

SHIELD AND HEAL LIP BALM- menthol

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 Lip Balm Kit

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

- children under 2 years of age: consult a doctor.
- adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily

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.

Product Packaging



Drug Facts

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Menthol 1 %	External analgesic

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Botanical 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, Fragrance, Tocopheryl Acetate, Butyrospermum Parkii (Shea) Butter Unsaponifiables, 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.

SHIELD AND HEAL LIP BALM

menthol kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81470-002
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81470-002-01	1 in 1 KIT; Type 0: Not a Combination Product	02/15/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	4.25 g
Part 2	1 TUBE	4.25 g

Part 1 of 2

SHIELD AND HEAL MEDICATED LIP BALM

menthol stick

Product Information

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
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SHEA BUTTER (UNII: K49155WL9Y)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
OATMEAL (UNII: 8PI54V663Y)	
ORANGE OIL (UNII: AKN3KSD11B)	
COCONUT OIL (UNII: Q9L0O73W7L)	
KARUM SEED OIL (UNII: 62160PU6FJ)	
GARCINIA INDICA SEED BUTTER (UNII: US2H3D7800)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
CASTOR OIL (UNII: D5340Y2I9G)	
GLYCERYL LAURATE (UNII: Y98611C087)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
LANOLIN (UNII: 7EV65EAW6H)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CANDELILLA WAX (UNII: WL0328HX19)	
ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)	
HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
JOJOBA OIL (UNII: 724GKU717M)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 KIT		
1		4.25 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

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

Part 2 of 2

SHIELD AND HEAL BOTANICAL LIP BALM

lipstick stick

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
INGR	CARNAUBA WAX (UNII: R12CBM0EIZ)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
INGR	ORANGE OIL (UNII: AKN3KSD11B)	
INGR	COCONUT OIL (UNII: Q9L0O73W7L)	
INGR	KARUM SEED OIL (UNII: 62160PU6FJ)	
INGR	GARCINIA INDICA SEED BUTTER (UNII: US2H3D7800)	
INGR	LAVENDER OIL (UNII: ZBP1YXW0H8)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	CASTOR OIL (UNII: D5340Y2I9G)	

INGR	GLYCERYL LAURATE (UNII: Y98611C087)	
INGR	SUNFLOWER OIL (UNII: 3W1JG795YI)	
INGR	LANOLIN (UNII: 7EV65EAW6H)	
INGR	EUCALYPTUS OIL (UNII: 2R04ONI662)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	CANDELILLA WAX (UNII: WL0328HX19)	
INGR	ACHILLEA MILLEFOLIUM FLOWER (UNII: YQR8R0SQEA)	
INGR	HIPPOPHAE RHAMNOIDES FRUIT OIL (UNII: TA4JCF9S1J)	
INGR	JOJOBA OIL (UNII: 724GKU717M)	
INGR	PROPOLIS WAX (UNII: 6Y8XYV2NOF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 KIT		
1		4.25 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		02/15/2021	

Marketing Information

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

Labeler - Shield and Heal Inc. (117700988)