

**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.*

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**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**



#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66184-154-01	1 in 1 CARTON; Type 0: Not a Combination Product	01/01/2012	

### 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

### 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: A2I8C7HI9T)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 in 1 PACKET; Type 0: Not a Combination Product		

### Marketing Information

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

## Part 2 of 2

### OUCH-RELIEF WAX STRIP KIT

depilatories strip

#### Product Information

#### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>ROSIN</b> (UNII: 88S87KL877)	
INGR	<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
INGR	<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
INGR	<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
INGR	<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
INGR	<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
INGR	<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
INGR	<b>.ALPHA.-HEXYLCINNAMALDEHYDE</b> (UNII: 7X6O37OK2I)	
INGR	<b>PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)</b> (UNII: 255PIF62MS)	
INGR	<b>ISOMETHYL-.ALPHA.-IONONE</b> (UNII: 9XP4LC555B)	
INGR	<b>CYMBIDIUM HOOKERIANUM FLOWER</b> (UNII: H2DJ03DI5I)	
INGR	<b>ALMOND OIL</b> (UNII: 66YXD4DKO9)	
INGR	<b>ROSEMARY</b> (UNII: IJ67X351P9)	
INGR	<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
INGR	<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		32 in 1 PACKET; Type 0: Not a Combination Product		

#### 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 (039056361)

Revised: 10/2021

Coty US LLC