

SALLY HANSEN OUCH-RELIEF WAX STRIP 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

6% 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. Not intended for use by children under 13 years of age

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

- 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

- Rub well (see enclosed instructions)
- Use wipes no more than 3 to 4 times daily.

Discard wipe after use.

Adults and children 13 years of age and older apply to the area to be treated 10 minutes before hair removal

Children under 13 years of age consult a doctor

Other information

As with all products containing benzocaine, localized allergic reactions may occur after prolonged or repeated use.

Inactive ingredients

ALCOHOL DENAT., AQUA/WATER/EAU, PROPYLENE GLYCOL, METHYLPARABEN

Questions or comments?

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

Principal Display Panel – Kit Label

**OUCH-RELIEF™
WAX STRIP KIT**

**PAIN-
RELIEF
TECHNOLOGY™**

FOR BODY
Pre-Treatment
for Pain-Free
Hair Removal

Results Last
up to
8 Weeks!*

Ready &
Easy to Use

*Individual hair re-growth results may vary

Body
Contouring
Strip

32 Wax Strips

Total 16 double-sided, 4 Benzocaine wipes, Azulene Finishing Oil 0.5 fl oz 14.7 ml, Instructions

Dermatologist & Salon Tested



SALLY HANSEN OUCH-RELIEF WAX STRIP KIT

benzocaine kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66 184-154
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66184-154-01	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKET	5
Part 2	1 PACKET	32

Part 1 of 2

OUCH-RELIEF WAX STRIP KIT

benzocaine cloth

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	0.0543 g

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	
Water (UNII: 059QF0KO0R)	
Denatonium Benzoate (UNII: 4YK5Z54AT2)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Methylparaben (UNII: A218C7H19T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 in 1 PACKET		

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

OUCH-RELIEF WAX STRIP KIT

depilatories strip

Product Information

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Rosin (UNII: 88S87KL877)	
INGR	Mineral Oil (UNII: T5L8T28FGP)	
INGR	High Density Polyethylene (UNII: UG00KM4WR7)	
INGR	Castor Oil (UNII: D5340Y2I9G)	
INGR	Sunflower Oil (UNII: 3W1JG795YI)	
INGR	Isopropyl Myristate (UNII: 0RE8K4LNJS)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	
INGR	.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
INGR	PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
INGR	ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
INGR	CYMBIDIUM HOOKERIANUM FLOWER (UNII: H2DJ03DI5I)	
INGR	Almond Oil (UNII: 66YXD4DKO9)	
INGR	Rosemary (UNII: IJ67X351P9)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		32 in 1 PACKET		

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(66184-154)

Revised: 3/2013

Coty US LLC