

**SALLY HANSEN MICROWAVABLE EYBROW, FACE AND LIP WAX KIT- benzocaine
Coty US LLC**

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.

Drug Facts

Active ingredient

5% Benzocaine

Purpose

Topical analgesic

Uses

for temporary relief of pain and itching associated with minor skin irritations due to hair removal

Warnings

Allergy Alert: do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.

For external use only

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last for more than 7 days or clear up and occur again within a few days

Do not use in

- large quantities, over raw surfaces, or blistered areas

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- shake well
- use no more than 3 to 4 times daily

Adults and children 2 years of age and older apply to treated area immediately after hair removal

Children under 2 years of age consult a doctor

Inactive ingredients

Aqua/Water/Eau, Ethylhexyl Palmitate, Paraffinum Liquidum/ Mineral Oil/Huile Minerale, Propylene Glycol, Glyceryl Stearate, Cetyl Alcohol, Palmitic Acid, Triethanolamine, Stearic Acid, Imidazolidinyl Urea, Parfum/Fragrance, Peg-100 Stearate, Methylparaben, Carbomer, Tocopheryl Acetate, Lanolin

Alcohol, Linalool, Benzyl Benzoate, Aloe Barbadensis Leaf Extract, Alcohol, Myristic Acid, Limonene, Geraniol, Citronellol, Eugenol, Citral, Soluble Collagen, Propylparaben, Citric Acid, Benzoic Acid, Tocopherol, BHT.

Questions or comments?

Call us at 1-800-953-5080 9:00AM - 5:00PM EST

Principal Display Panel – Kit Label

MICROWABLE

Eyebrow, Face & Lip

WAX KIT

WAX

- Results last up to 8 weeks!*
- With mini tweezers & brow guides

Topical analgesic with 5 % benzocaine

- *des resultants jusqu'à 8 semaines !**
- *avec mini pince à épiler et guides pour les sourcils*

analgésique local avec 5 % de benzocaïne

*Individual results may vary

**les resultants individuels peuvent varier*

Wax / cire NET WT. 1.25 oz 35 g, Extrasoothe™ Lotion / lotion 0.5 fl oz 14.7 ml,

Brow Guides / guides pour les sourcils, Temperature Indicator Applicator . applicateur avec indicateur de temperature, Mini Tweezers / mini pince à épiler, Orange Stick / bâtonnet orange, Instructions

SALLY HANSEN MICROWAVABLE EYBROW, FACE AND LIP WAX KIT

benzocaine kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66 184-155
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66 184-155-01	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	0.05 g
Part 2	1 JAR	189.9 g

Part 1 of 2**SALLY HANSEN MICROWAVABLE EYBROW, FACE AND LIP WAX KIT**

benzocaine lotion

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	0.05 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
ethylhexyl palmitate (UNII: 2865993309)	
mineral oil (UNII: T5L8T28FGP)	
propylene glycol (UNII: 6DC9Q167V3)	
glyceryl monostearate (UNII: 230OU9XXE4)	
cetyl alcohol (UNII: 936JST6JCN)	
palmitic acid (UNII: 2V16EO95H1)	
trolamine (UNII: 9O3K93S3TK)	

stearic acid (UNII: 4ELV7Z65AP)
imidurea (UNII: M629807ATL)
peg-100 stearate (UNII: YD01N1999R)
methylparaben (UNII: A2I8C7HI9T)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
lanolin alcohols (UNII: 884C3FA9HE)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
Benzyl Benzoate (UNII: N863NB338G)
aloe vera leaf (UNII: ZY81Z83H0X)
alcohol (UNII: 3K9958V90M)
myristic acid (UNII: 0I3V7S25AW)
geraniol (UNII: L837108USY)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
eugenol (UNII: 3T8H1794QW)
citral (UNII: T7EU0O9VPP)
propylparaben (UNII: Z8IX2SC1OH)
citric acid monohydrate (UNII: 2968PHW8QP)
Benzoic Acid (UNII: 8SKN0B0MIM)
tocopherol (UNII: R0ZB2556P8)
butylated hydroxytoluene (UNII: 1P9D0Z171K)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.05 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	01/01/2012	

Part 2 of 2

SALLY HANSEN MICROWAVABLE EYBROW, FACE AND LIP WAX KIT

depilatories strip

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	white wax (UNII: 7G1J5DA97F)	
INGR	calcium carbonate (UNII: H0G9379FGK)	
INGR	magnesium carbonate (UNII: 0E53J927NA)	

INGR	mineral oil (UNII: T5L8T28FGP)	
INGR	canola oil (UNII: 331KBJ17RK)	
INGR	coconut oil (UNII: Q9L0O73W7L)	
INGR	apricot kernel oil (UNII: 54JB35T06A)	
INGR	chamomile (UNII: FGL3685T2X)	
INGR	aloe vera leaf (UNII: ZY81Z83H0X)	
INGR	D&C Red No. 17 (UNII: ND733RX3JN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		189.9 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		01/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	01/01/2012	

Labeler - Coty US LLC (789573201)

Establishment

Name	Address	ID/FEI	Business Operations
Coty US LLC		039056361	MANUFACTURE(66184-155)

Revised: 3/2013

Coty US LLC