glyceryl Laurate, Hippophae Rhamnoides (Sea Buckthorn) Fruit Oil, Lavandula Angustifolia (Lavender) Oil, Pongamia Glabra Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Propolis Extract, Water, Achillea Millefolium Flower Extract.

Call toll free 888-933-3253 or learn more at www.shieldandheal.com

Product Packaging



SHIELD AND HEAL MEDICATED LIP BALM

menthol stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81470-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL LAURATE (UNII: Y98611C087)	
CASTOR OIL (UNII: D5340Y2I9G)	
ORANGE OIL (UNII: AKN3KSD11B)	
JOJOBA OIL (UNII: 724GKU717M)	
ACHILLEA MILLEFOLIUM WHOLE (UNII: 2FXJ6SW4PK)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
WATER (UNII: 059QF0KO0R)	
GARCINIA INDICA SEED BUTTER (UNII: US2H3D7800)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CANDELILLA WAX (UNII: WL0328HX19)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
TOCOPHEROL (UNII: R0ZB2556P8)	
COCONUT OIL (UNII: Q9L0O73W7L)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
KARUM SEED OIL (UNII: 62160PU6FJ)	
OATMEAL (UNII: 8PI54V663Y)	
LANOLIN (UNII: 7EV65EAW6H)	
SHEA BUTTER (UNII: K49155WL9Y)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81470-001-01	1 in 1 CARTON	02/15/2021	
1		4.25 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:81470-001-02	2 in 1 CARTON	02/15/2021	
2		4.25 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph not final	part348	02/15/2021	

Labeler - Shield and Heal Inc. (117700988)

Revised: 4/2023

Shield and Heal Inc.