

BURN GEL 01- melaleuca alternifolia (tea tree) leaf oil gel
Cosmuses Cosmetics (Ningbo) Co., Ltd.

burn gel

Drug Facts

Active ingredients

melaleuca alternifolia (tea tree) leaf oil 1%

Purpose

antibacterial and soothing

Uses

Temporary soothes aches and pains associated with minor burn

warnings

For external use only.

Flammable: keep away from excessice heat or open flame.

Ask a doctor before use if you have: sensitive skin

When using this product: Avoid contact with eyes and mucous membranes.

Do no apply to wounds or damaged skin.

Do not use with other ointments, creams, sprays or liniments.

Do not apply to irritated skin or if excessive irritation develops.

Do not bandage.

Wash hands after use with cool water.

Do not use with heating pad or device.

Stop use and ask a doctor if:

Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur.

If pregnant or breast-feeding: ask a health professional before use.

Keep out of reach of children. If accidentally ingested, get medical help or contact a Poison Control Center immediately.

Directions

- Adults & children over 2 years of age: rub a thnk film over affected areas no more than 4 times a day- massage not necessary

- Children under 2 years of age: consult physician.

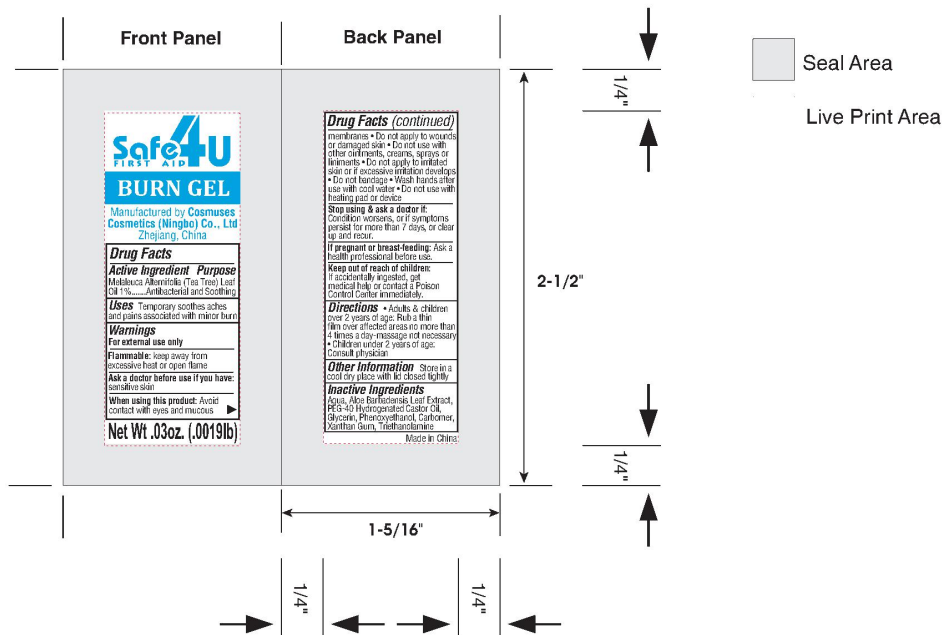
other information

Store in a cool dry place with lid closed tightly.

Inactive ingredients

Aqua, Aloe Barbadensis Leaf Extract, PEG-40 Hydrogenated Castor Oil, Glycerin, Phenoxyethanol, Carbomer, Xanthan Gum, Triethanolamine.

Packet Template with Drug Facts



melaleuca alternifolia (tea tree) leaf oil gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82953-045
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G) (TEA TREE OIL - UNII:VIF565UC2G)	MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ALOE BARBADENSIS LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEG-40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82953-045-01	0.85 g in 1 POUCH; Type 0: Not a Combination Product	04/06/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M004	04/06/2025	

Labeler - Cosmuses Cosmetics (Ningbo) Co., Ltd. (725290934)

Registrant - Cosmuses Cosmetics (Ningbo) Co., Ltd. (725290934)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmuses Cosmetics (Ningbo) Co., Ltd.		725290934	manufacture(82953-045)

